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An overview of the use of risk assessment for environmental regulation in the UK – key drivers and regulatory initiatives

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Abstract

The regulation of risk is high on the political agenda and viewed as an important component of modernizing government. The Environment Agency of England and Wales has responsibilities for regulating and managing a wide range of risks to and from the environment. In some areas of regulation, a structured and explicit treatent of risk is required; in other areas, the approach is more implicit and reliant on professional judgement. This paper presents an overview of the application of risk assessment in the Environment Agency and a summary of recent policy and regulatory drivers. It introduces some emerging issues with respect to current practice in environmental risk assessment.

1. Introduction

BACKGROUND

The handling and regulation of risk is a key component of the recently published plans for modernizing government in the UK. Activity in risk policy and regulation spans across government departments and agencies, covering, among others, aspects of defence, education, health service provision, health and safety in the workplace, food standards, and environmental protection. The government's White Paper 'Modernizing Government' places emphasis on quality public services, including regulation, a proportionality of approach, and the delivery of good practice in the assessment, management and communication of risks (HMSO, 1999a; ILGRA, 1998).

The principal aim of the Environment Agency (hereafter, the Agency) is to protect and enhance the environment and to contribute to the government's goal of sustainable development. The UK's sustainable development strategy (HMSO, 1999b), places an emphasis on *effective* protection of the environment within a wider context of social and economic progress. For its part, the Agency has set out an overarching environmental strategy and, more recently, an aspirational framework for establishing the measures that we might take to relieve pressures on the environment and means by which we might decide on appropriate actions (Environment Agency, 1997a, 2000a).

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Risks of harm to people and the environment can be increased by human activities. It is generally assumed that such risks are not created for their own sake, but arise as a by-product of some function or process, and thus need to be set against accompanying benefits. Equally, there are situations where risks already exist, either naturally – such as flooding – or because of historic human activities – land contamination, for example. In recognition of the risks inherent in all of these activities, systems for their regulation and management have been, and continue to be devised (POST, 1996; Slater and Jones, 1998; Environment Agency, 2000b).

CONTEXT OF RISK-BASED DECISION-MAKING

Much of the day-to-day activity of the Environment Agency's operational staff involves the administration of regulatory processes and, with it, some element of risk assessment and management. Regulatory decisions and judgements are made with close reference to specific statutory or supervisory duties and/or powers within the context of the primary legislation, accompanying regulations, policy and guidance from central Government and Agency policy and guidance on implementation. In the main, these responsibilities require decisions over the issuing, drafting and enforcement of environmental permits to discharge to, or abstract from the environment, or the delivery of flood and coastal protection. Risk assessment as a management tool is frequently used to inform these decisions and is generally conducted by the applicant or developer. Along with most regulators, the Agency reserves the right to undertake independent risk assessments in support of its duties and powers.

In some areas of the Agency's work, structured and explicit risk assessment procedures have been, or are being established; in others, the approach is more intuitive and more reliant on the expert professional judgement of the regulatory officer (Environment Agency *et al.*, 1997; Environment Agency and Health and Safety Executive, 1999; Environment Agency, 1997b; DETR and Environment Agency, 2000). Regulatory practice in risk assessment reflects developments in legislation over the years and the broad range of risk-related activities for which the Agency is responsible. The general trend, however, is towards a more explicit treatment of risk within the statute and accompanying guidance.

A summary of current approaches to risk assessment in the Environment Agency is presented in Table 1, which illustrates the range of tools and techniques of varying degrees of sophistication that are in use. Not all activities require risk assessment. Familiar activities where the risk is negligible or the impacts well understood may not require assessments. In these circumstances, the Agency may apply 'general binding rules' or 'default standards'. As uncertainty increases over potential consequences and their likelihood however, a formalized process of risk assessment assists in understanding the nature of the risk and how to avoid or manage it (Environment Agency, 2000c). The practical reasons why the Agency is increasingly adopting risk assessment to support its regulatory and supervisory activities include:

- a distinction between consequences (impacts) and the likelihood of occurrence;
- a *structured* way of considering risks and hazards, thus establishing a more logical basis for managing the risk;

Table 1. Environmental risk assessment in the environment agency

Agency Function	*Context/application*	*Approach/decision support tool*
Environmental Protection		
Radioactive substances regulation	Safety cases for radioactive waste disposal; radioactively contaminated land (not yet implemented).	Quantitative risk assessment within the performance assessment of radioactive waste disposal sites.
Waste management and regulation	Protection of groundwater with reference to EC Groundwater Directive; licensing of waste management installations; inspection frequencies.	Qualitative and quantitative risk assessment of waste management installations; quantitative assessment of leachate leakage; risk-ranking schemes for pollution hazard and operator performance.
Land quality	Designation of statutory contaminated land under the Environmental Protection Act, Part IIA.	Qualitative risk assessment and quantitative exposure assessment with reference to soil assessment criteria for the identification of statutory contaminated land.
Water quality	Groundwater protection with reference to EC Groundwater Directive; discharge consent setting; prioritization of pollution prevention visits; prioritization of anti-pollution works.	Qualitative and quantitative risk assessment with reference to groundwater protection policy, vulnerability maps and water quality criteria; distribution modelling of predicted environmental concentrations in surface waters; ranking tools for pollution prevention visits; tiered approaches for the protection of water resources from contaminated soil; risk assessment tools for Dee Water Protection Zone.
Process industry regulation	Authorisation of permits with reference to local and transboundary issues; safety cases for COMAH sites with reference to EC Seveso II Directive; IPC; inspection frequencies.	Quantitative distribution modelling of predicted environmental concentrations in air at ground level; fault- and event-trees for safety cases, risk-ranking schemes for pollution hazard and operator performance (OPRA); generic, quantitative exposure assessment models for the assessment of production chemicals.
Water Management		
Flood defence	Project risk appraisal for strategic plans and individual flood defence schemes; inspection of flood defence assets; risk-based approach to flood warning.	Hazard identification 'brainstorming techniques' (risk registers) for project risks; probabilistic modelling; fault- and event-trees for engineering risk; ranking schemes for asset management.

Continued overleaf

Table 1. *Continued*

Agency Function	*Context/application*	*Approach/decision support tool*
Water resources	Assessments of critical flow levels for the granting of water abstraction licences; licence conditions may provide for river support to be provided by abstractor.	Low-flow hydro-ecological modelling, objective setting; tiered approach varying from look-up tables to detailed biological response modelling for river assessment.
Fisheries, recreation, navigation and conservation	Pilotage of craft within ports and harbour areas operated by Agency; impact of regulated activities on designated habitats with reference to EC Habitats Directive.	Comprehensive hazard identification and semi-quantitative risk ranking on basis of expert knowledge; sensitivity mapping and 'environmental footprints' of regulated sites.
Environmental Strategy		
Sustainable development	Strategic appraisal of environmental pressures on all media; risks and values framework.	Environmental impact assessment according to harm attributes; semi-quantitative ranking tools for 'state of the environment' reporting'.
Environmental monitoring and assessment	Risk-based compliance and surveillance monitoring.	
Research and Development	Prioritisation of R&D implementation.	Qualitative/Semi-quantitative risk ranking based on delivery and business need.
Operations		
Areas and Regions	Prioritisation of regional and local Agency plans; Y2K risks to Agency and externally; as support to environmental impact assessments for which the Agency is a statutory consultee; flood risk mapping and development control.	Range of tools: most risk ranking approaches.
Finance		
Corporate Planning/ Internal Audit	Identification of business risks for internal control.	Qualitative 'boston box' approach of importance and ability to influence.
Personnel		
Health and Safety	Health and safety risk assessments at work.	Qualitative assessments and checklists.

- the targeting of regulatory effort;
- the opportunity to identify risk issues at the strategic planning stage of activities where the Agency is a consultec;
- a sound basis for the prioritization of risk management actions;
- the recording of decisions for future use; and
- making the judgement process and its underlying logic transparent for others to appraise.

2. Key policy and regulatory drivers

Practice in environmental risk assessment is influenced by the dynamic regulatory context in which this activity takes place, the individual requirements of statute and the competencies of practitioners (Renn, 1998). In recent years, improving public trust in regulatory authorities has been an underlying driver for many initiatives aimed at improving decision-making within Government and its Agencies (Löfstedt and Horlick-Jones, 1999). With respect to UK practice in environmental risk assessment, there exist a number of current policy and regulatory drivers, some of which are, in part, a response to this discourse.

QUALITY REGULATION AND EFFECTIVE ENVIRONMENTAL PROTECTION

The current emphasis on best value public services and quality regulation is encouraging a consideration of how regulators can be most effective in administering their functions. Risk assessment is playing a key role in responding to this with respect to the targeting and prioritising of regulatory effort (Slater and Jones, 1998). For example, in one of several current initiatives (Environment Agency, 1999a), the Agency is considering the adoption of risk-based approaches to the inspection of waste management installations, so as to concentrate efforts on those facilities posing the greatest hazard and operated at sub-optimal standards of performance. These proposals (DETR, 1999) have been prepared in partnership with the waste management sector and, if successful, will provide, in part, a credible response to recent appraisals of the Agencies' work in this area (CBI, 1998; 1999).

ADOPTION OF GOOD PRACTICE IN RISK ASSESSMENT

The Interdepartmental Liaison Group on Risk Assessment (ILGRA) promotes good practice in risk assessment, management and communication across government departments and agencies and reports periodically to ministers on progress. In its second report (ILGRA, 1998), ILGRA emphasized the importance of good risk communication and made a recommendation that departments and agencies published regulatory framework documents describing how risk is assessed and managed within their areas of control. These are being viewed as documents setting out each department's and agency's broad regulatory philosophy, the first of which has been issued by the HSE for discussion (HSE, 1999). 'Modernizing Government' (HMSO, 1999a) has embraced ILGRA's emphasis on good practice in risk assessment, management, and communication. The Environment Agency has responded by preparing a paper on the consideration of risks and values in environmental decision making (Environment Agency, 2000a) and co-producing guidance with

government on the principles for public domain environmental risk assessments (DETR, Environment Agency and IEH, 2000).

The Government's Office of Science and Technology has also issued guidance to government departments on the use of science in policy making (Department of Trade and Industry, 1998). These principles emphasize the importance of the early identification and anticipation of risk issues, the use of all available scientific information, early publication of data, a need for clarity over the existence of uncertainties and the need for early thought to be given to the presentation of information to the public. The need for departments and, by extension, agencies, to maintain a capacity to recognize the implications of policies and address risks is also stressed.

SUSTAINABLE DEVELOPMENT AND INCLUSIVE ENVIRONMENTAL DECISION MAKING

The assessment of risks, costs, and benefits of pursuing any single environmental objective, the importance of participation within environmental decision making and the application of the precautionary principle are among the guiding principles featured in the revised UK strategy for sustainable development (HMSO, 1999b). Each of these principles have implications for risk assessment practice in term of integration with other aspects of environmental appraisal, the accessibility of risk assessments to non-expert audiences and the criteria used to assess the significance of risks and attending uncertainties.

The theme of capturing and incorporating societal values within environmental decision making also features prominently in the Royal Commission on Environmental Pollution's 21st Report, 'Setting Environmental Standards' (1998). The Commission commented widely on the use of scientific understanding, the treatment of risk and uncertainty in environmental regulation, and the need for a participatory approach to environmental decision making. Beyond a robust critique of the advantages and limitations of risk assessment in its various forms as a management tool, their report emphasized the importance of synthesizing societal values, of sound science and the need for an evaluation of risk, technological assessment, and economic appraisal within an *integrated* decision framework. Integrated decision making also features in the government's sustainable development strategy as a key component of policy appraisal (DETR, 1998).

These calls for greater transparency in the delivery of decision-making processes need to be matched with effective mechanisms for stakeholder involvement. To date, procedures are not well defined and have not been clearly evaluated. We need to establish at what stages, and in what ways involvement can be meaningfully incorporated. The current debate on deliberative and inclusive processes will inform this development (House of Lords, 2000; ESRC Global Environmental Change Programme, 2000), and the Environment Agency has commissioned research on the application of participatory approaches to decision making to environmental risk assessment.

RISK WITHIN INDUSTRY AND BUSINESS

Industry and business converse in the language of risk, and look increasingly to integrate health, safety, and environmental risks within a broader business risk

framework. Strategic risk 'profiling' has become an essential aspect of corporate governance and a pre-requisite for internal financial control (Institute of Chartered Accountants of England and Wales, 1999). The rationalizing of various business sectors, such as the petroleum sector, and the globalization of business has necessitated the application of risk assessment in terms of pre-acquisition and divestiture (Pollard *et al.*, 1995). In terms of day-to-day operations, industry has generally welcomed the application of risk-based approaches to environmental regulation, whilst maintaining pressure on regulators to extend these principles (CBI, 1998).

REGULATORY DEVELOPMENTS

European environmental legislation is increasingly resulting in the embodiment of risk principles in Directives and subsidiary national legislation. For example, in the UK, we have seen with the transposition of the Seveso II Directive (COMAH Regulations) a formalization of risk assessment within the requirements of safety cases for major process plants. With reference to national legislation also, the requirements for risk assessment are becoming more explicit. For example, recent introduction of Part IIA of the Environmental Protection Act (Contaminated Land) in England (DETR, 2000) requires risk assessments to support the identification and assessment of statutory contaminated land.

3. Application of risk assessment

In general, the Agency applies risk assessment at two levels: at the operational level for front line environmental regulation and the exercising of its supervisory powers over flood defence and at the strategic level for the prioritization of plans and strategies. Risk assessment tools that can address the different types of uncertainty encountered in each case are required to support this work (van Asselt, 1999).

OPERATIONS

Application of risk assessment in the Agency for assisting regulatory decisions falls broadly into two principal classes:

(a) 'regulatory' risk assessment, whereby the Agency undertakes the risk assessment required by statute and guidance; for example, in work for the DETR and the European Community, on the notification of existing substances, or in support of proposed flood defence schemes; and
(b) 'applicant' risk assessment, whereby operators, dischargers, developers, abstractors, and/or other persons, are required, either by specific legislation or at the general request of the Agency, to undertake risk assessments in support of their applications for environmental permits.

The majority of activity is in guiding, reviewing and interpreting this latter class of assessment, largely as triggers for regulatory action, or for setting conditions on authorizations. To help guide these risk assessments, the DETR and Environment Agency have co-produced a revision (DETR, Environment Agency and IEH, 2000) to the 1995 'Guide to Risk Assessment and Risk Management for Environmental Protection', produced originally by the Department of the Environment (Department

of the Environment, 1995). This provides generic, high-level advice and advocates a proportionate, tiered approach to risk assessment and management. At a more detailed level, the Agency is preparing guidance to assist their staff, and others, on the risk assessment requirements of specific legislation. This includes guidance on authorizing the disposal of radioactive wastes, for sites that fall under the COMAH regulations, risk assessment guidance for waste management installations and guidance for identifying potentially contaminated sites, including those that fall under Part IIA of the Environmental Protection Act 1990.

For operational resource planning, the Agency has developed risk assessment procedures, in consultation with others, for prioritizing and resourcing regulatory and supervisory work. The development of 'operator and pollution risk appraisal' (OPRA) for determining regulatory inspection frequencies, and introduced for major process plant (Environment Agency 1997c; Slater and Jones, 1998) and waste management installations (DETR, 1999) is one example. Other examples of less-formalized risk-based procedures come from areas of corporate planning, flood defence project and asset management, and the delivery of the Agency's R&D programmes. At the corporate level, the Environment Agency's key business risks for 1999–2002 have been identified and published in the Corporate Plan and guidance has been issued to Environment Agency managers on managing business risk (Environment Agency, 1998a).

STRATEGIC RISK ASSESSMENT

For higher levels of analysis, the Agency has adopted an environmental management cycle (pressure-state-response) approach to the delivery of its environmental strategy and has undertaken research to inform the prioritization of national issues. Research and development work on strategic risk assessment is progressing which will inform this analysis further (Environment Agency, 1999b; Duarte-Davidson *et al.*, 1999).

NATIONAL CENTRE FOR RISK ANALYSIS AND OPTIONS APPRAISAL

To act as a central focus, and to support activity in risk-based decision making, the Environment Agency's National Centre for Risk Analysis and Options Appraisal has been charged with progressing activities in the development of tools and techniques (Environment Agency, 1997d). The Centre is a multi-disciplinary focus for environmental forecasting risk assessment and options appraisal practice. Proportionality of approach is an important principle and the Agency places a strong emphasis on the application of tiered approaches (Figure 1); for example, in guidance for the protection of water resources from contaminated soil (Environment Agency, 1999c). The tiered approach has many analogues in other fields of risk assessment.

Within each tier of risk assessment lie the following questions associated with the classical stages of risk assessment. These may be addressed using qualitative, semi-quantitative, or quantitative assessment criteria:

(a) 'What hazards are present and what are their properties?'; or *hazard identification*. Identification of the sources of the hazard and assessment of the consequences of the hazard if realized, including the identification of dose–response relationships, where appropriate;

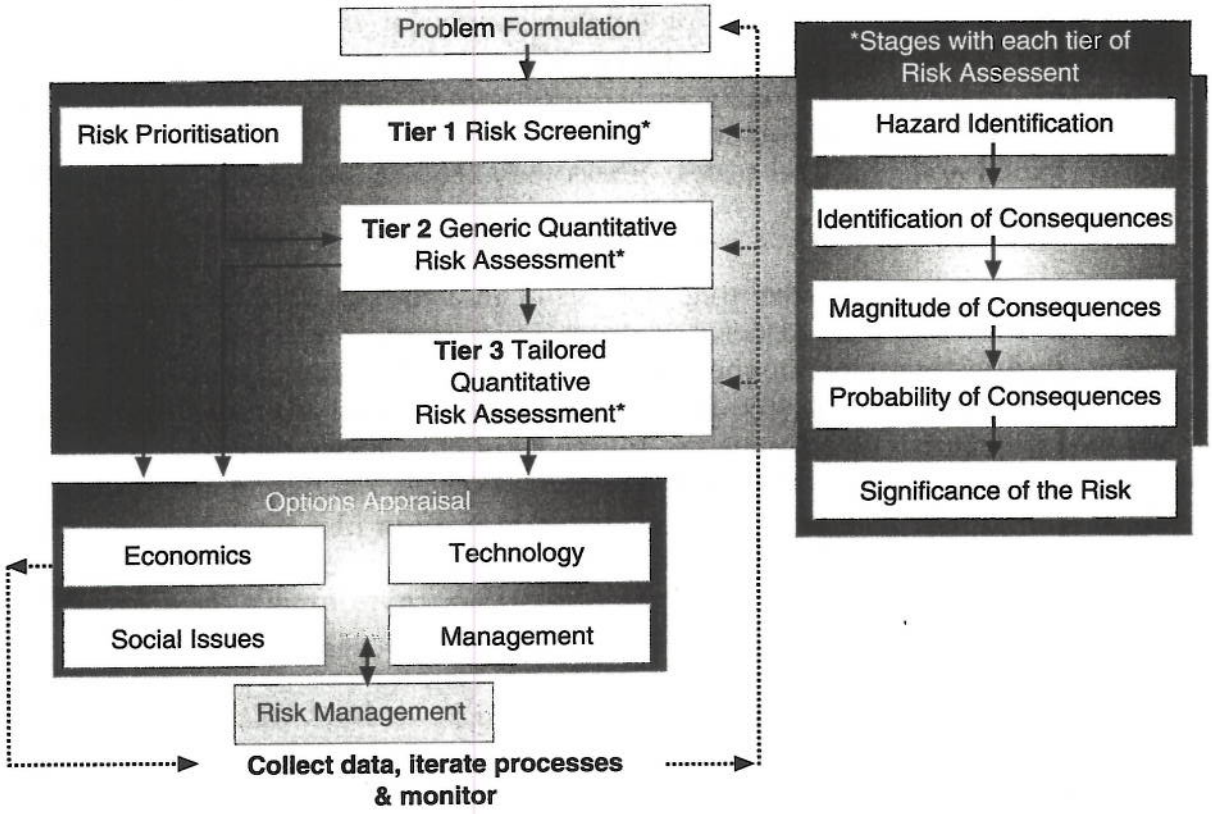

Figure 1. Tiered Approach to Risk Assessment and Risk Management (after DETR, Environment Agency and Institute for Environmental Health, 2000)

(b) 'How might the receptors become exposed to the hazards and what is the probability and scale of exposure?'; or *exposure assessment*. Evaluating the plausibility of the hazard being realized at the target, and by which mechanisms, allowing an assessment of the probability, magnitude, and duration of exposure;

(c) 'Given exposure occurs at the above probability and magnitude, what is the probability and scale of harm?'; or *risk estimation*: consideration of the consequences of exposure with reference to effects and dose, expressed as a likelihood or probability of the hazardous effects of exposure being realized; and expressed over a range of spatial and temporal fields;

(d) 'How significant is the risk and what are the uncertainties?'; or *risk characterization*: evaluating the acceptability and significance of risk with reference to standards, targets, background risks, cost–benefit criteria or risk 'acceptability' and 'tolerability' criteria, and commenting on the uncertainties associated with the assessment.

RISK CATEGORIES

Risk assessments focus on issues such as: the release of contaminants from 'closed' systems; the performance and environmental safety of process plants, containment systems or structures; the indirect exposure of substances to the wider environment;

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The Extent of Contaminated Land Problems and the Scientific Response

SIMON J. T. POLLARD, MALCOLM LYTHGO AND RAQUEL DUARTE-DAVIDSON

1 The Origins of Contaminated Land Problems

Background

The remediation and redevelopment of contaminated land is widely acknowledged as a major challenge for modern society.[1,2] Land, and the groundwater below it, used for siting industrial facilities or for waste disposal may be contaminated and its redevelopment often requires that unacceptable risks are assessed and managed so that the site becomes suitable for its new use. Over the years, development planning, corporate environmental auditing and environmental regulation have all contributed to the discovery and subsequent remediation of contaminated land and groundwater. Successful management of contamination, whether at the site, regional or national scale, relies on understanding and applying a large and multidisciplinary knowledge base that straddles the natural, physical, engineering and social sciences within a practical, commercial and regulatory context. Practitioners applying this knowledge work within a decision-making context far removed from that of the research environment. This said, practitioners and decision-makers are required to consider the significance of the science base that affects their decisions, particularly those aspects relating to the perception of risk, the environmental fate of contaminants, the capabilities of analytical science, the concepts of environmental exposure and the practical capabilities of remedial technologies.[3]

Decisions about contaminated land involve a multitude of stakeholders. New mechanisms and skills are required for engaging and involving audiences not familiar with the technically orientated language of environmental

[1] R. E. Hester and R. M. Harrison, eds., *Issues in Environmental Science and Technology*, No. 7, Royal Society of Chemistry, Cambridge, 1997.

[2] USEPA, United States Environmental Protection Agency, *Evaluation of Demonstrated and Emerging Technologies for the Treatment and Clean Up of Contaminated Land and Groundwater*, EPA542-C-99-002 (CD-ROM), Washington DC, 1999.

[3] S. E. Hrudey and S. J. Pollard, *Environ. Rev.*, 1993, **1**, 55.

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risk.[4] The sustainable development policy agenda[5] is resulting in new ways of thinking about risk, technology and decision-making. Increasingly, approaches to site remediation are being scrutinised by reference to their full life-cycle costs, and social, economic and technical factors are being considered alongside one another in appraising risk management options.[6,7] Industry, its professional advisors and environmental regulators are now having to consider afresh how these broader aspects can best be incorporated into decisions.

A vast literature has developed on the issue of land contamination and several excellent reports, texts and reviews exist that focus on historical perspectives, policy and legal developments and consulting best practice.[1,8–13] Here, we introduce the origins and extent of the problem and, as a contribution to the debate over effective solutions to this environmental challenge, we highlight some of the recent developments in the science base that underpin management decisions on land contamination. Given the emphasis in later chapters, we have concentrated on the assessment of contaminated land and research in the open literature. Specific developments in risk assessment, remediation, impacts on human health and the policy and regulatory frameworks are provided in detail elsewhere within this volume.

Origins

The challenge of managing contaminated land is not a new one. It has been recognised by governments internationally for at least thirty years and is closely associated, technically and legislatively with the issues of waste and hazardous waste disposal, the regeneration of derelict land, groundwater pollution and

[4] Scotland and Northern Ireland Forum for Environmental Research, *Communicating Understanding of Contaminated Land Risks*, Project SR97(11)F, SNIFFER, Edinburgh, 1999.

[5] Department of Environment, Transport and the Regions, Cm4345, *A Better Quality of Life: A Strategy for Sustainable Development for the United Kingdom*, HMSO, London, 1999.

[6] R. P. Bardos, T. E. Kearney, C. P. Nathanail, A. Weenk and I. D. Martin, in *Contaminated Soil 2000*, Thomas Telford Ltd., London, 2000, pp. 99–106.

[7] S. J. T. Pollard, J. Fisher, C. Twigger-Ross and A. Brookes, in *Special Session of the NATO/CCMS Pilot Study of Demonstrated and Emerging Technologies for the Treatment and Clean Up of Contaminated Land and Groundwater*, Wiesbaden 2001, United States Environmental Protection Agency, Cincinnati, 2001, EPA 542-C-01-002 (CD Rom).

[8] House of Commons, Environment Committee, Session 1989–1990, *First Report: Contaminated Land*, HMSO, London, 1990.

[9] G. Fleming, *Recycling Derelict Land*, Institution of Civil Engineers, Thomas Telford Limited, London, 1991.

[10] P. Attewell, *Ground Pollution. Environment, Geology, Engineering and Law*, E. & F.N. Spon, London, 1993.

[11] J. Petts, T. Cairney and M. Smith, *Risk-Based Contaminated Land Investigation and Assessment*, John Wiley & Sons, Chichester, 1997.

[12] Construction Industry, Research and Information Association, *Remedial Treatment for Contaminated Land*, Special Publication SP101-112, CIRIA, London, 1998.

[13] C. Ferguson, D. Darmendrail, K. Freier, B. K. Jensen, J. Jensen, H. Kasamas, A. Urzelai and J. Vegter, eds., *Risk Assessment for Contaminated Sites in Europe, Volume 1, Scientific Basis*, LQM Press, Nottingham, 1998.

industrial site decommissioning.[14] Whilst legislative boundaries and specific definitions may apply to these activities separately, these issues continue to overlap to a large extent and an examination of the origins of the problem needs to reflect on the historical emergence and development of this set of issues on the socio-economic and political landscape.

The widespread reporting of individual incidents and near misses associated with land contamination, coupled with increased government interest in waste management during the 1970s and 1980s led in many countries to the development of new legislative controls dealing with historically contaminated land and preventing future land contamination (see chapter by Lowe and Lowe). Highly publicised and often referred to international incidents such as those at Love Canal in the United States and Lekkerkerk in the Netherlands[8] resulted in increased public and political interest. A growing concern over waste management practices together with a realisation of the practical and technical difficulties of redeveloping past industrial land have also fuelled the debate. In the United Kingdom, a watershed was the publication of the 1990 House of Commons Environment Committee report on contaminated land,[8] which itself had been prompted by previous Commons and House of Lords committee reports on toxic waste and hazardous waste disposal.[15,16]

The modern origins of the problem, however, begin with industrialisation, development of the fossil fuel-based economy and growth of the downstream chemical, heavy engineering and manufacturing industries from the 1800s onward (Table 1). Coal gas production and later petroleum refining, together with the steel and chemical industries (*e.g.* dyestuffs, wood preserving, chloralkali), whilst bringing benefits to society often left a legacy of environmental contamination in an era when a different philosophy prevailed over environmental protection. Table 1 lists some common contaminants and their related past industrial land uses and processes. On- and off-site disposal of industrial wastes, by-products and production residues was commonplace and in some circumstances considered, at the time, to be beneficial. For example, using process residues to raise land levels on floodplains created land for development with a reduced flood risk.

2 The Extent of the Challenge

The Nature of Contaminated Land Problems—the Issue of Definition

It is not a simple matter to define contaminated land, or to categorise degrees of contamination. Setting aside natural contamination, there is, in practice, a continuum of land contamination that results in a range of impacts, from the acute impacts of specific sites, through varying degrees of diffuse, more chronic effects of large areas, through to pristine, uncontaminated land. There is little

[14] P. J. Young, S. Pollard and P. Crowcroft, *Issues in Environmental Science and Technology*, No. 7, ed. R. E. Hester and R. M. Harrison, Royal Society of Chemistry, Cambridge, 1997, p. 1.

[15] House of Commons, Environment Committee, Session 1988–1989, *Second Report: Toxic Waste*, HMSO, London, 1989.

[16] House of Lords, Select Committee on Science and Technology, Session 1988–1989, *Fourth Report: Hazardous Waste Disposal*, HMSO, London, 1989.

Table 1 Potential contaminants related to selected industrial processes. A comprehensive list for a wide range of industries can be found in the DETR set of industry profiles[17]

Industry	*Contaminant source/process*	*Example chemical*
Gasworks/coking plants	Coal gasification	Polynuclear aromatic hydrocarbons (PAHs), Phenols
	Gas purification beds	Free cyanide/complex ferrocyanides, sulfides, sulfate
	Metals	Ni, Cu, Pb, Co, Cr, As
Oil refineries	Petroleum refining and downstream processing	Benzenes, PAH MTBE, V, sulfur
	Acids, alkalis	Sulfuric acid, sodium hydroxide
	Lagging, insulation	Asbestos
	Spent catalysts	Pb, Ni, Cr
Petrochemical processing/ production	As oil refineries	
	Metals	Cu/Cd/Hg
	Reactive monomers	Styrene, acrylate, vinyl chloride
	Initiators	Toluene di-isocyanate
	Amines	Aniline
Timber processing and treatment	Coal tar creosote	Phenol, xylenols, PAH
	Delivery agents (*e.g.* diesel)	Hydrocarbons, benzene
	Chlorinated phenols	Pentachlorophenol, mono-, di- and polysubstituted phenols
	Metals	As, Cu, Cr, Zn
Tanneries	Acid	Hydrochloric acid
	Metals	Cr^{III}
	Salts	Chlorides, sulfides
	Solvents	Kerosene, white spirit
Textile manufacture and processing	Metals	Zn, Al, Ti, Sn
	Acids, alkali	Sulfuric acid, sodium hydroxide
	Bleaching	Sodium hypochlorite
	Degreasing	Perchloroethylene
	Aromatic hydrocarbons	Phenols
	Pesticides	Dieldrin, aldrin, endrin
	Dyestuff residues	Cd, benzidine

land in the United Kingdom (UK) that has not been subject to some degree of contamination, albeit by long-range aerial deposition. There are differing views internationally on how much of this continuum should be considered as 'contaminated', by reference to pristine and/or background concentrations and the significance of the concentrations found. The UK has adopted an approach based on how suitable land is for its current or intended use. Land not suitable for

[17] Department of the Environment Transport and the Regions, *Industry Profiles*, DETR Publications, list at www.contaminatedland.co.uk/gov-guid/doe-pb.htm

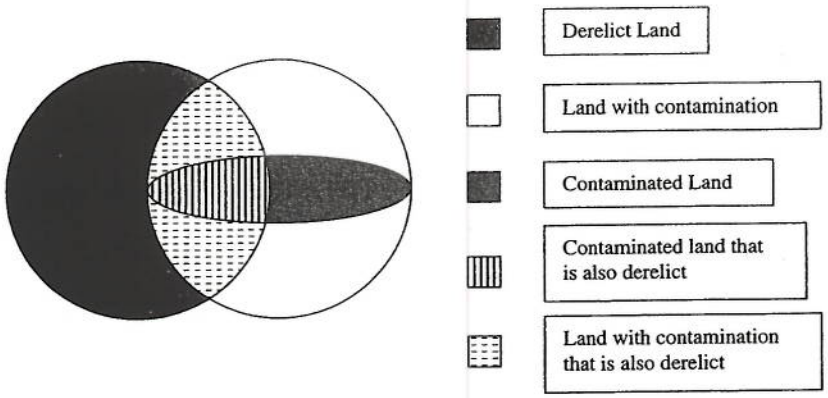

Figure 1 The relationship between derelict land, contaminated land and land with contamination. Different terminologies have arisen due to the contexts (planning, regeneration, environmental protection) in which land is being considered for remediation. With enactment of Part IIA of the Environmental Protection Act 1990 the term 'contaminated land' has a statutory defintion[18]

use is considered to be so contaminated that it needs to be remediated. This approach works well on a site-specific basis, but the definition can be problematic when trying to scale up for national estimates.

There are several terms in use to describe land in need of remediation. Although the terms may be similar, there are fundamental differences. Figure 1 illustrates the relationships between these terms. The term derelict land, for example, refers to 'land so damaged by past activities that it is incapable of beneficial use without treatment'.[14] The statutory definition of contaminated land in the UK is given in Part IIA of the Environmental Protection Act 1990 (see Lowe and Lowe), that is:

> "'Contaminated Land' is any land which appears to the local authority in whose area it is situated to be in such a condition, by reason of substances in, on or under the land, that
> *(a) significant harm is being caused or there is a significant possibility of such harm being caused; or*
> *(b) pollution of controlled waters is being, or is likely to be, caused*"

This statutory definition covers largely those sites at the chronically contaminated end of the continuum and relies on an assessment of the significance of the risks posed by the contamination at the site-specific level. An identified level of a particular contaminant may pose a significant risk of harm at one site with a sensitive land use, such as housing, but not at another less sensitive site, maybe where the land is used for parking. The same principle applies to the pollution of controlled waters, depending on the sensitivity of the receiving water. It might be argued that more general definitions would assist an understanding of the problem at the national scale, but generic descriptions without reference to the site-specific nature of the problem could undermine the risk-based approach and introduce blight on land values or saleability.

Extent and Significance

To date, there has not been a national survey of contaminated land, but there are

[18] Department of the Environment, Transport and the Regions, Circular 2/2000, *Environmental Protection Act 1990—Part IIA—Contaminated Land*, DETR, London, 2000.

provisions in recent legislation[18] for the environment agencies to report on the state of contaminated land in the UK and there is in hand work to produce a National Land Use Database (NLUD) that will provide estimates of the extent of derelict land. Current estimates of the extent of contaminated land in England and Wales range from 50 000 to 200 000 ha.[19] This is thought to represent approximately 100 000 contaminated sites, of which the Environment Agency estimates that between 5000 and 20 000 sites may require remediation because they pose an unacceptable risk to human health or the environment.[20] In 1998, the Welsh Office identified 949 contaminated sites in Wales, covering 4100 ha using a definition of contaminated land that excluded sites in active use, or those smaller than 0.5 ha.[21] In 1998, the Scottish Executive estimated that there were 3458 ha (52%) of derelict and vacant land that was known or suspected to be contaminated in Scotland and that the contamination status of a further 5553 ha was unknown.[22]

Estimates of the extent of contaminated land in the United Kingdom are often based on different definitions and therefore need to be viewed cautiously. They are often based on available but incomplete sources and they may mix between definitions. Further, some industry sectors have better information on the impact of their activities than others, and this might be misconstrued to imply that these sectors have caused more contamination. It is hoped that the provisions of the new contaminated land regime in the UK will refine and improve our estimates.

3 Developments in the Science Base

Developments in Environmental Science

From the first stirrings of political interest in contaminated land there has been a response from the scientific communities in terms of research output. Through the translation of research to the field, environmental science continues to underpin and contribute substantially to the practice of managing land contamination (Table 2). For example, our understanding of the fate and transport of contaminants in the environment has shaped our view on where and how to analyse for them, the exposure pathways associated with various classes of compounds and the technologies best suited to managing the risks posed.[3] The interdisciplinary nature of environmental science allows us to cross-fertilise between disciplines, for example, in applying analytical techniques used for petroleum exploration to the characterisation of oil contamination at sites or the application of process engineering design to remedial technology optimisation. Similarly, developments in the social sciences, not least with respect to risk perception and the communication of risk, are forcing a reappraisal of how we involve others in the process of managing land contamination.

A developing theme throughout the last 30 years has been the assessment, characterisation and management of risks to human health and the wider

[19] Royal Commission on Environmental Pollution, *Sustainable Use of Soils*, HMSO, London, 1996.
[20] Environment Agency, *The State of the Environment of England and Wales: The Land*, HMSO, London, 2000.
[21] Welsh Office, *Survey of Contaminated Land in Wales*, HMSO, London, 1998.
[22] Scottish Executive, *Scottish Vacant and Derelict Land Survey 1998*, ENV/1999/1, Scottish Executive, Edinburgh, 1999 available at: www.scotland.gov.uk/library2/doc05/lssb-00.htm

environment from contaminated sites.[13] Once it became clear that many environmental contaminants were ubiquitous at concentrations of parts per billion and less, a need developed to establish levels of significance for the potential risks posed by non-zero concentrations.[3] The risk assessment/risk management paradigm, adapted from the pharmaceutical and nuclear sciences, has since developed to a point whereby it has become a central point of reference for much of the supporting science and the basis for public policy and environmental regulation on contaminated land.[18] The application of risk assessment to contaminated land problems has inevitably highlighted issues of risk acceptance, the tolerability of risk and of equity.

Addressing Social Issues

Concerns over the potential risks to human health from exposure to contaminated soils have fired a broader debate over the wider social impacts of contaminated land on the quality of life. Many former industrialised areas form a focus for low cost or social housing, driven partly by positive issues such as access to work opportunities and partly by negative issues such as low land values. Some of the more deprived communities have resided in these contaminated areas. In addition to this social issue of environmental justice, a wider recognition of the importance of a sense of place and community attachment, and a broader interpretation of 'environment' beyond the strictly technical one, are bringing issues like the value of urban ecology, the importance of industrial heritage and the need for wider stakeholder involvement to the fore.

A move to more inclusive processes for environmental decision-making is emerging, influenced in part by 30 years of risk communication literature and by placing social progress centre stage in the strategy for sustainable development.[5] The regeneration of contaminated land has always required a multi- and trans-disciplinary approach, but increasingly scientists, engineers, planners and lawyers are turning to the social sciences for a re-interpretation of the issues historically viewed as driven by technological and economic concern alone. As a result, we are gaining valuable insights into the value of institutional trust, into 'process' issues in terms of involving others in decision-making, into issues of equity and the perceptions and reporting of risk. This work now needs to be integrated within the existing management frameworks for contaminated land management.[7]

Developments in Site Investigation and Assessment

The confidence with which decisions can be taken on the remediation of contaminated sites relies heavily on the quality of the site investigation and its attendant data. Risk assessments conducted in the absence of quality data provide a false sense of security in what can be meaningfully said about any site. Prioritising remediation across a 'portfolio' of sites requires comparability in data sets and summary information regarding the nature, extent, magnitude and depth of contamination. Developments in the statistical design of site investigations, in analytical science and the presentation of site data are all improving practice in this area.

Table 2 Selected developments and example references in environmental science of importance to contaminated land management

Example reference	*Development*	*Significance of development*
Alexander, 1965[23]	Emergence of soil microbiology and knowledge into biotransformations in soil/groundwater systems.	Development of bioremediation as a credible remediation technology. Optimisation of bioremediation technologies.
Schwille, 1967[24]	Developments in the characterisation of non-aqueous phase liquids (NAPLs) and their transport characteristics in the unsaturated and saturated zones.	Understanding of bulk flow and recovery of oil and solvents in porous media, sub-surface contaminant transport and contaminant dissolution from non-aqueous phase liquids.
Mackay, 1979[25]	Understanding of the fundamental physicochemical properties of contaminants as they dictate the environmental fate and transport of chemicals in the environment.	Better design of sampling protocols. Improved exposure assessment and understanding of remediation performance by reference to intra- and inter-phase transfer.
LeBlanc, 1984[26]	Development of commercially available computer software for the numerical simulation of contaminant transport in groundwaters.	Visualisation of plume fronts and behaviour. Predictive tools for natural attenuation and groundwater risk assessments.
Gauthier *et al.*, 1987[27]	The characterisation of the soil matrix and, in particular, soil organic matter together with postulated models for intraparticle diffusion.	Understanding of fate and transport of hydrophobic contaminants in the soil environment and the thermodynamics and kinetics of release.
Paustenbach, 1987[28,29]	Codification of exposure models for estimating chronic intakes and characterising potential risks to human health from contaminated land.	Defensible basis for risk management. Targeting of risk management effort to principal exposure routes.

Swallow *et al.*, 1988[30]	Commercially available analytical instrumentation, including coupled techniques (AAS; ICP; ICP-MS; HPLC; GC-MS) for the routine analysis of metals and organics in soils and groundwaters.	Reduced detection limits and rapid turnaround times for commercial laboratories undertaking contaminated land and groundwater analysis. Competitive market.
Chudyk, 1989[31]	Development and application of field analytical techniques for use in on-site characterisation.	Rapid, on-site analysis for directing detailed sampling regimes and on the spot decisions for soils shift operations.
USEPA, 1999[2]	Demonstration and evaluation of novel treatment technologies at the pilot and field scale. Practical examination of the interface between risk assessment and management.	Increased confidence in the transferability of laboratory-validated treatment techniques to the field. Identification of opportunities and constraints for individual techniques under heterogeneous conditions.
SNIFFER, 1999[4]	Application of risk communication research to issues of contaminated land.	Improved stakeholder dialogue and involvement in decisions regarding site investigation assessment and remediation.

[23] M. Alexander, *Adv. Appl. Microbiol.*, 1965, **7**, 35.
[24] F. Schwille, in *The Joint Problems of the Oil and Water Industries*, ed. P. Hepple, Elsevier, Amsterdam, 1967, pp. 23–54.
[25] D. Mackay, *Environ. Sci. Technol.*, 1979, **13**, 1218.
[26] D. R. LeBlanc in *Movement and Fate of Solute Transport in a Plume of Sewage-Contaminated Ground Water, Cape Cod, Massachusetts, United States Geological Survey Open File Report, USGS, Virginia*, 1984, pp. 11–45.
[27] T. D. Gauthier, W. R. Seitz and C. L. Grant, *Environ. Sci. Technol.*, 1987, **21**, 243.
[28] D. Paustenbach, *Comments Toxicol.*, 1987, **1**, 185.
[29] D. J. Paustenbach, *J. Toxicol. Environ. Health* (*Part B, 3*), 2000, 179.
[30] K. C. Swallow, N. S. Shifrin and P. J. Doherty, *Environ. Sci. Technol.*, 1988, **22**, 136.
[31] C. Chudyk, *Environ. Sci. Technol.*, 1989, **23**, 504.

Source Characterisation. Adoption of a risk-based approach to remediating land requires an understanding of the hazards posed by the source of contamination. Without these data, the development of practical solutions to remediation is fundamentally compromised. Soil contamination is invariably complex and heterogeneous in its distribution[32,33] and its volume is often difficult to estimate. This is a particular problem for non-aqueous phase liquids (NAPLs) that have migrated below ground level because they rarely flow vertically or laterally in a uniform manner.[24] However, recent developments in the combination of geotechnical and field analytical methods may offer site investigators increased confidence over their below-surface distribution.

Figure 2 illustrates results from a membrane interface probe cone penetration test at a trichloroethylene-contaminated site.[34] A standard cone penetrometer fitted with a hydrophobic membrane is advanced vertically below the ground using a truck-mounted hydraulic rig and the membrane heated as the probe advances. Volatile hydrocarbons passing the membrane flow to a gas chromatograph (GC) at the surface where they are quantified. Lithographic data are collected simultaneously and the data presented as a depth of contamination profile alongside the site geology. Selection of different detectors for the GC allows hydrocarbon and chlorinated solvents to be identified separately. Figure 2 includes data sets from electrical cone penetrometer (ECP) and membrane interface penetrometer (MIP) tests. Data from the photoionisation (PID), flame ionisation (FID) and electrolytic conductivity (DELCD) detectors are shown. The traces show the presence of mainly aromatic contamination in the top 4 m of the soil, with some chlorinated compounds in the top 11.5 m. The majority of the chlorinated compound is seen as dense (D)NAPL at 11.5–15 m below ground level. Without the DELCD, this distinction between the solvent types would not be realised. This novel approach has value both in informing the subsequent positioning of groundwater monitoring wells, for example, and in estimating the amounts of material requiring removal should this become necessary.

The interpretation of site investigation data, especially for large sites, requires statistical analysis. Many risk assessment tools require contaminant distributions or at least the input of worst-case and mean concentrations into deterministic exposure assessment models. The statistical design of site investigations and the representative sampling of contaminated soils has been reported on extensively. A central concern has been the collection of representative data sets that allow hot spots and total contaminated areas to be delineated and that provide randomised data that can be used in statistical risk assessment packages. Site assessments undertaken for the purposes of liability management have, by and large, adopted deterministic sampling approaches, concentrating effort at former process and waste disposal areas of the site by reference to the historical land use

[32] R. O. Gilbert, *Statistical Methods for Environmental Pollution Monitoring*, Van Nostrand Reinhold, New York, 1987.

[33] CCME, *Guidance Manual on Sampling, Analysis, and Data Management for Contaminated Sites, Volume 1: Main Report*, Canadian Council of Ministers of the Environment, Winnipeg, 1993, pp. 9–37.

[34] P. A. Jacobs, *Proceedings of the Conference on Implementation of In-Situ Remediation Techniques—Chlorinated Solvents and Heavy Metals*, Utrecht, October 9–10, 2000.

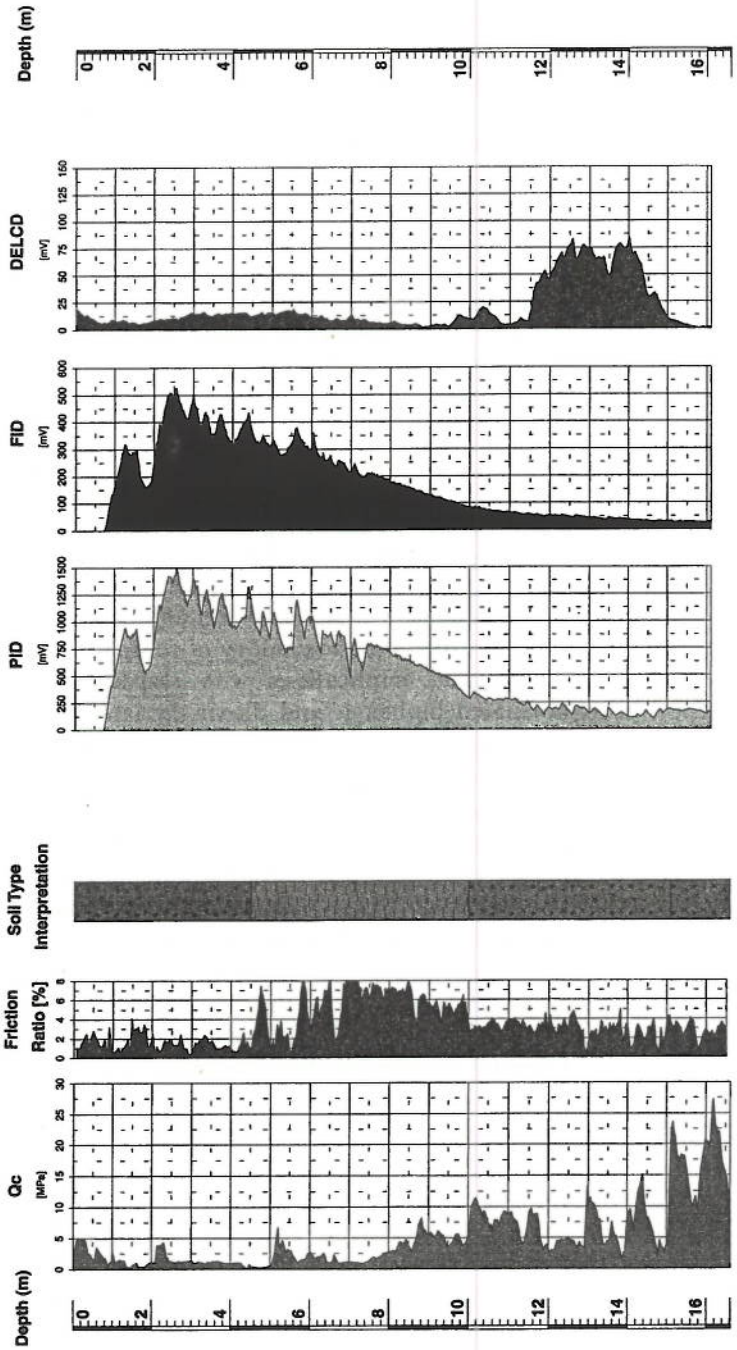

Figure 2 Membrane interface cone penetration test data for the volumetric delineation of below ground trichloroethylene (TCE) contamination (After ref. 34, with permission)

record. However, with the move to risk-based decision-making, the need to generate random, or at least stratified random, data sets on which statistical analyses can be performed is increasing. Where different needs are combined in the same site investigation, the separation of data sets to avoid the introduction of bias will be required.[33]

Analytical Methods. More powerful analytical instrumentation has become increasingly available and affordable over the last decades. Individual and coupled analytical techniques are now in widespread use and the routine availability of bench-top techniques has given greater access to more sensitive and selective measurements. Our appreciation of the complexity of contaminants in soil and groundwater systems is gradually driving a move to more sophisticated and informative analytical methods. The availability of improved techniques in itself has been an important driver towards a better understanding of these systems. Developments in risk assessment methods, which are increasingly concerned with specific and toxicologically relevant compounds[35] (see below), are driving changes in analytical method development, for example in the analysis of hydrocarbon residues in soils. The total petroleum hydrocarbon (TPH) risk assessment methodology[35] developed in the United States, for example, is requiring a new sophistication in the 'splicing' of the carbon number range in samples isolated from oil contaminated sites. Similar developments in our understanding of the toxicology of complex mixtures of contaminants (see below) have had implications with respect to the congener analysis of polychlorinated biphenyl- and dioxin-contaminated soils (Figure 3) and the analysis of polynuclear aromatic hydrocarbons (PAH) in soils.

In terms of metals analysis, the availability of inductively coupled plasma mass spectrometry (ICP-MS) is now providing better detection limits for important elements and wider simultaneous determinand suites than ICP-OES, though it is not reliable for the measurement of some contaminants such as mercury. Applied research into sequential extraction methods and physiologically based extraction techniques is informing our understanding of the role and importance of contaminant bioavailability in risk assessments.[29,36,37]

Detection limits continue to drop and legal disputes over cross boundary contamination are emphasising the need for quality assured data, inter-laboratory comparisons[38] and the development of standard methods for the purposes of analytical consistency (Figure 4). Alongside these developments in chemical analysis, biological diagnostic methods, such as enzyme-linked immunosorbent assays (ELISA) systems, are being increasingly used for rapid on-site analysis and

[35] D.J. Vorhees, W.H. Weisman and J.B. Gustafson, *Total Petroleum Hydrocarbon Criteria Working Group Volume 5: Human Health Evaluation of Petroleum Release Sites: Implementing the Working Group Approach*, Amherst Scientific Publishers, Amherst, 1999.

[36] S.E. Hrudey, W. Chen and C. Rousseaux, *Bioavailability in Environmental Risk Assessment*, CRC Press, Boca Raton, 1995.

[37] M.V. Ruby, R. Schoof, W. Brattin, M. Goldade, G. Post, M. Harnois and D.E. Mosby, *Environ. Sci. Technol.*, 1999, **33**, 3697.

[38] N. Boley, and D. Woods, *CONTEST Report, Round 27, March 2000*, Laboratory of the Government Chemist, Teddington, 2000.

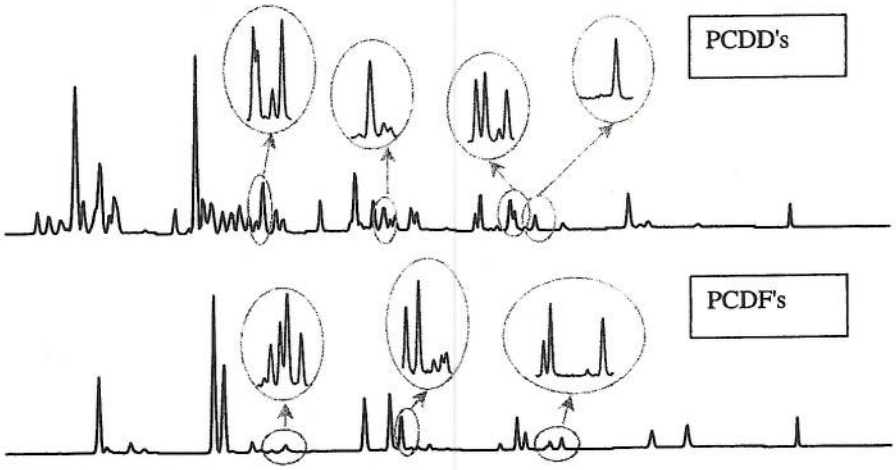

Figure 3 Analysis of 2,3,7,8-substituted congeners in soil; circled regions show sections of the traces separated by a second GC column. (Dr Nick Green, Environmental Sciences, Lancaster University, with permission)

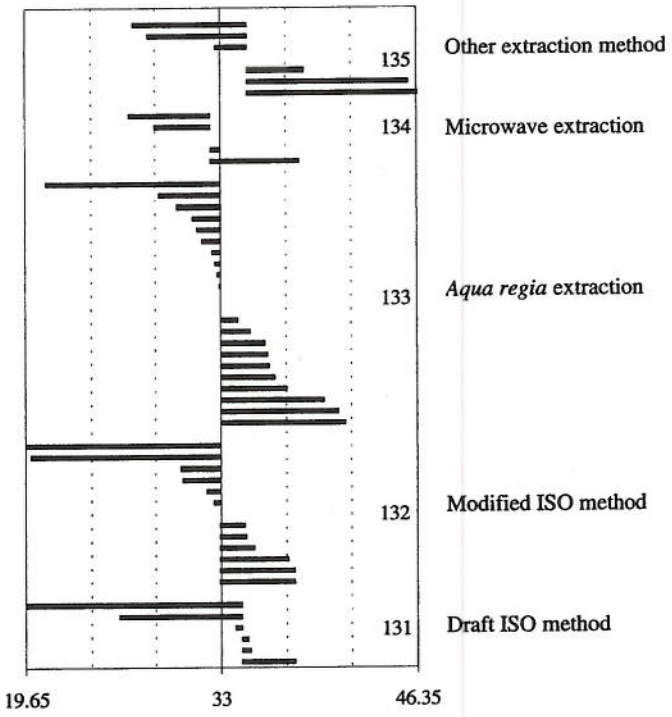

Figure 4 Distribution of analytical data for arsenic in a sample of homogenised soil, showing the performance of a range of laboratories (individual bars) and analytical methods (groups 131–135) about the grand median value of arsenic in the sample of 33 mg kg^{-1}. (After ref. 38, with permission)

to support the segregation and disposal of contaminated soils to on- and off-site facilities. The development and future application of lux-based (bioluminescent) bioassays for site characterisation, used alongside chemical analysis, offers site investigators the opportunity to evaluate and correlate the chemical mass and toxicity burden of polluted soils.

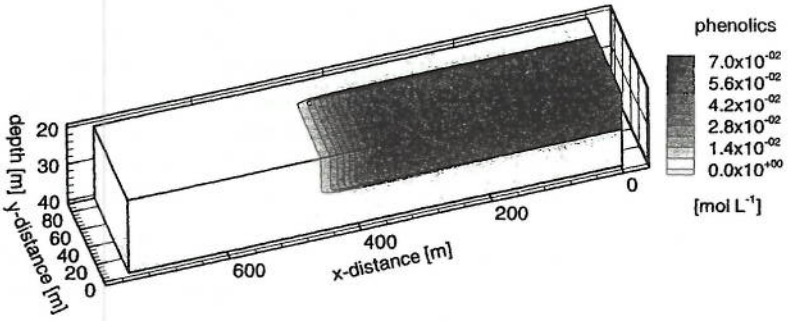

Figure 5a Three-dimensional section of modelled phenol plume in groundwater, showing the distribution of contaminant concentration (mol L^{-1}) away from the source area. (After ref. 39, with permission)

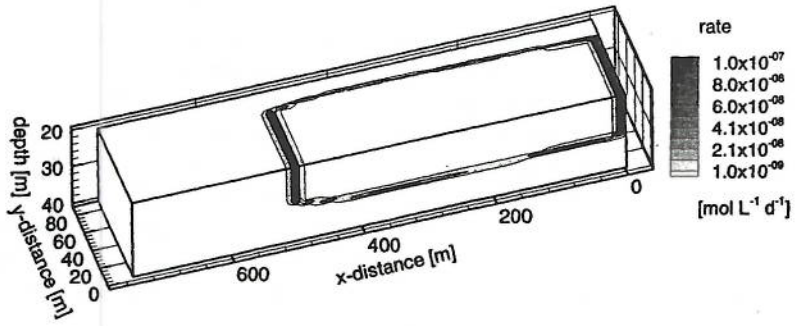

Figure 5b Three-dimensional section of modelled phenol plume in groundwater, showing the distribution of contaminant degradation rates, with highest rates occurring at the plume fringe. (After ref. 39, with permission)

Visualisation Techniques. The development of numerical modelling packages and computer-based visualisation techniques for the simulation and presentation of spatial distributions of sub-surface contamination has greatly enhanced our understanding of the transport of bulk contamination. For example, these techniques allow the presentation and 'manipulation' of plume fronts[39] (Figures 5a and b) and inform estimates of travel times with or without the natural attenuation, including biotransformation, of substrates. Resources invested early in the interpretation of site data help refine detailed assessment and monitoring programmes and can lead to a greater understanding of site-specific effects, such as the relative importance of transverse diffusion or substrate biodegradation to plume advancement, for example. These techniques are now being routinely used to improve the quality of site decisions – from the design of supplementary site investigation to informing cost–benefit estimates of pump and treat strategies and post-remediation monitoring.

Risk Analysis

Many countries, including the UK, have adopted a risk-based approach to contaminated land management and use the familiar source–pathway–receptor approach to risk analysis (see chapter by Quint). Here, we highlight some of the recent contributions towards development of the risk assessment for contaminated land management.

[39] K. U. Mayer, S. G. Benner, E. O. Frind, S. F. Thornton and D. N. Lerner, *J. Contaminant Hydrol.*, 2001, *in press.*

Sources. No single analytical method is capable of measuring the range of contaminants present in the complex mixtures most commonly found at contaminated sites. Screening methodologies are now widely used for identifying key pollutants during an initial assessment of the site. Selecting the appropriate surrogates for screening is an important task and involves assigning toxicity and environmental behaviour criteria to well defined, inclusive groups of constituents based on toxicity studies completed on individual constituents, mixtures and whole products.

The TPH risk assessment methodology[35] approach above derives petroleum hydrocarbon 'fractions' with similar transport and fate characteristics, and assigns toxicity criteria to these fractions based on those of a representative 'surrogate' compound or, ideally, mixture. Using the actual mixture of concern allows for interactions such as synergism and antagonism that may occur among the constituents of the mixture, and changes in the relative mass of each fraction at the receptor to be accounted for in the risk assessment. Various working groups have contributed towards this debate by establishing appropriate surrogates for specific petroleum hydrocarbon fractions.[35,40–44] Examples of the fractions and toxicity effects derived by two of these working groups are summarised in Tables 3a and b. Screening approaches such as these offer a practical means of assessing the significance of potential health impacts from a chemically complex source. Based on the information obtained remediation or more detailed assessment of the site can be progressed.

Pathways. Exposure assessment models are continually being refined to take account of new scientific developments. There are now many commercially available tools for predicting the fate and transport of chemicals in the soil environment and for estimating the subsequent exposure of receptors to these contaminants through a variety of environmental pathways. Models only provide illustrative estimates of exposure, however, and require careful application on account of the numerous assumptions contained within. For example, the use of different contaminant transport models can lead to wide ranging predictions of exposure to specific contaminants with exposure point concentrations varying by orders of magnitude depending on the model selected.

Consider recent developments in our understanding of vapour intrusion into buildings. A number of soil vapour intrusion models have been developed including:

[40] American Society for Testing and Materials, *Standard Guide for Risk-based Corrective Action Applied at Petroleum Release Sites, Standard E1739-95*, ASTM, Philadelphia, 1996.

[41] M.S. Hutcheson, D. Pedersen, N.D. Anastas, J. Fitzgerald and D. Silverman, *Reg. Toxicol. Pharmacol.*, 1996, **24**, 85.

[42] Massachusetts Department of Environmental Protection, *Characterizing Risks Posed by Petroleum Contaminated Sites: Implementation of the MADEP VPH/EPH Approach. Draft for Public Comment*, MADEP, Boston, 1997, at: www.state.ma.us/dep/bwse/vph_eph.htm

[43] CONCAWE, *Environmental Risk Assessment of Petroleum Substances: The Hydrocarbon Block Method. Report No. 96/52*, CONCAWE, Brussels, 1996.

[44] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Total Petroleum Hydrocarbons*, ATSDR, Atlanta, 1999.

Table 3 Examples of hydrocarbon fractions, reference doses (RfDs) and reference concentrations (RfCs) recommended by two working groups[41,42,45–47] (a) TPHCWG and (b) MADEP

(a) *Hydrocarbon fractions, RfDs and RfCs from TPHCWG*

Carbon range (equivalent carbon number, EC)	*Oral RfD* ($mg\,kg^{-1}\,day^{-1}$)	*Inhalation RfC* ($mg\,m^{-3}$)
Aliphatic fractions		
EC_5–EC_8	5.0	18.4
> EC_8–EC_{16}	0.1	1.0
> EC_{16}–EC_{35}	2.0	—
Aromatic fractions		
EC_5–EC_7 (benzene)		
> EC_7–EC_8	0.2	0.4
> EC_8–EC_{16}	0.04	0.2
> EC_{16}–EC_{35}	0.03	—

(b) *Hydrocarbon fractions and RfD from MADEP*

	Reference compound	*RfD* ($mg\,kg^{-1}\,day^{-1}$)
Aliphatic fractions (alkanes, cycloalkanes and isoalkanes)		
C_5–C_8	n-Hexane	0.06
C_9–C_{18}	n-Nonane	0.6
C_{19}–C_{32}	Eicosane	6.0
Aromatic fractions		
C_6–C_8	BTEXs	
C_9–C_{32}	Pyrene	0.03

- the Risk-Based Corrective Action (RBCA) Tool Kit;[48]
- the British Columbia (BC) model;[49]
- the British Petroleum RISC[50] (based on refs. 51 and 52);

[45] Total Petroleum Hydrocarbon Criteria Working Group, *Development of Fraction Specific Reference Doses (RfDs) and Reference Concentrations (RfCs) for Total Petroleum Hydrocarbons, Volume 4*, Amherst Scientific Publishers, Amherst, 1997, available at www.aehs.com/publications/catalog/contents/tph.htm

[46] Total Petroleum Hydrocarbon Criteria Working Group, *Selection of Representative TPH Fractions Based on Fate and Transport Consierations, Volume 3*, Amherst Scientific Publishers, Amherst, 1997, available at www.aehs.com/publications/catalog/contents/tph.htm

[47] Massachusetts Department of Environmental Protection, *Interim Final Petroleum Report: Development of Health-based Alternative to the Total Petroleum Hydrocarbon (TPH) Parameter*, MADEP, Boston, 1994, available at www.state.ma.us/dep/bwse/vph_eph.htm

[48] Groundwater Services Inc., *Guidance Manual for Risk-Based Corrective Action*, Groundwater Services Inc., Houston, 1995.

[49] I. Hers, R. Zapf-Gilje, R. Petrovic, M. Macfarlane and R. McLenehan, in *Environmental Toxicology and Risk Assessment (6th Volume)*, eds. F. J. Dwyer, T. Doane and M. L. Hinman, American Society for Testing and Materials, Philadelphia, 1997.

[50] BP Oil Europe, *BP RISC Software for Clean-Ups—Risk Assessment Software for Soil and Groundwater Applications, Version 3*, BP Oil Europe, Sunbury, 1997.

[51] P. C. Johnson and R. Ettinger, *Environ. Sci. Technol.*, 1991, **25**, 1445.

[52] P. C. Johnson, M. W. Kemblowski and R. L. Johnson, *Assessing the Significance of Subsurface Contaminant Vapour Migration to Enclosed Spaces—Site Specific Alternatives to Generic Estimates*, American Petroleum Institute, Publication Number 4674, Washington, 1998.

Table 4 Indoor concentrations of benzene measured and modelled (all values $\mu g\,m^{-3}$) after ref. 56

Measured concentration	*GSI*	*BC diffusion*	*BC advection*	*RISC diffusion*	*RISC advection*	*Ferguson diffusion*	*Ferguson advection*
1.6[a]	1.9	103	278	1.7	254	3.8	11
18[b]	760	7230	—	558	—	3.4E+04	—
44[c]	—	—	895	—	1270	—	7.6E+05
1479[d]	1470	—	2660	—	3660	—	2.8E+05

[a]Paulsboro data; [b]Chatterton data (diffusion); [c]Chatterton data (advection 30 Pa); [d]Chatterton data (steady-state advection 10 Pa).

- a model developed by Ferguson *et al.*;[53] and
- the VOLASOIL model.[54]

These models provide various representations of soil vapour intrusion following the migration into buildings of volatile organic compounds from a contaminated source. Differences in model predictions are caused by, amongst other aspects, differences in the processes being simulated and the assumptions made, the mathematical expressions used to simulate fate and transport and the practicality and reliability of obtaining and using input parameters required to run the models. As site-specific data become available, measured and predicted data can be compared and the information obtained used to refine these generic models.

Comparison of the processes simulated by these various models with sensitivity analysis performed on key input parameters (*e.g.* advection, soil moisture content, biotransformation rates) and calibration of the outputs from the models against site-specific data[55] can provide information on how each model performs against theoretical expectations and measured values (Table 4). This review showed that the predicted indoor air concentrations varied by over an order of magnitude (Table 1 in ref. 56). Incorporation of the key findings from this type of applied research work contributes towards improving the predictability of contaminants from contaminated land to various receptors.

Receptors. Developments have continued on the incorporation of human bioavailablity factors in human health risk assessment[37,57,58] and in the assessment of risks from contaminated land to ecological receptors.[59,60]

Dependent on the soil matrix and contaminant, only a fraction of the exposure

[53] C. C. Ferguson, V. V. Krylov and P. T. McGrath, *Building Environ.*, 1995, **30**, 375.
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point concentration of a contaminant may become bioavailable (for example, for ingestion exposures, absorbed through the gastro-intestinal wall, thereby entering the blood system and becoming available to the body's metabolic processes). Few risk assessments, with the exception of those for soil lead in the United States (US), attempt to address the human bioavailability of contaminants and they therefore tend to overestimate uptake. Recent research has focused on developing and validating *in vitro* laboratory test methods for estimating 'bioaccessibility' in soil[58] (the fraction of a substance that is released from the soil matrix when being digested in the human gastro-intestinal tract, thereby becoming available for absorption). Being able to represent and estimate bioaccessibility will be a major step towards assessing bioavailability. The findings of ongoing research will improve the scientific basis of estimating human health risks in soils and help support risk management decisions.

Ecological risk assessment for contaminated land has become a routine activity for site assessments in the US since the production of regulatory guidance in 1998[59] and is of growing interest in Europe on account of the EC Habitats Directive. The US has adopted a tiered, twin track approach that considers chemical exposure assessment alongside the analysis of ecological response. In practical terms, the measurement of ecological response has considered increased mortality rates at the population level, but the selection of appropriate end-points remains a contentious issue. Given the range of potential ecological end-points for characterising the significance of ecological harm, practitioners in the US have placed particular emphasis in the development and refinement of conceptual models[60] for ecological exposure and the characterisation of vulnerable or 'sentinel' species.

Effects. Most risk assessments concentrate on individual chemicals, and there is a considerable challenge to develop approaches that consider the health effects caused by whole mixtures. Although still at early stages, approaches are being developed that account for the combined effects of mixtures. One example is the Toxic Equivalent Factor (TEF) approach, whereby the toxicity for each individual chemical in a group of chemicals related by their mechanism of toxic action is estimated based on its relative toxicity to the most potent chemical within the group. The toxic equivalent (TEQ) for a group of chemicals is estimated by (i) multiplying the concentration of each individual compound in the exposure medium (here, soil) by its TEF; and (ii) adding the individual TEQs to derive a total TEQ, assuming that the combined effect of all the compounds in the group is additive. This approach is commonly used to estimate the toxicity for 2,3,7,8-substituted dioxins, dioxin-like polychlorinated biphenyls (PCBs) and, to a lesser extent, those polynuclear aromatic hydrocarbons (PAHs) found to exhibit a similar toxicity mechanism to benzo[*a*]pyrene.

Direct toxicity assessment (DTA) can also be used to account for the combined effects of contaminants. Measurements taken from biological and ecotoxicological tests are more directly related to ecological risk, because they measure the biological effects from a mixture of contaminants and, in doing so, provide an implicit indication of the bioavailability of the contaminants. Some tests can be simple and cost-effective in comparison to screening for multiple chemical

components. Lysosomal stability in earthworms, for example, has been used effectively to establish chemical exposure in contaminated soils, but more work is required to establish the cost-effectiveness of the technique and the relevance of results for predicting individual health.[61]

4 Conclusions

- The origins of contaminated land problems are well understood and relate largely to historical waste management practices in an era when a different environmental philosophy prevailed.
- Assessing the extent of the problem has been hampered historically by a lack of clarity over definitions. New legislation will help clarify the extent of land that is so contaminated that it poses a risk of significant harm to human health or the pollution of controlled waters.
- The scientific developments in this field have been considerable, especially with respect to environmental diagnostics, our understanding of the sub-surface, the advances made in the development of remediation technology and our understanding of the fate and transport of soil contaminants.
- A vast research literature has developed in the field of contaminated land management that continues to underpin policy and regulatory practice. The process of risk management has emerged as a central focus for much of this research. Several national and international research initiatives[62,63] have provided a basis for sharing expertise.
- Future research efforts are likely to continue along established paths and also seek to address the sustainable development agenda; focussing on the economics of contaminated land management, decision-making processes and sustainable technologies for remediation.

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Integrating decision tools for the sustainable management of land contamination

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Abstract

The approach to taking decisions on the management of land contamination has changed markedly over 30 years. Change has been rapid with policy makers and regulators, practitioners and researchers having to keep pace with new technologies, assessment criteria and diagnostic methods for their measurement, techniques for risk analysis and the frameworks that support decision-makers in their efforts to regenerate historically contaminated land. Having progressed from simple hazard assessment through to 'sustainability appraisal' we might now consider piecing together the experience of decision-making for managing land contamination. Here, we critically review recent developments with a view to considering how better decisions can be made by integrating the decision tools available. We are concerned with the practicality of approach and the issues that arise for practitioners as decision criteria are broadened.
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Keywords: Land contamination; Decision-making; Sustainable development; Risk-based land management

1. Introduction

The approach to taking decisions on the management of contaminated sites has been changed markedly over 30 years. We have moved from a cost-centred approach in the mid-1970s, through the technology feasibility studies of the mid-1980s, the risk-based approaches of the mid-1990s and into a new millennium where environmental decisions must be 'socially-robust' within a context of sustainable development (Urban Task Force, 1999; ESRC Global Environmental Change Programme, 2000). These decades represent our efforts to ensure regeneration is affordable, feasible, effective and latterly, sustainable. Now, and as a result of our acquired understanding, successful management of land contamination whether at the site,

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regional or national scale relies on applying a large and multidisciplinary knowledge base that straddles the natural, physical, engineering and social sciences within a practical, commercial, regulatory and often community context (Pollard et al., 2001a).

Decision-makers must not only be able to synthesise and apply this knowledge but also to work in a modern decision-making environment with an emphasis on 'process', wider participation and deliberation. A decade ago, Renn (1992) voiced the need for 'a (decision) process that facilitates the involvement of all affected parties and at the same time produces a prudent and informed judgement based on expertise and knowledge' as one of the major challenges of a modern democratic society. The success of such a process, whether for decisions on land contamination or other environmental pressures, depends on time, openness, the equal position of all parties and a willingness to learn. Socially robust decisions make the presumption of access to resources, flexibility in the decision-making process and an inherent capacity and desire for change (Homan et al., 2001; Brookes et al., 2001).

The new expectations of stakeholders including the public are there to see. There is growing public interest in, and engagement with, the process of decision-making, an increasing expectation of access to the documents and judgements of technical experts that support decisions on risk, and increased public scrutiny of the risk work of companies, their professional advisors and of the regulators (House of Lords Select Committee on Science and Technology, 2000; Green Alliance, 2000). Stakeholders and publics wish to understand and influence decision-making processes and their outcomes (Fischer, 1993; ESRC Global Environmental Change Programme, 2000). The response required of decision-makers is to make judgements transparent, explicit and open for challenge and to be clear about where those opportunities exist in the decision-making process (ILGRA, 1998; Petts, 2000).

1.1. Making decisions about land contamination

Decision-makers managing land contamination in the new millennium face complex issues of financial liability, securing development funding, the management of a series of regulatory interfaces, of interpreting sophisticated analytical data and risk assessments, the relative capabilities of remediation technologies and the maintenance of public confidence in remediation projects-all of which impact on the decision process and outcome (Vegter et al., 2002; Pollard and Earl, 2003). Other than for large-scale regeneration projects that progress over 5–10 years and beyond, the application of integrated frameworks that consider environmental, social and economic factors (Stern and Fineberg, 1996; Presidential/Congressional Commission, 1997; Van Der Vorst et al., 1999) may be hard to justify. Most projects require fast turnaround, development-led decisions, often with little capacity for the revisiting of data and tiered approaches to chemical analysis and risk assessment. Short timescales force a linear approach to taking decisions and there is pressure to reach decisions quickly. Acknowledging the practical and developing needs of risk management, governments, research organisations and industry bodies have developed practical guidance for decision-makers on negotiating the maze of factors influencing land contamination decisions (CONCAWE, 1997; ASTM, 1995, 2001; Environment Agency, 2003). However, having acknowledged the complexity of the decision making context, do we apply integrated decision-making in practice? Here, we explore some of the decision tools available beyond the well-referenced technique of risk assessment and, in the context of land contamination, explore the practical challenges for integrating these tools within the decision frameworks that are beginning to emerge.

1.2. Sustainable development, decision-making and land contamination

The UK strategy for sustainable development (Cm 4345, 1999) has the key objectives of (i) social progress which recognises the need of everyone (equity within and between generations); (ii) effective protection of the environment (proactive approach to limiting environmental damage); (iii) prudent use of natural resources (clean and efficient use of non-renewable and renewable

resources); and (iv) maintenance of high and stable levels of economic growth and employment (improved living standards for all; quality goods and services; education and skills). Application of the sustainable development agenda to soil quality (Puri and Gordon, 1998; DETR, 2000a; Defra, 2001) is focussing on historic land contamination and the wider aspects of soil quality, including: (i) bringing land back into early beneficial use; (ii) reducing pressure on greenfield sites and the pollution of groundwater, thus conserving agricultural land and natural habitats; (iii) adoption of a suitable-for-use approach towards land remediation; (iv) the efficient use of national resources to tackle issues of highest risk at priority sites; (v) prioritising remedial action so as to address the worst risks first in relation to the use of the land concerned; (vi) the application of sustainable remediation technologies that conserve land and resources; (vii) development and maintenance of new partnerships and fora among key stakeholders with agreements on a common research and practice agenda; (viii) the consideration of point and diffuse sources of soil pollution over the long term; (ix) the development of monitoring systems that allow early detection of adverse soil, water and ecosystems changes; and (x) the distribution of impacts from land contamination on communities. In the UK, these issues are being addressed through a combination of policy, regulatory, voluntary and technological responses, supported in turn by the application of decision tools at the strategic and operational level.

Environmental regulators, land-use planners and practitioners have at their disposal a considerable array of tools (Table 1) to assist with screening environmental impacts, assessing risk/benefit trade-offs, engaging wider stakeholder communities within decision-making and the integration of technical, socio-political and economic factors that inform environmental decisions (e.g DETR, 1998; RCEP, 1998; Sexton, 1999; USEPA, 1999; Alker et al., 2000). These tools are not only used increasingly at the strategic (policy and programme) and operational (plan and project) levels (Fig. 1), but across a wide spectrum of environmental issues (DETR, 1998; Nijboer, 1998; USEPA, 1999; Brookes et al., 2001). At the heart of the technical assessment, practitioners have developed frameworks making use of the well-established processes of risk assessment, management and communication (Ferguson et al., 1998). However, many of these processes have developed rather in isolation of each other and often without an explicit reference to the decision being taken.

Current approaches to the management of risks from land contamination have much in common with many modern environmental decisions that demand an holistic approach. Increasingly, national and international reports (USEPA, 2001; Vegter et al., 2002; Environment Agency, 2003) encourage practitioners to connect these aspects of decision-making within an overarching philosophy of risk-based land management (RBLM) and adopt a broader range of support tools (Assmuth, 1998; Bardos et al., 1999; Earl and Kearney, 2000; Pollard et al., 2001b; Pollard and Earl, 2003 Table 1) including:

- brainstorming techniques (e.g. for project risk assessment, hazard identification and conceptual model development);
- statistical data analysis (e.g. in geotechnical and geoenvironmental site investigation);
- environmental fate and transport modelling (as a component of exposure assessment);
- scoping, screening and prioritisation techniques (in qualitative risk assessment; in remedial technology selection);
- sensitivity and uncertainty analysis (in quantitative risk assessment);
- public consultation workshops;
- economic appraisal of costs and benefit (in comparing remedial approaches, including the costs of 'do nothing' and the assessment of appropriate times for intervention); and
- the collection of opinions and lay-perspectives on risk (for risk communication and decision making).

The challenge to practitioners to widen their perspective and embrace formal and integrated tools comes at a time where achieving the balance of economic, social and environmental benefits of dealing with land contamination is increasingly critical at all levels of delivery. Money is in short supply, societal pressures, particularly in relation

Table 1
Broad typology of decision tools for environmental decision-makers with application to land contamination (after Pollard et al., 2001b)

Tool	Use	Environmental arena in which tool has been conventionally applied	Land contamination decision context
Environmental risk assessment	Estimation of probability and consequence, usually for adverse environmental impacts at the site-specific level, but can be applied at policy level as strategic risk assessment (SRA).	Chemical product licensing, manufacture and use; production plant safety; environmental health protection; environmental planning and environmental permitting; flood defence; liability auditing; contaminated land assessment; policy analysis; strategy setting.	Context well established; identification and analysis of hazards and potential environmental harm from contaminated sites; use of probabilistic techniques for dealing with uncertainties in exposure assessment; sensitivity analysis to assist in remedial technology selection; increasing focus on dose-response assessment and ecological risk assessments.
Environmental (impact) assessment	Environmental, impacts of proposed developments; summarised in non-technical language; participatory approach advocated; can also be applied at the policy or sectoral level as strategic environmental assessment (SEA).	Environmental development planning; siting of contentious installations (e.g. incinerators, landfills, tidal barrage); policy analysis; business sector analysis. May be supplemented by environmental risk assessment where health effects are of concern.	Siting of plant for the long-term treatment of residuals (e.g. secondary treatment of pumped groundwater); siting of containment facilities: scoping matrix approach for principal environment impacts. Strategic environmental assessment may extend to land regeneration programmes and strategies.
Social impact assessment	Assessment of the impacts of planned developments on the social fabric of communities, includes equity issues and impacts on social processes.	Not as yet conventionally applied in UK, more focused in USA and developing countries, but might provide useful basis for assessing the 'social' part of sustainable development.	Not in explicit current use. On more complex sites, SIA could be used to analyse the social context of a site or regeneration programme and to identify key pressures and benefits/possible constraints on remediation
Health impact assessment	Assessment of the health impacts of a development or process. Akin to EIA with broader emphasis on health (not just toxicological) impacts of developments.	Recent call for it to be integrated into EIA – little distinction in practice from human health risk assessment within a planning context. Application in the context of air quality impact assessments for siting incinerators.	Nested within human health risk assessment. Broader health impacts (e.g. psychological impacts, anxiety etc.) recognised though not formally assessed.
Cost-benefit analysis	Systematic and consistent appraisal and evaluation of economic and environmental costs and benefits of alternative projects, strategies and policies.	Appraisal of proposed investments in flood defence projects; BATNEEC and BPEO assessments of pollution control measures; policy appraisal and regulatory impact assessments.	Not routinely used in UK. Comparative assessment of risk reduction and costs for a variety of remedial technologies; assessing intervention times for groundwater plume remediation; at the strategic level may contribute to policy appraisal of statutory instruments and regulatory policies for contaminated sites. Formal cost-benefit tools being applied especially for optimising remediation of soils and water

Table 1 *(Continued)*

Tool	Use	Environmental arena in which tool has been conventionally applied	Land contamination decision context
Multi-criteria analysis (MCA) and multi-attribute techniques (MAT)	Integrated assessment of technical, social and economic impacts of alternative projects, strategies and policies. This incorporates monetisable/quantifiable and non-monetisable/quantifiable impacts.	Assessment of risk management options; consistent appraisal of environmental benefits of water quality improvements by water industry so as to prioritise these measures in terms of their cost-effectiveness of securing environmental benefits.	Assessment of technical, socio-political and economic factors associated with a range of remedial options; integrating 'soft' data on risk perception and political risk with quantitative cost estimates and remediation efficiencies. Initial decision tools produced in the Netherlands. These allow for greater stakeholder discussion over broader benefits of remediation.
Environmental audit	Account of activities and production and resulting effects on environment; usually undertaken by an independent team with management support; the collation, analysis, interpretation and documentation of practices relevant to environmental requirements; checklist and Y/N guide approaches are common.	Improvement plans; setting insurance premiums; corporate environmental accounting and statements; liability (mergers, acquisitions and divestitures); regulatory compliance; efficiency of environmental management systems (EMS); due diligence; waste minimisation.	Well established for multi-site comparisons and merger and acquisition assessments; focus is on qualitative risk assessment: source-pathway-receptor approach, worst-case and 'reasonable' worst-case scenarios to drive remedial cost (liability) estimates. Considerable uncertainty in absence of site-specific information; multi-site comparisons undertaken by reference to source, receptor characteristics and regulatory pressure.
Life cycle analysis	Energy and mass balance from cradle to grave of products.	Manufacture; product replacement and substitution; supply and product chain management.	The design of sustainable remediation technologies and programmes; extension beyond simple CAPEX and OPEX expenditure to issues of energy/resource consumption and the secondary issues of treatment residuals management.
Sustainability appraisal	Developing area. Appraisal framework using sustainability objectives; potential application at all levels; flexible iterative process; indicators to monitor process; matrix/checklist approach.	Appraisal of regional planning guidance and regional strategies; policy and strategy level appraisal. Relatively recent developments.	Potential application to the appraisal of national or regional or site scale land regeneration programmes. Best viewed in terms of the integration of the above techniques.
Stakeholder analysis	Approach to analyzing the stakeholders involved in the decision process. Informal to formal approaches available; enables systematic consideration of all relevant parties and the relationships	Carried out in an informal way within the EIA process. Associated more with social impact assessment advocated by stakeholder dialogue practitioners as a component of other decision-making processes.	Enables a systematic approach to understanding the range of stakeholders involved with a site/regeneration programme. Potential application to understanding the potential range of opinions and values that might be expressed regarding specific remediation options.

Table 1 *(Continued)*

Tool	Use	Environmental arena in which tool has been conventionally applied	Land contamination decision context
	between those parties. Can provide an audit trail.		
Engagement techniques	Citizen's juries – Involves major stakeholders in the process of the identifying and appraising of options – lay people brought together to deliberate on an issue, call witnesses and come to a verdict. Citizen's advisory groups - lay people brought together over a period of weeks to act as the voice of the community – can turn into a monitoring group once the decision has been made.	Applied in the context of hazardous and radioactive waste management.	Potential application for complex contentious sites where a number of remediation options are possible and an informed public debate is desirable. Increasing interest in participatory decision-making for contaminated land rather than risk communication as a 'bolt-on' on project completion.

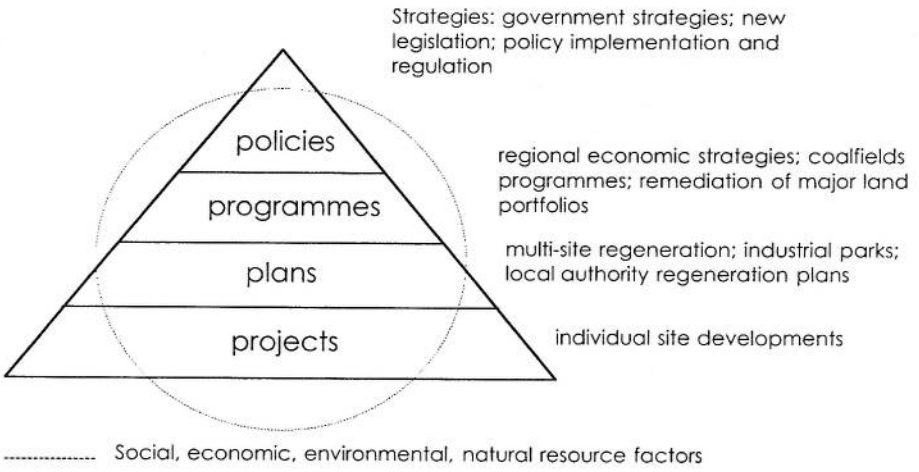

Fig. 1. Decision-making at different scales: from policy to project level assessment with examples of various contexts for land contamination.

to land use and development density, are increasing and predictions about the long term quality of human health and the environment are if anything, increasingly uncertain.

Decisions about different aspects taken in isolation are no longer sufficient. The regeneration of brownfield land offers a good example of the need for robust and integrated decision making. The drivers for regeneration have traditionally been economic, leading to a demand for a simplified assessment of risk with minimum costs of requirements to deal with risks. At a political level, the new drivers are often social, but this can equally lead to biased views about the benefits of remediation in relation to the use of the land, or a narrow targeting of remediation on particular areas where there is immediate demand for new uses of land. At a wider level, however, there is a need to provide a higher overall quality of life, sustainable water resource management and biodiversity, without simply transferring the problem to another environmental medium, geographical location or generation. This means that long term health and environmental risk assessment have to be at the heart of regeneration decisions, rather than simply one of the processes that takes place to deliver prejudged outcomes.

1.3. Risk and economic appraisal: an example of integration

One component of the appraisal of sustainable remediation, economic appraisal, brings new considerations to the decision-making process (Martin et al., 1998; Environment Agency, 2000a) such as issues of market failure, 'opportunity costs', the law of diminishing returns and the 'valuation of impacts'. The purpose of an economic appraisal is not only to estimate the level of the costs and benefits of the options for risk management, but also to identify the key factors determining them so as to seek out and refine better options for all concerned with lower costs and greater environmental and social benefits. Economic appraisal relies on the findings of the risk assessment.

For regulatory authorities considering the remediation of orphan sites, an appraisal might typically involve determining whether statutory requirements or other remediation aims or objectives set by an overarching authority exist, for example, by the Department for Environment, Food and Rural Affairs (Defra), the Office of the Deputy Prime Minister (ODPM) or the European Commission (EC). Statutory requirements may stipulate some qualitative caveats regarding the stringency with

which agencies should apply them such as 'unless excessively costly' or 'unless there are overriding public interests'. In such cases, the analysis would have to consider how these qualitative caveats are translated into the decision process. For example, under Part IIA of the Environmental Protection Act 1990 in England and Wales (DETR, 2000a), the main aim for remediation is to ensure that a significant pollutant linkage no longer exists, to the extent that this can be achieved using the best combination of practicability, effectiveness and durability that is reasonable with regard to the balance of costs and benefits and by reference to the seriousness of the risk.

Taking into account any pre-set remediation objectives and other regulatory or policy constraints, the full range of objectives that are theoretically possible, and at least practically feasible, should be identified. This should consider alternatives for the timing of remediation. For example, in land restoration programmes, remediation may have as its aims not only the removal of a significant pollutant linkage in relation to Part IIA (DETR, 2000a), but also in the long term the return of the land to a different beneficial use.

It is then necessary to integrate the economic impacts with the environmental, economic and social impacts of the different remediation objectives to determine the most appropriate aim of remediation of the site. The appraisal should include the costs of the options and their environmental impacts (both positive and negative) and consider impacts assessed in monetary terms (e.g. impacts on local properties) and intangible impacts (e.g. on human health and ecosystems). In situations where more than one option is necessary, it may be cost-effective and practicable to consider the integration of the options into an overall strategy. Such appraisals should set out as fully as possible the level, nature and significance of these impacts building on scientific assessments of the overall reduction in the environmental impact that the remediation provides. Such assessments might be encouraged to include the social benefits of remediation such as increased amenity value.

Finally, the law of diminishing returns reflects the reality that the trade offs between reducing environmental damage and the costs of this reduction become more significant as remediation progresses (Earl and Kearney, 2000; Environment Agency, 2000b). This has significant implications for the economic appraisal of remediation options.

1.4. Integration in practice

Accounting for a multitude of decision factors generates considerable challenges for decision-makers including the effectiveness, practicability and cost of implementing integrated approaches and the inevitable issues of terminology (Table 2).

With respect the effectiveness of integrated decisions, one might ask whether structured approaches to decision-making provide for greater decision-making power and better decisions. Pragmatists often argue that the incremental costs associated with the environmental appraisal of remediation projects are rarely justified when viewed in terms of the final outcome, which may have been arrived at through professional judgement without recourse to a particularly structured analysis. However, structured analysis, which does not need to override professional judgement, does improve consistency and offer a transparency of approach, providing the aims and boundaries of the assessment (risk assessment, options appraisal) are clearly set out. A further response is to view not only the cost-effectiveness but also the *uptake* of a decision by stakeholders (including the risk takers) as a critical indicator of success (Brookes et al., 2001).

Practicability is important if the credibility of decision tools is to be upheld. Option appraisal tools should be integral to the decision-making process and practised iteratively. Application of these tools need not be onerous (Brookes et al., 2001). Many appraisals can be completed using inexpensive, but transparent screening techniques (*rapid appraisal*) with more sophisticated tools (*technical appraisal*) being reserved for contentious, complex, or higher priority projects. Screening is an accepted methodology in environmental impact assessment and is becoming recognised (in the UK) as a means of targeting resources at the most deserving issues at more strategic levels. Checklist approaches, although with recognised limitations, have been used widely. The approach

Table 2
Integrating decision-support tools: some key challenges

Challenge	General commentary	Land contamination decision context
Identifying the full aspects of a problem	Time needs to be invested at the outset to determine All these aspects. For example, there may be a mix of traditional EIA issues, risk and potential social and Economic impacts. Application of brainstorming and 'risk register' techniques may help. Wide consideration of stakeholder views needed. Key practical challenge is of how to include all diverse impacts, aspects and considerations of a problem in a systematic manner without 'double-counting'.	Emphasis is usually on scoping out technical detail and conceptual model development, but often less emphasis on economic and social aspects of remedial programmes at the outset. Less the case for land regeneration subject to strategic assessment under the auspices of, for example, a local or regional plan. Need for site work to be risk-led and risk-based when dealing with historic land contamination.
Setting boundaries for the analysis	These need to be established and agreed both for consistency and for transparency and to make the appraisal practical. For example, there is a growing interest in EIA approaches encapsulating the entire life cycle of a project, ranging from the winning of raw materials to the final decommissioning and disposal stages. But there is a danger of becoming overwhelmed in excessive and unnecessary detail, so the analysis should concentrate on issues of significance to the environmental, economic and social impacts.	Tend to be established by regulatory context and owner/developer. Often technically, or financially driven with less emphasis on social issues. Greater consideration and involvement of the range of audiences earlier on may help avoid difficulties later with respect to disagreements over the scope of studies, the communication of risk assessment output and remedial technology selection, though not a guarantee against disagreement.
Selecting individual techniques to potentially solve a problem	It is difficult to find off-the-peg techniques that are scientifically, professionally and socially acceptable. There is a dearth of guidance. At present a wide range of methods exist from formal frameworks such as Risk Assessment, EIA and CBA to deliberative approaches. Any single problem may require unique or novel approaches tailored to the case in question, or adaptation of an existing decision-making tool. This can take time in the short run, but can avoid significant problems at a later stage.	Most decision tools require tailoring to the specific circumstances of the site because the context of application often requires an emphasis on certain aspects. An obvious example is the emphasis put on exposure assessment within the application of risk assessment for land contamination. This may require adjustment to site-specific circumstances with the input of local knowledge and data on exposure scenarios.
Maintaining professional rigour whilst working in a multidiscipline fashion to integrate techniques	It is essential to apply rigorous professional standards in each discipline's contribution, while still enabling their combination for the development of integrated techniques.	Clear specification of the impacts of remediation option across disciplines (technical, economic, Social), without double counting, during appraisal. Recognition of the need for multidiscipline teams and recognition of limitations regarding the boundaries of professional knowledge (engineering; analytical chemistry etc.)

Table 2 *(Continued)*

Challenge	General commentary	Land contamination decision context
Linking tools and techniques together as appropriate	This is difficult because of the specific boundaries that surround techniques and the form in which each technique produces its findings. For example, risk assessment may report on the significance of a contaminant exceeding a threshold, whereas options appraisal techniques also need an analysis of risk reduction and residual risk to allow decisions to be made. Often it will be necessary to combine qualitative and quantitative information. Furthermore, models on which techniques are based may be incompatible.	Clearest example is of using risk assessment output to inform remedial objectives. These processes still often viewed as distinct, however. There is a greater need to practice early iteration of risk management decisions following screening level risk assessments, so as to refine detailed risk assessment work.
Appropriate terminology to avoid misinterpretation of key terms and jargon	The above challenges are compounded by differences in the language and jargon customarily used by different Disciplines and the interpretations attached to specific terms. Differences in understanding between and within disciplines, between stakeholders need to be addressed early on.	A common problem across the field of risk. Terminological differences can be overcome by focusing attention on the fundamental questions for which answers are sought. For example: hazard identification – what hazards are present on site? How might the consequences be realised? Who or what is at risk from these consequences? etc.
Non-dominance	No single technique or discipline must dominate the others or be perceived as dominating in reaching a final decision.	Historically, cost has dictated remedial selection. Structured, integrated analysis may result in challenges to the way that this is presented. Multidiscipline approach means a range of factors are seen as valid, though not necessarily to an equal degree.
Consideration of increased public involvement	Current calls for increased public participation. There is considerable experience in EIA but less so in risk assessment, CBA or technology assessment. Structured and focused approaches are necessary, together with an examination of institutional structures and their capacity for meaningful public involvement. Monitoring and validation of these mechanisms is critical.	Increasing interest in risk assessment design and output. Approach to date has been on technical risk assessment followed by 'risk communication' exercises to discuss output. US experience suggests limited success in this regard and many commentators now point to a need to apply engagement and participatory approaches. UK experience suggests the earlier this is done the better.
Considering values	Deliberation is one way of uncovering people's values, but there are challenges as to how those values are incorporated into decision-making and how representative groups are, such that deliberative analysis of small groups views may need to be supplemented by surveys of a larger sample of the relevant population.	Likely to have a complex range of values associated with a contaminated site. Potential for inadvertent scientific and professional bias in risk assessments; consideration of broader stakeholder values with respect to remedial objectives. Early discussion of varied agendas is important.

Table 2 *(Continued)*

Challenge	General commentary	Land contamination decision context
Risk perceptions and lay epidemiology	Understanding the perspectives from which lay people address problems and valuing their local knowledge – challenge as to how local knowledge sits alongside expert knowledge.	Local effects attributed to sites by individuals/ communities. Difficulties of establishing causality and reconciling reported observations alongside exposure assessments.
Handling uncertainty	Recognition that in addition to uncertainty, there may be areas of ignorance where, in the presence of significant risk, the precautionary principle may be appropriate. To reflect the prevailing uncertainties results of appraisals need to be shown as ranges rather than discrete numbers. Uncertainty and sensitivity analysis can assist in highlighting the significance of ranges.	Integral to most environmental decision-making tools. Issues of blight and financial risk ensure this is problematic for most contaminated sites. Emphasis on quality assurance and control with respect to consulting advice, site investigation design and practice and remedial monitoring. Often an over cautious approach is adopted to overcome uncertainty.
Using experts	The appraisal community is now taking on board participatory methods, combining scientists and non-experts. This raises important challenges and methods of eliciting and sharing technical information need to be developed and interrogated.	Use of experts at public inquiry especially with respect to remedial design and exposure assessments. Issues with respect to human health effects and toxicological data are difficult and tend to be addressed with reference to the deliberations of authoritative expert panels and committees. Application of expert elicitation techniques is common place in radioactive performance assessment for elicitation of receptor characteristics and representative 'futures'.
Deciding which timescale is appropriate	For example, sustainable development requires a longer-term perspective to be taken. There may be a need to undertake 'scenario-building' in parallel with a particular appraisal technique.	Issues of deciding when to intervene, for example, with respect to plume transport towards a public water supply. Balancing times required for detailed assessment alongside plume advancement. Use of 'what-if' scenarios and futures to compare decisions.
Trading-off one option against another	There are particular challenges regarding how to present information on the trade-offs concerning risk management options. This also raises issues surrounding the choice of decision factors, the use of ranking, rating or scaling and, more controversially, weightings.	Challenges are particularly difficult where there is considerable uncertainty in the component parts of the decision. Issue of comparing quantitative and qualitative information is heightened.
Post-project analysis	It is imperative that the process is evaluated and lessons learned.	Improved project design and decision-making processes.

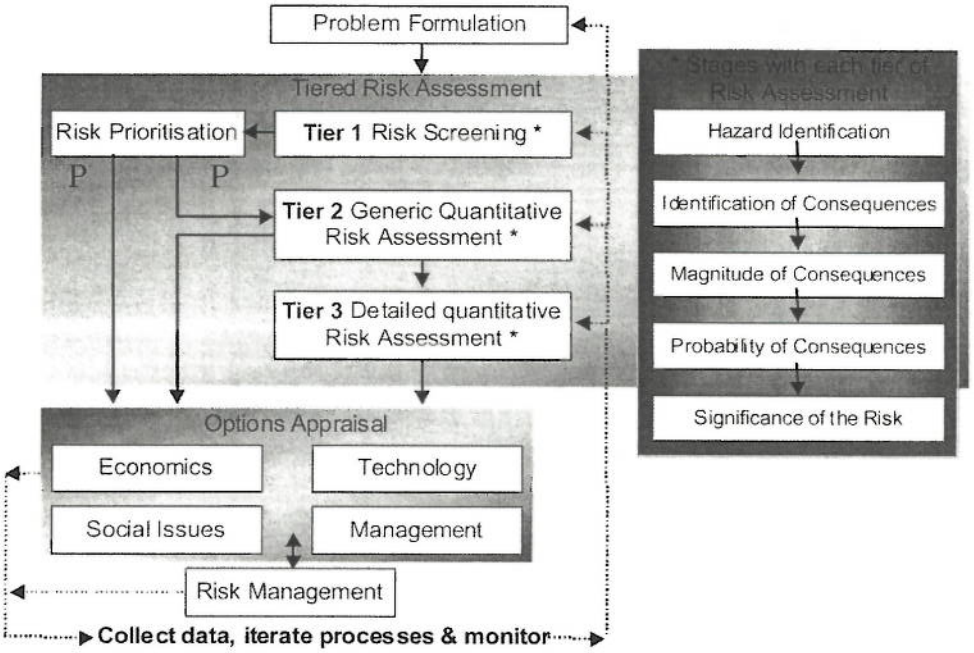

Fig. 2. Example framework for environmental risk management illustrating a tiered approach, iteration and early opportunities () to progress to risk management after rapid (in this case, *risk*) appraisal (*after* DETR, 2000b).

is analogous to the Government's tiered approach to environmental risk management (DETR, 2000b; Defra, 2002; Fig. 2) and has been adopted for land affected by contamination in the Environment Agency's model procedures for the management of land contamination (Environment Agency, 2003). Many appraisals have core (fixed) and non-core (variable) aspects to their analysis and decision-makers can streamline their appraisal efforts accordingly by identifying core issues at a screening stage and focusing any additional effort on decision-critical aspects of the analysis.

Decision-makers applying these frameworks find themselves responding to the expectations of a variety of stakeholders, many of whom have interests focused both on and beyond the technical analysis (Fischer, 1993; Homan et al., 2001; Petts et al., 2003a,b). The multiple terminologies of appraisal can be alienating to lay audiences and under these circumstances, while offering some clarity, structured risk management frameworks run a potential danger of implicitly assuming that the technical perspective is somehow pre-eminent (Petts, 2000) to other considerations. In many regulatory settings, some commentators have argued a potential disparity exists between a practical need to define regulatory procedures and the desire to engage the public in risk decisions where the 'technical' language of risk will compete with the colloquial language of the public (Petts, 2000). Being clear about expectations, therefore at the outset is critical if they are to be managed and met.

2. Conclusions

A growing literature exists on the integration of tools for decision-making on land contamination, much of which comes from the 'environmental assessment' research and practitioner community. This in itself is evidence of increased integration, though as we illustrate, as these tools are read across to issues of land contamination potential traps exist for decision-makers on the capacity of these tools to deliver improved decisions. Assistance is required on how best to integrate the

outputs of various techniques through demonstrating their use in the practical context of land regeneration. We conclude that

i. Decision-making frameworks can add value by making the routes to decisions transparent.
ii. The current literature on environmental decision-making suggests that technically driven decisions made in isolation of other concerns is insufficient for many stakeholders.
iii. Recent developments suggesting a move forward to sustainable land management in the context of brownfield regeneration will necessitate the development and application of a broader and integrated portfolio of decision techniques.
iv. There is a need to work through the implications of applying these tools alongside one another and develop the interfaces so they become commonplace and demonstrably beneficial for practitioners.

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Biosolids—A Fuel or a Waste? An Integrated Appraisal of Five Co-combustion Scenarios with Policy Analysis

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An integrated appraisal of five technology scenarios for the co-combustion of biosolids in the UK energy and waste management policy context is presented. Co-combustion scenarios with coal, municipal solid waste, wood, and for cement manufacture were subject to thermodynamic and materials flow modeling and evaluated by 19 stakeholder representatives. All scenarios provided a net energy gain (0.58–5.0 kWh/kg dry solids), having accounted for the energy required for transportation and sludge drying. Co-combustion within the power generation and industrial (e.g., cement) sectors is most readily implemented but provides poor water utility control, and it suffers from poor public perception. Co-combustion with wastes or biomass appears more sustainable but requires greater investment and presents significant risks to water utilities. Incongruities within current energy and waste management policy are discussed and conclusions for improved understanding are drawn.

Introduction

Sewage sludge (biosolids) is an unavoidable byproduct of wastewater treatment. It has valuable attributes but can be odorous and often contains persistent environmental pollutants that restrict its further use. Applying it to land as a nutrient and a source of organic matter has been the dominant reuse outlet in the UK, absorbing about 50% w/w of total production (*1*), and this is often the best practical environmental option for reuse (*2*). However, the reduced availability of land, the increased public concerns over food chain safety, and the associated uncertainties and costs of reuse have required water utilities to explore alternative management options that can contribute to a more sustainable biosolids strategy.

Policy Context. Co-combusting biosolids with fuels or wastes could provide one secure outlet, among others, and generate income through energy recovery. The changing UK energy policy climate (*3*) lends support, in principle, to the use of biomass and locally generated waste as fuel, as part of a move toward the low carbon economy. New energy legislation and policy initiatives, such as the renewables obligation (*4*) and the climate change levy (CCL) (*5*), are stimulating renewables in the UK, offering, in principle, a more favorable environment for biosolids to be considered for use as fuel. However, the classification of biosolids as "waste" imparts legislative demands that constrain its onward use (*6*, *7*). Further, the introduction of a new fuel stream to an industrial facility can require operators to comply with additional legislation, a perceived barrier to using biosolids, unless there are significant economic or operational benefits. Enright (*7*) collates European case law on the Waste Framework Directive (*8*) as it relates to the use of wastes as secondary products (e.g., as a fuel), and has suggested that the absence of legal clarity on the definition of waste remains a critical barrier.

This policy incongruity between renewable fuel incentives and environmental protection presents an obstacle to the development and implementation of biosolids strategies. Given the multitude of influences including technical, sociopolitical, operational, and economic, a central question can be posed: Are biosolids a fuel or a waste? This paper adopts an integrated approach, examining the environmental impact, energy balance, risks, costs, and sustainability of biosolids' co-combustion with coal, municipal solid waste (MSW), and biomass co-fuels and as a supplementary fuel in other industrial processes (e.g., cement manufacture). While similar approaches have been adopted for wastewater treatment (*9*, *10*), this analysis has been historically lacking in biosolids management, although often called for as a prerequisite to project-based environmental assessment (*11*, *12*). The aim was to undertake a generic assessment and explore, with data, the complexities of the tradeoffs required and the implications these might have for an improved policy context.

Experimental Methods

Approach. Five biosolids co-combustion scenarios were selected, with the assistance of UK water utility biosolids managers, reflecting a range of operational scales, project party structures, technologies, and growth potential feasible in the UK. Assessments of the prior art, and a series of 1.5 h structured interviews with representatives of the water industry, the power sector, regulatory bodies, and the nongovernmental (NGO) sector elicited views on the risks, benefits, barriers, and opportunities for biosolids co-combustion for each scenario. The technical and environmental feasibility of each scenario was assessed using a materials flow and energy model. An economic analysis compared indicative costs and income potential for the five scenarios.

Co-combustion Scenarios. The principal factors defining biosolids co-combustion are the thermal capacity (MW_{th}) of the combustion process, the type of materials co-combusted, and the extent of organizational involvement that a utility might have in financing and operating a facility. Secondary factors include the conversion technology employed, the supply chain security, and the type and amount of biosolids available. Potential co-fuels include fossil fuel, plant biomass (i.e., wood, such as coppiced willow), and MSW. The operating options open to a water utility include the following: supply to third party only, with no involvement in the combustion of the biosolids into energy, the biosolids being delivered to

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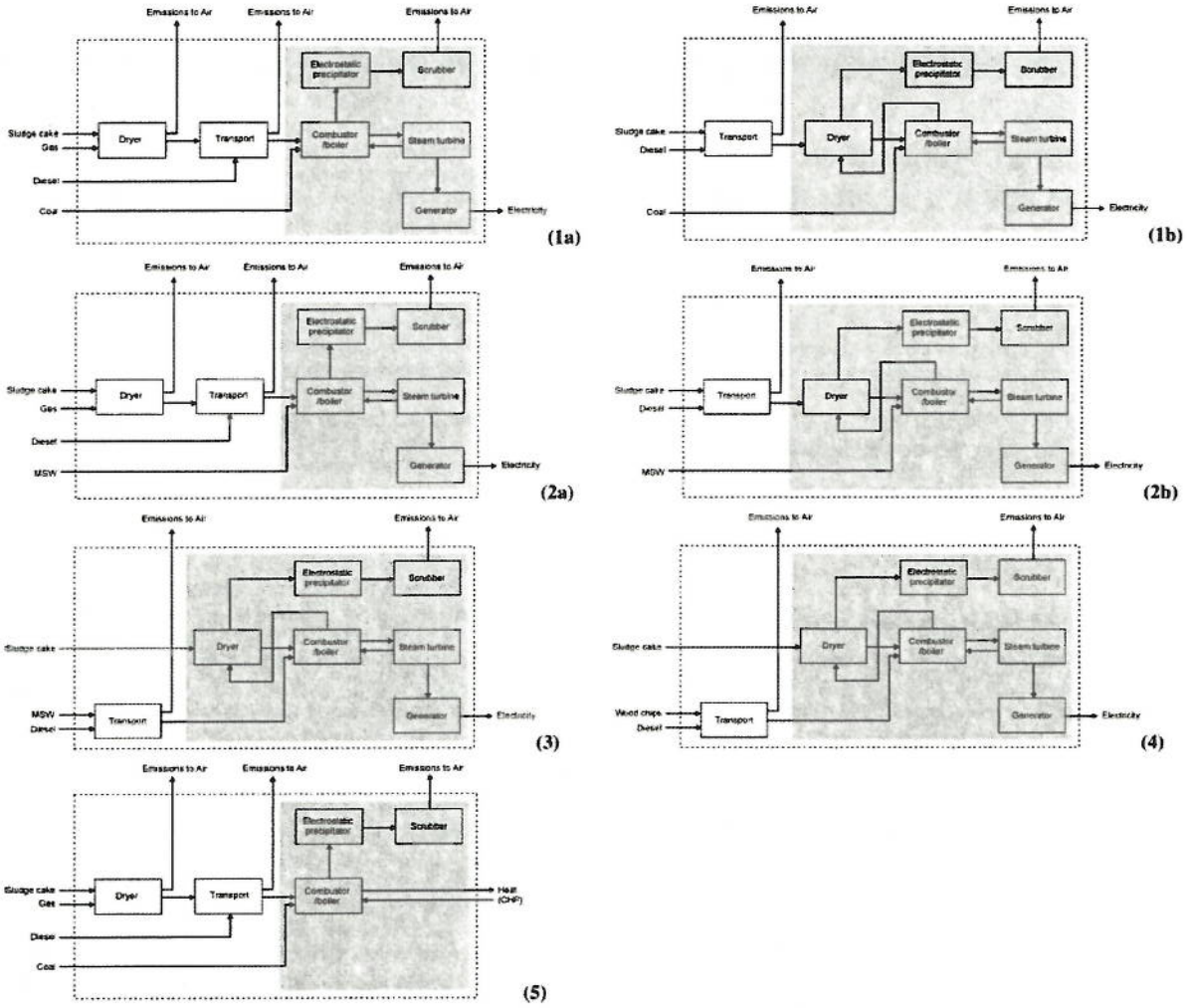

FIGURE 1. Five co-combustion scenarios: (1a) a pulverized fuel coal power station boiler, biosolids dried at wastewater treatment works (WwTW), (1b) a pulverized fuel coal power station boiler, biosolids supplied as cake and dried at power station, (2a) with MSW at third party facilities, biosolids dried at WwTW, (2b) with MSW at third party facilities, biosolids dried at combustion premises, (3) with wastes at water utility facilities; (4) with wood chips at a water utility facility, and (5) in cement kilns.

the combustion facility and a gate fee possibly imposed on the water utility, or a fuel income received by the water utility; a joint venture with a third party, where the water utility is technically and financially involved in the operation; and stand alone, where the water utility operates a facility without the involvement of a third party. There are five representative scenarios (Figure 1) adopted in this study:

(i) Scenario 1, co-combustion with coal in a third party large scale combustion facility with no participation of the water utility in power generation or sale.

(ii) Scenario 2, co-combustion with wastes at a third party energy-from-waste (EfW) facility.

(iii) Scenario 3, co-combustion with wastes at an EfW facility operated by the water utility.

(iv) Scenario 4, co-combustion with supplementary fuel (plant biomass) at a water utility combustion facility with possible third party involvement.

(v) Scenario 5, co-combustion in a cement kiln or other industrial user of power and/or heat (CHP).

Theoretical Basis of a Mass and Energy Flow Model. A thermodynamic model was constructed to perform mass and energy balances for transportation, drying, incineration, steam generation, and electricity generation. A unit process approach allowed scenarios 1−5 to be simulated. The potential combinations of co-fuel, energy market, partner organization, and scale (Table 1) provided 14 combinations. The system boundaries for the model were similar to those from Hellweg et al. (*13*). Scenarios were modeled using digested (d) and raw (r) biosolids as fuel input. In addition, scenarios 1 and 2 considered the delivery of biosolids to the combustion unit either as dried product (95% w/w dry solids; DS) or as dewatered cake (25% w/w DS). Where biosolids were dried, off-site drying was assumed to be performed by a gas-powered dryer (a). Where delivered as cake, on-site drying was assumed to be performed by a theoretical flue gas dryer (b) to allow a combustion temperature of >900 °C to be achieved, compliant with the EC Waste Incineration Directive (WID) (*14*).

Thermodynamic Modeling. Inputs to the thermodynamic model are the biosolids and supplementary fuel mass flow rates (kg DS/h), moisture contents (%w/w), ash content (%w/w DS) and their ultimate composition [C, H, O, S, N, Cl, and F as % DS Table 2), and the higher heating value, (MJ/kg DS)]. From these parameters, a mass and flow balance (Figure 2) was performed for fuel consumed, energy converted, air consumed, and the fractional composition of the flue gas (N_2, CO_2, SO_2, and NO_x). The model derives the quantities of steam produced and electricity generated on

TABLE 1. Summary of Scenarios Modeled

		biosolids				co-fuel			
No.	description	type	drying	distance (km)	feed rate (kg DS/h)	type	distance (km)	feed rate (kg DS/h)	comment
1a,r	co-firing of sludge in a pulverized fuel coal power station boiler	raw	natural gas	250	15 400	coal		754 600	assumes 2 GW power station, sludge 2% of input on DS basis
1a,d		digested	natural gas	250	15 400	coal		754 600	
1b,r		raw	flue gas	250	15 400	coal		754 600	
1b,d		digested	flue gas	250	15 400	coal		754 600	
2a,r	co-combustion with MSW at third party facilities	raw	natural gas	50	2784	MSW		157 80	assumes 200 ktonne/y (~163 ktonne DS/y) incinerator, sludge 15% of input on DS basis
2a,d		digested	natural gas	50	2784	MSW		15780	
2b,r		raw	flue gas	50	2784	MSW		15780	
2b,d		digested	flue gas	50	2784	MSW		15780	
3,r	co-combustion with MSW at WSP facilities	raw	flue gas		570	MSW	50	100	assumes 5 ktonne DS/y sludge incineration, MSW 15% of input on DS basis
3,d		digested	flue gas		570	MSW	50	100	
4,r	co-combustion with wood chip at a WSP facility	raw	flue gas		340	wood chip	100	340	assumes 3 ktonne DS/yr sludge, woodchip 50% of input on DS basis
4,d		digested	flue gas		340	wood chip	100	340	
5,r	co-combustion of sludge in cement kiln	raw	natural gas	250	1700	coal		32530	assumes 300 ktonne DS/y coal consumption, sludge 5% of input on DS basis
5,d		digested	natural gas	250	1700	coal		32530	

[a] WSP: water service provider; MSW: municipal solid waste.

TABLE 2. Compositional Data for Fuel Input and Literature Sources[a]

component	unit	raw sludge	digested sludge	coal	MSW[c]	woodchip (willow)[c]
moisture content	% as received	75.0	75.0	7.1[f,g]	18.7	10.9
volatile matter	%DS	65.0[a]	50.0[a]	31.5[f,g]	70.7	82.0
ash	%DS	30.0[a]	40.0[a]	9.4[f–h]	18.5	1.9
C	%DS	37.0[b]	33.5[b]	74.9[f–h]	42.9	49.1
H	%DS	4.5[b]	2.5[b]	4.6[f–h]	6.0	6.0
O	%DS	19.5[b]	12.5[b]	7.3[f,g]	29.7	42.1
N	%DS	3.3[b]	1.1[b]	1.6[f–h]	0.7	0.6
S	%DS	0.65[b]	0.40[b]	$1 \times 10^{f-h}$	0.35	0.06
Cl	%DS	0.07[c]	0.05[c]	0.[f–h]	0.60	0.02
F	%DS	0.02[c,d]	0.02[c,d]	0.01[f]	0.02	0.00
Cd	mg/kg DS	1.6[d]	1.6[d]	0.5[i]	8.3	2.4
Tl	mg/kg DS	0.2[e]	0.2[e]	1.0[i]	1.0[k]	0.5[i]
Hg	mg/kg DS	1.5[d]	1.5[d]	0.1[i]	0.7	0.1
Sb	mg/kg DS	2.4[e]	2.4[e]	1.0[i]	10.0	2.5
As	mg/kg DS	2.5[d]	2.5[d]	10.0[i]	4.9	1.3
Pb	mg/kg DS	99[d]	99[d]	40.0[i]	215.0	237.5
Cr	mg/kg DS	24[d]	24[d]	20.0[i]	58.3	13.7
Co	mg/kg DS	12.0[a]	12.0[a]	5.0[i]	25.9	0.6
Cu	mg/kg DS	373[d]	373[d]	15.0[i]	218.8	13.2
Mn	mg/kg DS	150.0[a]	150.0[a]	70.0[i]	112.3	9.7
Ni	mg/kg DS	20[d]	20[d]	20.0[i]	37.0	26.2
V	mg/kg DS	30.0[a]	30.0[a]	40.0[i]	24.7	0.3
HHV	MJ/kg DS	18.0[c]	14.5[c]	30.49[f,g]	18.65	19.53

[a] Mininni, G. (*16*). [b] Metcalf and Eddy (*19*). [c] ECN (*20*). [d] Gendebien et al (*21*). [e] Eriksson, J. (*22*). [f] Luts et al (*23*). [g] Dugwell et al (*24*). [h] Werther and Ogada (*15*). [i] Clarke and Sloss (*17*). [j] Readymix Zement (*25*). [k] assumed.

the basis of the mass flow of fuel input (Figure 2). Efficiency values were assumed or determined from industrial plant suppliers. All efficiency values are presented in Figure 2 or in the Supporting Information.

Environmental Impact Modeling. Compounds of environmental concern include heavy metals, dioxins and furans, ash, and other pollutants (NO_x, SO_x, HCl, and HF). The formation of CO_2, NO_x, N_2O, and SO_x was estimated from the model data, though the formation of NO_x and N_2O is not straightforward and requires high temperatures. Estimation of HCl and HF was performed on the basis of proximate, elemental, and heavy metal content. Emission of dioxins and furans is not generally a problem for biosolids combustion, provided temperatures above 600 °C are maintained and flue gases are rapidly cooled through the 250–400 °C range (*15, 16*). For each scenario, a combustion temperature of >900 °C was assumed. The potential for acidification and winter smog was estimated on the basis of empirically derived fractionations, by considering whether the contaminants were oxidized or partitioned to the ash, water (in the scrubber), or air (*17*).

Qualitative Risk Assessment. A series of 19 structured interviews with 11 industry, 6 regulatory, and 2 NGO stakeholders was used to build a characterization of the key risks posed from each of the five scenarios and combinations of management control (first party, water utility, or third party), co-fuel type, and technology type. Interviews lasted ca. 1.5 h with interviewees invited to score the relative

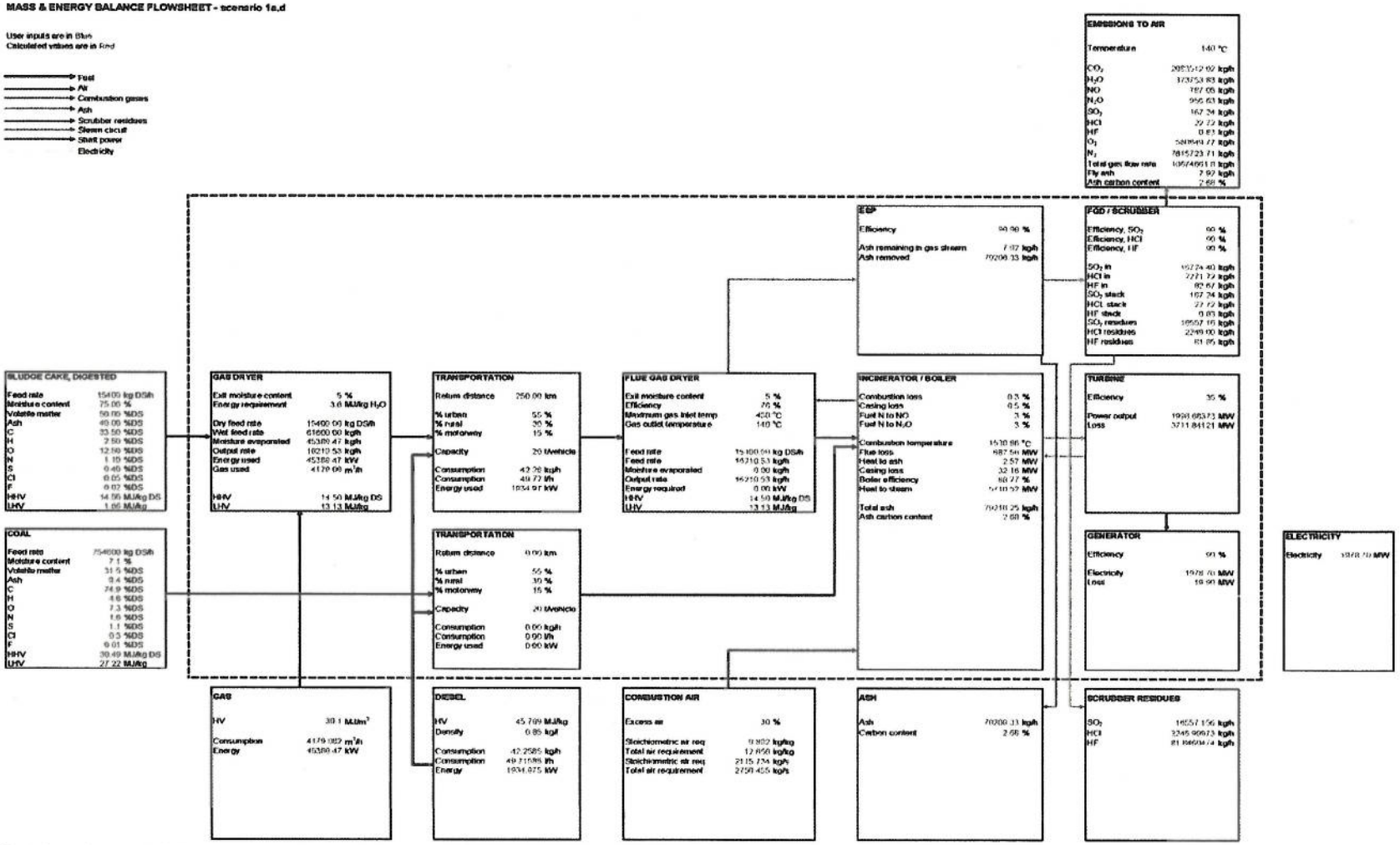

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FIGURE 2. Input/output worksheet of the mass/energy balance model for scenario 1a (a pulverized fuel coal power station boiler, digested biosolids dried at sewage treatment works premises using a gas-powered dryer).

TABLE 3. Descriptors for Sustainability Indicators for Scenario Options

score	economic performance	social impact	environmental performance	flexibility
−2	relatively high cost, and benefits are uncertain	unacceptable social risks and/or impacts on vulnerable groups	severe environmental degradation and depletion of natural resources	rigid and incapable of coping with future changes in circumstances
−1	relatively costly for the benefits obtained	some social risks and impacts on vulnerable groups	some environmental degradation and depletion of natural resources	some limited capability to adapt to future changes in circumstances
0	marginally cost-effective, with benefits just recovering costs	neutral in terms of its social acceptability and impacts	neutral (or mixed) in its impact on the environment	no increase in the risk of exposure to future changes
1	cost effective, with moderate benefits which exceed costs by a satisfactory margin	some positive social impacts, especially for vulnerable groups	contributes to environmental protection and prudent use of natural resources	a degree of increased flexibility to respond to future changes
2	very cost-effective, with relatively low cost and relatively high benefits	significant improvements in social welfare, especially for vulnerable groups	strongly protects/enhances environmental quality and achieves wise use of natural resources	a much enhanced degree of flexibility and robustness across a broad range of future changes

magnitude of the key risks and comment on the benefits, barriers, and opportunities for the biosolids co-combustion for the five scenarios using a common questionnaire. Risks associated with each scenario were presented on a semi-quantitative, Likert-type (*18*) 1−5 scale, distinguishing between the likelihood and consequences common to each scenario. Combined rankings were banded as negligible (scores 1−5), low (scores 6−10), medium (scores 11−15), high (scores 16−20), and very high (scores 21−25).

Economic Analysis. The economic analysis assessed the incremental costs and revenues to a water utility, comparing the five scenarios and identifying where there were additional costs for unit operations (e.g., biosolids drying and emission control) and whether these could be offset through additional income streams (e.g., energy sale and gate fees). The analysis assumed that the initial feedstock was dewatered at 25% w/w DS and that co-combustion requires precombustion drying to 95% w/w DS, unless otherwise stated. The analysis assumed costs associated with taking raw biosolids at 2−4% w/w DS through to 95% w/w DS for co-combustion, but that dewatering to 25% w/w DS was performed at the wastewater treatment works. While generic cost estimates can be derived, actual costs and revenues are site- and context-specific.

Sustainability Appraisal. Government guidance in England and Wales (*26*) provides 20 UK framework indicators to evaluate the progress of projects against sustainability objectives. Four broad indicators were constructed for this project to capture the main dimensions of sustainability with the respect to co-combustion: economic performance, based on the analysis of costs of the co-combustion options; social impacts, based on the impacts on public health risk and the acceptability of the options to communities; environmental performance, based on emissions and net energy consumption of the options; and flexibility, based on the robustness and adaptability of the options. A simple scoring system (Table 3) was used to assess the relative performance of the options drawing on the preceding analysis. Options were scored against each indicator on a scale −2 (very negative), through 0 (neutral, or balance of negative and positive), to +2 (very positive).

Results

Technical Appraisal. Model output (Figure 3) is represented in terms of the net biosolids energy provided by co-combustion after we accounted for transport and drying, the electricity generation, and the incremental environmental impacts of biosolids combustion, representing the difference in model output for the scenarios operating with biosolids and with the co-fuel only.

The net biosolids energy from supplying sludge to the combustion facility, estimated by subtracting the energy required for transporting and drying the sludge from the gross energy supplied by the sludge, is presented in Figure 3. In each case, net sludge energy is positive, though for scenarios with longer transport distances and higher drying requirements (scenarios 1 and 5, Table 1) it is reduced. Raw sludge scenarios present a higher net energy than digested sludge scenarios because of the higher calorific value of raw sludge.

Incremental environmental impacts of combustion were estimated by comparing outputs with and without sludge, allowing the incremental impacts of using sludge to be modeled directly. Most scenarios produce less electricity when sludge is substituted as a co-fuel, as expected; the exception is dried sludge when compared to MSW (scenario 2a). Scenarios 1 and 5 have reduced global warming potential due to the replacement of nonrenewable fuels with carbon neutral sludge. Effects on global warming potential for the remaining scenarios, each using a carbon neutral co-fuel, are negligible, with the exception of scenario 2a, where a gas-powered dryer is assumed. In these generalized scenarios, theoretical acidification and winter smog potential are both increased by burning sludge, due to the higher sulfur and ash content compared to the co-fuels. Digested sludge is preferable in these categories owing to its lower sulfur content. Sludge produces an increase in heavy metals where it offsets coal (scenarios 1 and 5), and a reduction in heavy metals where it offsets MSW. The effects where sludge offsets wood chips are negligible. Our analysis of WID (*12*) compliance for these generalized scenarios indicates that WID emission criteria appear to be achievable for all scenarios, with the exception of mercury, which is difficult to remove using conventional flue gas treatment techniques. Overall, the use of sludge in the scenarios examined is energy positive although less electricity is produced with sludge than with fuel alone, except for MSW.

Risk Analysis. A collated summary of the risk rankings provided by the structured interviews is presented in Figure 4. Stakeholder views on the combustion of wastes in the UK are mature and highly developed. Interview responses on the business risks to water utilities for the five scenarios showed considerable agreement, even between what one might consider as opposing parties. These parties recognize the influence that various stakeholder perspectives might have on the significance of risks to a water utility considering the scenarios examined in this work, with respect to the potential for campaigning opposition, for example (Figure

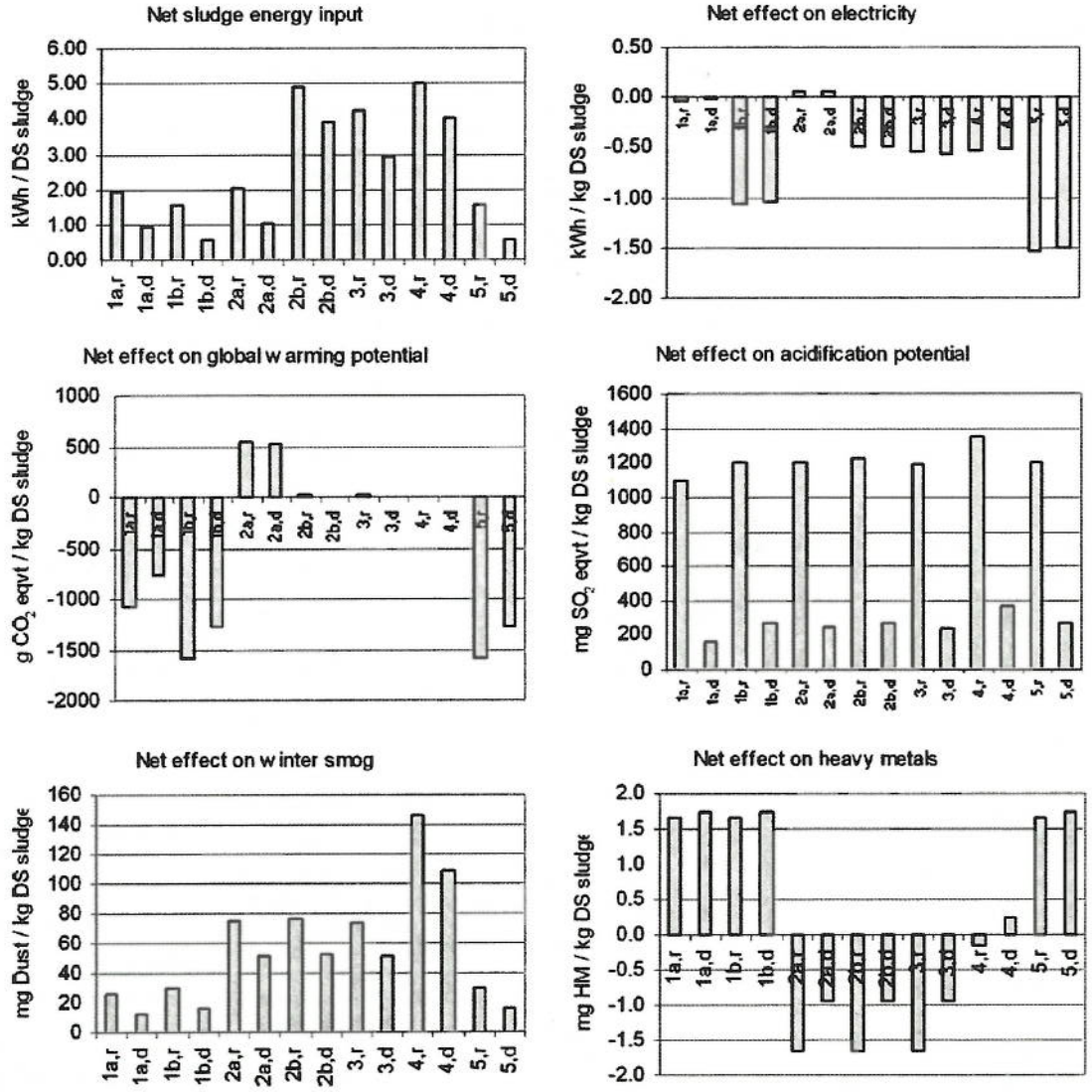

FIGURE 3. Environmental impacts of five generalized co-combustion scenarios for biosolids normalized to unit/kg DS.

4). One should not infer, however, that such agreement extends to the perceived public health risks posed by co-combustion. To avoid over-reaching, scores were banded with lower risk scenarios and key attributes contributing to high risk shaded for illustrative purposes. The collective analysis across all risk categories is of most value. There are important risks for water utilities adopting a first party role as the operator of co-combustion facilities, in terms of the uncertainty around returns on investment and technological risk, and as potential recipients of campaigning opposition to the siting and operation of the plant. Security of the waste supply chain where used as a co-fuel with biosolids and the risks of regulatory delay are also issues for first parties. Generally, it would be better to contract out (risk transfer) co-combustion to third parties (scenarios 1 and 5, shaded) unless the water utility has a partner waste company, but even here, security of the waste supply chain may be a concern.

Economic Analysis. Estimates of the costs to the water utility of co-combustion scenarios are presented in Table 4. Costs range from ca. 296 Euro/t DS for co-combustion in coal fired power stations to ca. 390 Euro/t DS for co-combustion with MSW or biomass, inclusive of revenues to the water utility from power generation or environmental credits. The gate fees paid by water utilities to third parties reflect dry matter content and pretreatment costs for the biosolids, such as pelleting, which can determine the suitability for co-combustion. The revenue accruing to third parties taking biosolids for co-combustion is also outlined in Table 4. These users would most likely incur additional capital and operating costs associated with co-combusting biosolids. For illustration, the costs for the land application of sludge cake are ca. 56 Euro/t at 25% w/w DS, that is ca. 144 Euro/t DS, the benchmark against which to compare the cost of other options. Application to land is the most financially attractive option where land is available. Co-combustion by third parties appears more financially attractive than water utility (first party) co-combustion. There is a tradeoff between transporting dried cake to a co-combustion unit where it can be further dried using flue gases, and drying at the wastewater treatment works. It makes sense to use cheap heat for drying at the point of combustion, but this requires the expensive transport of wet (heavy) cake. Third party interest in co-combustion depends on the availability of gate fees and access to renewable and climate change credits and a company commitment to reduce fossil fuel use.

risk category	there is a risk to the water utility of: scenario	1	2	3	4	5
process, technology	using unproven technology with increased downtime	*	●	●	*	*
	business interruption due to poor security over co-fuel supply	*	O	●	*	*
	low availability of this option if the land route were to closed quickly	O	●	●	●	O
operational	damaged employee relations	*	*	O	*	*
environmental	litigation because of environmental impact	*	*	*	O	O
	litigation through uncontrolled releases	*	*	O	*	*
planning, regulatory	extended planning objection	*	*	O	O	*
	excessive costs due to planning inquiry	*	*	*	*	*
	additional challenge during permitting	O	O	O	*	O
	philosophical regulatory opposition	O	O	O	O	O
	extended delays because of uncertain regulatory climate	O	*	*	*	*
public	localised opposition	*	●	●	●	*
financial	exposure to contract liability	O	O	O	*	O
	difficulty in raising project finance	*	*	●	O	*
	failed return on capital investment	*	*	O	O	*
	poor security over income stream	*	*	O	O	*
	increased transportation costs	O	O	O	*	O
contractual, legal	poor risk control within project	*	●	●	*	*
political	campaigning opposition	O	●	●	●	O
	damaged reputation	*	O	O	O	*
	local political interference	*	●	●	O	*
market	insufficient market maturity	●	●	●	*	*
	increased 3rd party demands re. sludge quality	O	O	*	*	O

Risks characterised as: negligible (-); low (*); medium (O); high (O); very high (●)

FIGURE 4. Risk characterization for scenarios 1–5.

TABLE 4. Estimate of Biosolids Co-combustion Costs and Revenues (Euro/t DS; 2003 prices)

	scenario						
	1a	1b	2a	2b	3	4	5
facility type	power station	power station	with MSW	with MSW	with MSW	with biomass	cement kiln
combustion party			third party	third party	at WSP	at WSP	co-fuel
drier location	WSP	power station	WSP	RDF facility	WSP	WSP	WSP
distance (km)	250	250	50	50	0	0	250
			Costs to WSP				
drying costs	281		281				281
incinerator costs					390	468	
storage					8	8	
transport costs	33	120	9	34			33
ash disposal					11	11	
subtotal	314	120	290	34	409	487	314
gate revenue/fees	16	−156	−55	−234	0	0	−16
subtotal delivered for combustion	298	276	345	268	409	487	329
			Revenues to WSP				
RO credits						67	
electricity					17	39	
CCL rebate					3	6	
subtotal					20	112	
net costs to WSP after credits	298	276	345	268	386	375	329
			Revenues to Third Parties				
RO credits	84	84					
electricity	48	48	31	30			
CCL rebate	8	8	6	5			8
gate fees	−16	156	55	234			16
total revenues	**124**	**296**	**92**	**269**			**24**

[a] WSP, water service provider; MSW, municipal solid waste; CCL, climate change levy; RO:renewable obligation.

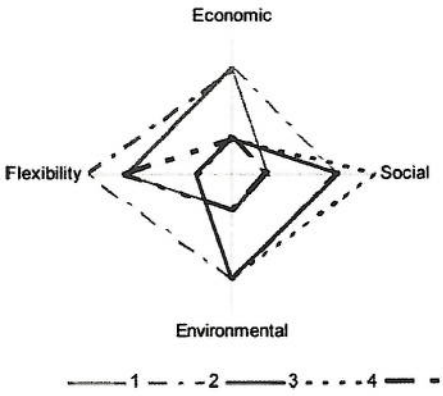

FIGURE 5. Sustainability appraisal of biosolids co-combustion scenarios 1–5.

Sustainability Appraisal. The relative performance of the options against the criteria is mapped in Figure 5. On sustainability grounds, scenario 2 appears to perform best, assuming equal weights are given to sustainability criteria, followed by scenario 4. In practice, the relative sustainability of the options will vary according to local circumstances and the weights given to the criteria used to guide preferences. The rationale guiding this analysis includes the following considerations:

(i) Scenarios 1 and 2 appear to cost the least, allowing for the "credits" attributable to renewable obligation caretificates and climate change levy exemption. These credits are indicative of environmental economic benefits.

(ii) Long distance transport of biosolids is perceived to be less socially acceptable, and local community and smaller scale options may be more acceptable (scenarios 3 and 4), depending on how they are designed and operated.

(iii) In environmental terms, scenarios 2 and 3 appear to have a relatively low environmental footprint. However, relative emissions depend on the fuel being substituted, the degree of abatement being greatest where fossil fuels are replaced. Net energy gain (Figure 3) is sensitive to transport distance, and it is greatest for options that offer economies of scale.

(iv) Scenarios 1, 2, and 5 provide greater relative flexibility. These are existing facilities that take biosolids if there are incentives to do so, whether through environmental credits or gate fees. Scenario 3 could offer considerable flexibility in terms of locally relevant solutions, but it is dependent on the development of appropriate technologies and management regimes that are reliable and efficient and that can gain public assurance.

Discussion

The co-combustion of biosolids with other fuels, as a component of a sustainable biosolids strategy, is receiving substantial attention (*1*). However, this has not translated into many projects on the ground in the UK in contrast with other countries, Germany, for example, where co-combustion projects have been in operation for over 10 years. The Heilbronn power plant (750 MW_e) uses raw and digested dewatered sludge at 25% DS (at a rate of approximately 60 000 tonnes of sludge cake per year) in addition to pulverized coal. No additional drying process is employed by the WSP since drying occurs within the coal mills. The station is equipped with a "SCR-DeNox" plant using electric precipitation technology and a desulfurization plant based on the limestone/gypsum method for the treatment of flue gases (*27*).

Even though there are limited co-combustion projects in the UK at present, the opportunities for biosolids co-combustion in the UK are regarded as potentially substantial. They vary in the level of investment required and the time frame over which they can be implemented. This study has illustrated the tradeoffs involved in making these decisions for biosolids, discussed by others (*9*, *10*) for wastewater treatment, and suggests that the scenarios that can be most rapidly implemented (1 and 5) are those suffering from poor water utility control and public perception, while those with potentially greater security and sustainability (2, 3, and 4) require a greater level of investment and incur greater financial risk by the water utilities.

Barriers to the development of co-combustion include an absence of policy and legal clarity, the legal classification of biosolids as a waste when used as a fuel, and the uncertainties surrounding continued eligibility of energy produced from biosolids for renewable and climate change credits. Many stakeholders perceive these barriers to be problematic at present, and the market is insufficiently mature for biosolids co-combustion to proceed with confidence.

The generic risk issues that arise include the poor ready availability of alternative outlets for biosolids, potential exposure to long-term contract liability (third party capture), the likelihood of organized campaigning opposition to a new plant, an absence of market maturity for advanced thermal technologies, and the possibilities of reputation damage through contentious developments. Policy interventions are not required here because conventional means exist for managing contract liabilities and potential reputation issues associated with new business ventures such as biosolids co-combustion. That said, market maturity with respect to perceived new technology, the possibility of organized campaigning, and water utility sector risks from being in a low state of preparedness in the event of the land route being closed are issues beyond the immediate control of the utilities alone. These require multi-stakeholder action.

The key policy issue relating to this study is the need for coherence in the signals sent to industry of the use of wastes as fuel. Wastes are increasingly viewed as resources and as replacements for fossil fuel within a low-carbon economy. Progress, however, can be constrained by historical policy and legislative structures that have yet to gain pace. The co-combustion of biosolids with wastes is an example. The legal scrutiny of recovered materials and their candidacy as co-fuels has focused on whether they remain "waste" (i.e., their position in the chain of utility, refs *6*, *7*) and if they do remain waste, the applicability of emissions regulations to facilities that co-combust. A recent judgment in the UK regarding a power station co-firing dried sewage sludge has reinforced the view that use of a waste as a fuel constitutes discarding the waste, even if it had an economic value (*6*). Materials that are discarded are subject to the full weight of waste management legislation that may extend to the residues (ash) from facilities co-combusting wastes.

Within this policy and legal climate, water utilities are having to develop long-term "mixed outlet" reuse strategies for biosolids so as not to be held captive to a single route that might come under pressure at short notice (*28*). This study illustrates the complexities and tradeoffs involved and has shown, for five co-combustion scenarios, that net sludge energy is positive, although less electricity is produced with sludge than with fuel alone (except for MSW). There appears to be considerable agreement among stakeholder communities with respect to the business risks faced by water utilities seeking to co-combust biosolids. Supply chain security (wastes or biosolids), organizational capacity (technology availability), and market maturity (risk aversion) are the key business risks and, in the current climate, are best managed by water utilities through risk transfer to third parties, either to power companies or, preferably, to industrial users (e.g.,

cement kilns) already using wastes (e.g., solvents, tires) as a supplementary fuel.

The economics of co-combustion encompass a complex set of volatile revenue and cost streams including gate fees, power production revenue, renewable and carbon credits, and cost savings whether more costly fuels are displaced. Transport costs and the wet/dry weight of biosolids play an essential role. Again, environmental permitting issues are critical because of the regulatory requirements on sludge driers, which third (nonutility) parties are reluctant to install and operate.

Current hopes for addressing these conflicting issues rely on a review of European waste policy and the definition of waste under a revised European thematic strategy. The UK will become a net importer of gas by 2006 and of oil by 2010, and greater emphasis can be expected on the diversity and security of energy generation and supply. This, along with an emissions reduction target for carbon dioxide (CO_2) of 60% of current levels by 2050, means that, although there are no support mechanisms specifically for biosolids co-combustion currently, all fuel sources, including waste biomass, that are domestically derived, should be regarded more favorably in the future (*3*).

Are biosolids a fuel resource or a waste? Our work has shown that the use of biosolids in all scenarios considered results in a positive energy balance, and it can be considered as a fuel. When thermally dried and granulated, it is a premium product that, providing suitable health and safety controls are in place, is easy to transport and feed directly into combustion units without loss of performance. Water utility costs are sensitive to whether biosolids are classified as a waste or a resource, and their eligibility for credits. Three things need to take place for biosolids to be more widely regarded as a fuel:

(a) Consistency in the classification of biosolids between the waste and energy policy regimes is called for.

(b) WSPs must view co-combustion as a power production activity and produce and promote biosolids that are suitable for co-combustion applications.

(c) There would appear to be a strong case for the commencement of biosolids co-combustion demonstration projects, with active and early stakeholder involvement, to reduce project risk.

The integrated appraisal methodology adopted here has wider utility for the strategic analysis of technology options for integrated waste management and would benefit from a more quantitative platform. Issues of supply chain security, waste logistics, the "bankability" of technologies, and market maturity are receiving growing attention in the UK as it responds to the demands of European and domestic waste legislation. We are developing this research by undertaking quantitative technology appraisals that critically evaluate the compliance of emerging waste technologies with newly introduced policy and regulatory targets for landfill diversion and recovery.

Acknowledgments

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Supporting Information Available

Equivalent input/output worksheets of the mass/energy balance model as per Figure 2. This material is available free of charge via the Internet at http://pubs.acs.org.

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10

Environmental Risk Management

Simon Pollard and Peter Young

The environmental risk management challenge

Risk has become a familiar concept in the 21st century. The term is widely used and means different things to different people. All individuals live with risk – some risks are more controllable than others; some better understood than others – most are managed implicitly without any formal analysis of risk.

This chapter is about environmental risk assessment and management. The management of risk, from or to the environment, has developed into a systematic process for making better and more accountable environmental decisions. Risks are assessed so that they can be managed better – by focusing first on the problems that are of greatest concern. The analysis of risk usually reveals the key drivers of risk to or from the system under study. Because we all have different concerns, it is important that risk-informed decisions are influenced by a range of stakeholders, including those that bear the risk, and that decisions and the basis for them are communicated throughout the process (Pollard, 2005).

Very often the questions faced by environmental professionals are not those where data is plentiful, the mechanisms fully understood or society's demands clearly stated. In uncertain circumstances, risk assessment and management can help balance technological development and society's need to protect the environment from harm. It is generally assumed that risks to or from the environment arise as an undesirable 'by-product' of some function or process, and need to be weighed alongside the accompanying benefits that such processes offer. There are also situations where risks exist naturally – such as flooding – or because

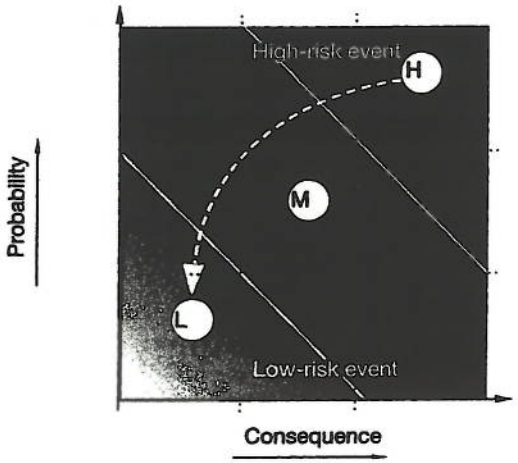


Figure 10.1 Fundamental concept of risk management showing regions of high (H), medium (M) and low (L) risk and objective of risk management (dashed arrow)

of human activities – for example, land contamination. In recognition of the risks inherent to these situations, regulatory and supervisory systems for their management have been devised.

Environmental risk assessment has developed into a management tool for organizing and analysing the available information on environmental problems. It has some aspects in common with other decision-making tools, such as environmental impact assessment (EIA) and strategic environmental assessment (SEA), though its explicit treatment of probability, consequences and uncertainty makes it ideally suited to distinguishing between the adverse environmental impacts (consequences) that could occur and the likelihood (probability) of those impacts actually occurring (Figure 10.1). This is the principal power of risk analysis and is a function not performed by EIA. This is an important methodological distinction for those charged with managing risk because separate strategies exist for managing the probability and consequences of environmental impacts.

Working definition and practice

What does environmental risk assessment involve? Put simply, assessing the likelihood and consequences of events that impact on the environment. That is, understanding what consequence(s) might happen as a

result of an activity and how likely it is to happen – and then making judgements on whether to be concerned about this combination of consequences and likelihood (the risk) and how, and in what order, to manage unacceptable risks so they are no longer of concern (Figure 10.1). Risk assessment originated in the nuclear, chemical and oil industries where the language of risk was defined. For environmental applications, the most important distinctions are those between:

- a 'hazard' – a substance or an activity with a potential for harm; the 'harm' – the undesirable consequence or damage that results from exposure to the hazard; and the 'risk' – the likelihood of the harm being realized;
- the 'probability' of an event (that is, the likelihood of it occurring) and the 'consequences' if it were to occur; and
- the 'source' of a hazard, a 'receptor' (that which one wishes to protect) and the 'pathway' (the mechanism by which the receptor may suffer harm from the hazard).

The 'source–pathway–receptor' approach can be illustrated by imagining being on holiday in a caravan park on the banks of a river (Environment Agency, 2000). Under normal river flow conditions, this would be an attractive setting, but under extreme flood conditions there is a risk that the caravan park might be flooded and the caravans washed away. The *source* of the hazard is unusually heavy rainfall. The *hazard* associated with this source is potential loss of life or property damage. The *pathway* is the passage of water through the catchment, resulting in a rise in river level and the overwhelming of the flood defences. The *receptors* are the caravans and their occupants. If any one of these is absent, then *harm*, that is, actual damage, cannot occur. So, for a risk to be present there must be a source of a hazard, a receptor and a pathway between the source and the receptor and these must be connected during the event. Understanding risk in these terms is essential and helps inform risk management because we can manage risks by intercepting the source–pathway–receptor linkage. We may:

- remove receptors (steer development away from areas that flood; use flood warning and evacuation);
- block or alter pathways (install flood defences, alleviation channels or set up sustainable drainage systems); or
- address the source (difficult in this case for rainfall, but action on climate change may address the future severity).

Businesses need to take and manage risks to survive in a competitive market-place. Like all organizations, they have to manage risks from hazards such as competition; changes and quality within their supply chain; fluctuations in demand for their goods and services; skill shortages; and damaged reputations. On the environmental side, they may be exposed to risks from historical land acquisitions, inherited safety cultures or through non-compliant, albeit accidental, environmental releases. Risk 'profiling' across organizations has become essential to good corporate governance and a prerequisite for sound ethical, social and operational (including environmental) management. As a result, many large corporations have risk management committees that report periodically to the board, group risk managers whose responsibility it is to monitor risks across business functions and risk management systems that allow unacceptable risks to be anticipated and managed.

Environmental risk is a concern to organizations because of the liabilities that may accrue and the damaged reputation that can result from the potential or actual harm caused to the environment. Businesses operate in an increasingly regulated environment. Regulatory decisions about their actions are made by close reference to the statutory duties and powers of the regulator and the responsibilities of operators. One aspect of a regulator's work includes the issuing, drafting and enforcement of environmental permits allowing business to discharge to, or abstract from, the environment. This is where many environmental professionals first encounter the requirement for an environmental risk assessment; because the regulator often requires an assessment of risk to inform the siting (planning), or environmental permitting of industrial activities, it acts as a check on the operator's understanding of their own processes and can reveal specific vulnerabilities in systems that warrant close operational and regulatory scrutiny.

Best practice

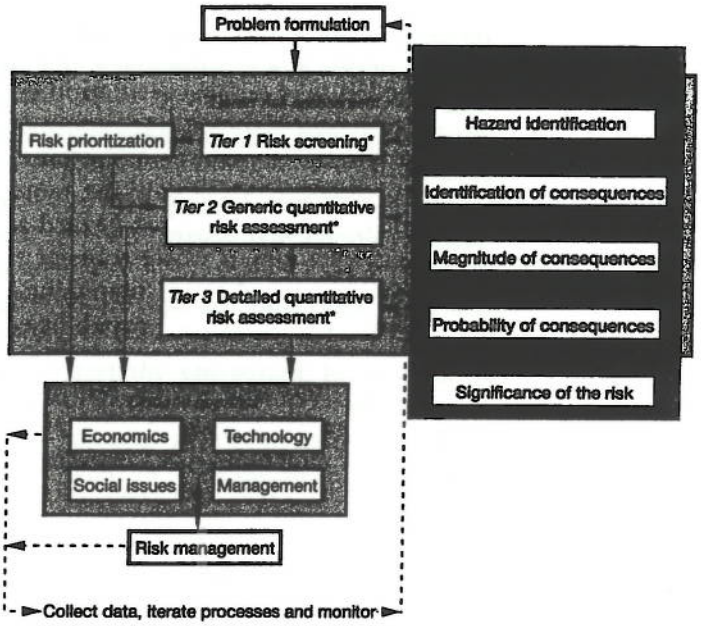
A wide range of regulatory philosophies exist internationally on the implementation of risk assessment and management through environmental regulation. To different extents, individual countries adopt (i) quantitative and/or qualitative approaches to risk analysis; (ii) preventative or reactive approaches to risk management; and (iii) greater or lesser degrees of precaution with respect to the introduction of new technologies.

In the UK, the application of environmental risk assessment within pollution control has grown substantially over recent years. It now

features as an explicit requirement of environmental planning and permitting within the requirements of European and domestic legislation. The environment agencies in the UK take a risk-based approach to regulating industry; that is, by targeting activities and operators posing the greatest likelihood of severe harm to the environment and public health. To assist risk-based regulation, regulatory risk ranking systems have been developed that distinguish between the inherent hazard associated with an industrial operation (e.g. operating a waste transfer station or a cement kiln) and the operator's competency in managing the risks posed by such an operation. The risk management capability of organizations is of increasing interest as many environmental regulators consider the implications of moving towards greater self-regulation.

What might one expect an environmental risk assessment to include? Regulatory expectations of environmental risk assessment in the UK were first published in 1995, in the then Department of the Environment's *A Guide to Risk Assessment and Risk Management for Environmental Protection*. These were revised and issued in 2000 as *Guidelines on Environmental Risk Assessment and Management* for England and Wales (DETR *et al.*, 2000). The Department for Environment, Food and Rural Affairs (Defra) re-endorsed their use in 2002 within the Department's risk management strategy (Defra, 2002). Good problem definition, use of a staged and tiered approach, the principles of proportionality and consistency of use, the explicit treatment of uncertainty and the need for presentational transparency are common themes in the revised Guidelines, colloquially referred to as 'Green Leaves II'. The guidance provides a generalized risk management framework (Figure 10.2) to which specific risk guidance, such as that for waste management regulation, genetically modified organisms, historically contaminated land, groundwater protection and major accident hazards, for example, can in turn refer.

Operators and developers of a wide range of programmes, plans and projects are required to submit environmental risk assessments to local authorities and the environment agencies in support of their regulatory and supervisory responsibilities. Risk assessments help regulators assess the significance of the risks associated with these and then identify, and prioritize, by reference to the risk, the risk management measures that are required to reduce risks to, and from, the environment and to human health. Regulators stipulate these measures as 'conditions' in their permits to develop land or operate plant. Preparation of the environmental risk assessment and implementation of risk management is usually the applicant's responsibility, in line with the 'polluter pays' principle. Because situations change and industrial processes develop



(after DETR *et al.*, 2000)

Figure 10.2 Framework for environmental risk assessment and management

over time, risk assessments are living documents requiring updating as and when modifications to an operation are proposed, or when new or additional information, relevant to the operation or local environmental setting, becomes available.

Not all activities necessarily require complex environmental risk assessment. For example, where the risk is undisputedly negligible or the impacts well understood, or where accepted mechanisms for effective control exist, a simple risk screening may be all that is necessary. For example, a risk assessment is usually required when there is concern about a known hazard and there is a sensitive receptor. A major chemical plant storing large quantities of hazardous bulk chemicals is an example of the former; residential housing close to a landfill site is an example of the latter. Sometimes an accepted approach to managing a well-recognized risk exists, such as bunding oil tanks or the use of wheel washes at waste transfer stations to avoid the release of mud onto approaching roads. In this type of circumstance, risk assessment may not be required, unless there is an intention to depart from the well-accepted solution.

As uncertainty increases and the likelihood of severe consequences becomes less clear, however, a formalized process of risk assessment assists in understanding the severity of the risk and how best to manage it. Advantages to risk assessment include:

- the distinction made between the consequences (impacts) and the likelihood of occurrence;
- a structured approach to assessing risk and thus establishing a logical basis for managing risk;
- providing a basis for the prioritization of risk management actions and the targeting of regulatory effort;
- the recording of decisions for future use; and
- ensuring decision processes, and their underlying logic, are transparent for others to appraise.

For operations and processes that impact on the environment, permits are required. Permit applicants use risk assessments to evaluate where pollution control measures are required and in turn to identify the type and level of financial investment (cost) required for risk reduction (benefit). The regulator has the role of technically reviewing the risk assessment in the context of the statute to inform its decisions on authorizing the specific activity, although it does not generally 'approve' the assessment as such.

In preparing these risk assessments, operators and their professional advisors are expected by the regulator to adhere to the general and specific guidance issued on environmental risk assessment and management. In reviewing an applicant's submission, the regulator evaluates it from a regulatory and technical perspective, assessing the quality and suitability of the submission, by reference to statutory requirements, the supporting science and relevant published guidance. On receipt of the risk assessment, and depending on the type of facility and quality of submission, the regulator will normally:

- conduct a technical and regulatory review of the submission, consulting internally and externally as required, and probing the submission for its technical soundness and completeness by reference to the legislation, available guidance and current state of the science base;
- request further work of the operator, if deemed necessary;
- consider the need for an independent review of the operator's risk assessment where there are reasonable differences of opinion or where a second opinion might prove valuable;

- consider the need for an independent risk assessment for any operation or proposal; and
- review the operator's proposed risk management measures, or those additional measures that should be considered, to mitigate the risks to an acceptable level of residual risk.

Risk assessments are therefore used by both parties to assess the magnitude and significance of the risk posed by the activity, identify the key drivers of the risk, prioritize risk reduction measures and assess the level of residual risk following application of these measures. Risk reduction is secured by applying conditions to the environmental permit, operating the process in accordance with the conditions as a minimum standard and by the regulator enforcing the conditions. Measures may range from technological interventions (e.g. the application of the best available technology) to a requirement for environmental management systems, training or even substitution of a product. Adherence to these measures is enforced through regulatory inspection and related regulatory mechanisms.

Whilst individual legislation specifies the use of environmental risk assessment for specific regulatory processes, the environment agencies have general duties and powers (for the Environment Agency, sections 4 and 5 of the Environment Act 1995) which they can use to request risk assessments of operators, permit holders and applicants. Furthermore, the adoption of various principles, tools and techniques for environmental decision-making feature in the Ministerial Guidance provided to the Environment Agency on its contribution to sustainable development (e.g. Defra, 2000). In short, the agencies may generally request a risk assessment for any activity that they regulate where pollution of the environment is suspected. The general expectations of environmental risk assessment work submitted for regulatory review are set out in the revised *Guidelines on Environmental Risk Assessment and Management* (DETR *et al.*, 2000).

The application of risk assessment in regulation

Individual statutory instruments set out the context and objectives of the legislation and usually state whether risk assessment is to be applied and for what purpose. Supplementary guidance, whether statutory or non-statutory will usually describe the detail on how risk assessment should be used and what the regulatory expectations are. Further

technical guidance is sometimes developed in support of this. Some of the more common regulatory applications of risk assessment, the specific context and the guidance that supports their application are discussed in the following sections.

Environmental planning

For certain development projects such as waste management facilities (incinerators, landfill, hazardous waste facilities), it has become commonplace for applicants to submit a project-level environmental risk assessment as part of the environmental impact assessment required under planning legislation. Risk assessment offers greater resolution over EIA with respect to the relative likelihood of effects that the development may pose. It allows planners and their consultees the opportunity to scrutinize in detail the relative significance of potential impacts. With respect to the potential impacts of development projects on human health, the increasing application of health impact assessment (HIA) is seeing the outputs of project-level EIA, risk assessment and HIA converge.

Risk assessments submitted during planning may be refined, adapted or expanded upon at the environmental permitting stage contingent on the requirements of the permitting regime. At the permitting stage, the environment agencies have powers to require permit applicants to furnish additional information, within a specified period, for the purposes of determining the application.

IPPC and COMAH

Risks from the process sector were historically addressed through the Integrated Pollution Control (IPC) regime. The IPC approach was largely 'effects-based' and driven by the need to render releases from regulated processes to the environment 'harmless'. In risk terms, the approach used environmental criteria, and their exceedence, as a surrogate for assessing the consequences and probability of environmental harm.

Under integrated pollution prevention and control (IPPC) and the control of major accident and hazards (COMAH) legislation, risk assessment assumes a more formalized role. For COMAH, there is a requirement for operators to undertake an environmental risk assessment and to demonstrate that risks have been identified, and all necessary measures put in place, to prevent major accidents or to limit their consequences.

Each site is different and a systematic approach allows for the identification of the most important high-risk accident scenarios and the prioritization of resources, resulting in a transparent, proportionate approach to the management of major hazards from dangerous substances. As a general principle, IPPC requires that all industrial operators applying for authorization are required to assess the risk of accidents and their consequences and that necessary measures be taken to prevent accidents and limit their environmental consequences.

There is some element of overlap between IPPC and COMAH for certain sites and there is recognition that certain information required for both regimes may be interchangeable. However, the accident provisions for IPPC may fall beneath the threshold for COMAH classification. Whilst IPPC risk assessments may require consideration to be given to smaller incidents, these may still have significant impacts on the environment, individually or cumulatively.

Contaminated land

Risks from land contamination have historically been addressed on a 'suitable-for-use' basis with most sites being assessed for their future use under the planning regime. With the introduction of Part IIA of the Environmental Protection Act 1990 – 'the contaminated land regime' – in 2000, an increased awareness by regulators and industry has developed of the risks posed by historically contaminated land (DETR, 2000; Environment Act 1995).

Part IIA has made much more explicit the role of risk assessment in contaminated land decision-making. It firmly establishes the role of the conceptual model and the source–pathway–receptor relationship. A tiered approach to risk assessment is used with defined stages and roles for risk screening, generic and detailed quantitative risk assessment as well as formalized options appraisal for risk management. Technical guidance is available to assist regulators and industry to assess risks to human health, controlled waters and buildings. In addition, more general guidance covers the development of soil and groundwater sampling strategies and the communication of risk.

Planning and redevelopment of sites affected by land contamination still represents the most cost-effective and beneficial way of dealing with such risks in the longer term. One of the benefits of Part IIA is that its explicit approach to the assessment of risks is raising the standard of similar assessments under the planning regime, as its principles become more familiar among practitioners.

Waste management

Environmental risk assessment is fundamental to all phases of development for waste management facilities, from the strategic planning level through to the regulation of an individual facility. At the strategic level, risk assessment informs decisions about land use and underpins assessment of the environmental impact associated with the site location, considered through the development planning process. In the context of a permit, risk assessment is used to enable the operator and the environment agencies to identify whether, and what, risk management options, or mitigation measures, are required to adequately prevent, control, minimize and/or mitigate the identified risks to the environment from the facility. These measures are stipulated for waste management licences as licence conditions or in the working plan, and for pollution prevention and control (PPC) permits in the conditions or in the PPC authorization.

Under the 1994 Waste Management Licensing Regulations applicants for waste management licences submit site-specific risk assessments and previously, for landfill facilities, Regulation 15 (EU Groundwater Directive; see also European Commission, 2003) groundwater risk assessments in accordance with published guidance. Quantitative risk assessments, using the 'LandSim' probabilistic risk assessment tool (Environment Agency, 2001, 2003), for example, have represented good practice for many years for the assessment of hydrogeological risks from landfills. The risk management measures are subsequently addressed by specific licence conditions and working plan specifications. The complexity of the measures required depend upon the type and magnitude of risks that the operations present to the environment. Risk management measures may be relatively simple, such as operational procedures requiring simple action and documentation, or more complex, such as engineered systems with fully documented and quality assured stages of design, construction, testing and validation, operation and maintenance.

Some waste management facilities, including landfill facilities, now fall within the PPC Regulations 2000 as prescribed by Schedule 1, section 5. Under the EU Landfill Directive, all landfills are now required to adhere to new requirements regarding their design and operation, with waste management licences being replaced with new PPC permits that comply with the Directive's requirements. Under the Landfill (England and Wales) Regulations 2002, operators are required to demonstrate that necessary measures are taken to protect the environment and human health and to prevent accidents. The risk assessment

requirements for the Landfill Regulations indicate the operator should have regard to:

- the generic Government guidance on environmental risk assessment and management;
- the specific technical requirements for landfills falling under the Landfill Directive;
- the European Commission's decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 and Annex II of the Landfill Directive; and
- the requirements of the Groundwater Directive; and hence
- Environment Agency *Guidance on Hydrogeological Risk Assessments for Landfills and the Derivation of Groundwater Control and Trigger Levels* (Environment Agency, 2002a).

The last document describes the framework for compliance with respect to groundwater for the above Directives and sets out the requirements for environmental risk assessment under the new legislative regime. The framework is supported by the quantitative risk models – 'LandSim v2', familiar to many practitioners, and now also the 'GasSim' model (Environment Agency, 2002b). In the future, the separate aspects of hydrogeological, human health and ecological risk, among others for waste management facilities, are expected to be drawn together within a single technical requirement.

Radioactive waste performance assessment

The Radioactive Substances Act 1993 provides the framework for controlling the creation and disposal of radioactive wastes so as to protect the public from hazards that may arise from their disposal to the environment. Regulatory guidance for disposal facilities sets down two criteria for assessment of the radiological safety of radioactive waste disposal facilities:

1. a dose limit for a facility's operational phase; and
2. a post-closure radiological risk target.

Post-closure, a radiological risk target is considered an appropriate protection standard because of the uncertainties inherent in assessment of future performance of a disposal system. The assessed radiological risk from a facility to a representative member of a potentially exposed group at greatest risk should be consistent with a risk target of less

than one in a million risk per annum of a radiological health effect. Here, radiological risk is the product of the probability that a given dose will be received and the probability that the dose will result in a serious health effect, summed over all situations that could give rise to exposure to the group. Development of exposure scenarios and the conditions of institutional control (either by the operator or some successive regime) post-closure are essential aspects of risk analysis and management for radioactive waste management facilities.

If, for a chosen facility design, the assessed risk exceeds the risk target, the developer should show that the design is 'optimized' and that the radiological risk has been reduced (benefit) to a level that represents a balance between radiological and other factors, including social and economic factors (cost). This is consistent with the 'as low as reasonably achievable' (ALARA) approach to risk management. Where the risk is below the risk target and the regulator is satisfied that the safety case has a sound scientific and technical basis and that good engineering principles and practice are being applied, then no further reductions in risk need be sought.

Groundwater regulations

Activities likely to lead to the direct or indirect discharge of List I or List II substances, as defined by the Groundwater Directive, require prior authorization. Many activities authorized by the regulator under the Groundwater Regulations are intermittent agricultural discharges or disposals, and due to the large numbers of authorizations, a tiered system of risk assessment has been developed. This approach allows the regulator to match the scale of the operation with the complexity of the assessment. A simple risk screening system is applied to the bulk of the applications. This risk screening system (tier 1) uses several indicators that are readily ascertained from the application forms and readily accessible national data sets to score the application and determine whether the application for discharge can be: approved subject to standard conditions; refused; or needs to be supported by further data or a more detailed analysis of the risk.

A second level risk assessment tool for the land spreading of wastes (the majority of activities) has now been developed that relies on soil property data and a soil leaching equation. Other tools, such as the Environment Agency's 'ConSim' software package that takes account of processes within the unsaturated zone, are available for more detailed assessment of point source disposals.

The close relationship between codes of good practice and risk assessment is stressed. Many of the risk assessments are predicated on adherence to good practice, as noted in recognized codes, a number of which are now statutory. The assumption of good practice is reflected in standard conditions on authorizations and a system of site inspections to check for compliance with the terms of authorizations.

Tools and techniques for practitioners

A wide range of tools and techniques are in use for undertaking risk assessments. They range from straightforward examinations of the connectivity between the source of a hazard and the receptor, to sophisticated numerical packages for dealing with probabilistic analysis. In practice, many risk problems can be addressed, at least initially, using a qualitative analysis, providing the logic is sound and transparent. The ready availability of quantitative and probabilistic methods has driven an increasing trend towards quantitative expressions of risk estimates. However, given the extreme complexity of dynamic environmental systems, there is a continual need to ensure risk analysts do not 'overreach' with quantified risk estimates and infer more precision of their analyses than can be supported by their understanding of the system under study.

Complex environmental issues with significant consequences will invariably require a combination of qualitative and quantitative analysis, usually because certain aspects of the system are better described than others. Fitness for purpose is the rule. For example, in radioactive waste disposal, whilst the engineering features of a disposal facility can be described in quantitative detail, future exposure scenarios in thousands of years' time can only ever be represented by illustrative 'futures'. These types of complex assessments require formalized procedures for combining: experimentally derived data with elicited expert judgement; predictive and illustrative exposure scenarios; and qualitative with quantitative expressions of risk with their associated uncertainties, all set within a risk assessment framework. Problems of this type rapidly become specialist activities.

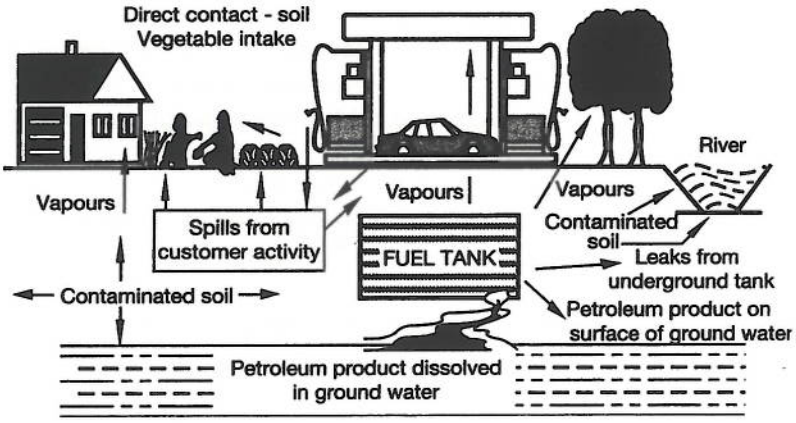
A tiered approach to risk assessment allows for risk screening, prioritization and, in general, a qualitative treatment in advance of quantification. Because there is often considerable uncertainty involved in assessing environmental risk, particularly in the assessment of environmental exposures and impacts, resources should be targeted

accordingly, that is where risks or uncertainties are high, or where the costs of the assessment are justified by the benefits to decision-making. A simple 'risk screening' approach is used first to state clearly the issues of concern, establish the logic of the risk assessment and determine the key risks and priorities. If the decision cannot be made based on this approach then more detailed approaches are used, focusing on the key risks identified at screening. A further consideration is the type of risk being assessed. One may be concerned with:

- the risk of an initiating event, or combination of events, occurring that subsequently results in a release to the environment (e.g. the overtopping of a coastal flood defence by large volumes of sea water; the release of firewater from an on-site collection tank; a process plant failure; a landfill liner failure);
- the risk of an environmental receptor being exposed following a release (e.g. derogation of a drinking water supply by a leachate plume; grounding of a plume downwind of an incinerator stack; the incidental exposure to contaminated soil);
- the risk of harm resulting from exposure (e.g. risks to human or ecological health as a result of exposure to toxic/asphyxiant gases; damage to property following the entry of flood waters; harm to a wetland following over-abstraction or periods of drought; leaf damage to acid-sensitive trees following acid deposition).

Given these factors, experience has shown that it is invariably better to start simple and build in complexity as you need it. Sound guidance is to start simply by drawing out the problem as a diagram. Include aspects to be assessed and decide what aspects the assessment will and will not cover. Using the diagram (or conceptual model, Figure 10.3), write out possible source–pathway–receptor linkages; each linkage should have only one source, one pathway and one receptor. Ask whether, in each case, the source, pathway and receptor are linked or potentially linked; screen out those for which the answer is 'no'. Make simple but justifiable assessments (high, medium, low) separately for probability and consequence, for each linkage, recording the reasoning.

In comparing probabilities, consider the nature of the pathway – do direct or indirect routes (those requiring barriers to be overcome) exist between the source and receptor? In considering consequences think about the relative potencies of the source of the hazard and in comparing receptors, think about their relative inherent vulnerability (children or older people) and sensitivity to the specific hazard



(© Energy Institute)

Figure 10.3 Example conceptual model showing potential environmental exposures at a petrol retail forecourt, illustrating sources, pathways and receptors

(immuno-compromised individuals, for example). Establish your assessment criteria and group source–pathway–receptor linkages accordingly; for example, those with high probability and high consequence, and prioritize those risks accordingly.

The type of risk influences the technique used to assess it. For example, event/fault tree analysis may be used to assess the performance characteristics of engineered systems and unit processes as there may be engineered safeguards to prevent the initiation or escalation of accident sequences (Figure 10.4). The event tree structure provides useful information by showing the combination of conditions required to achieve a particular undesired outcome. Additional value can be obtained by assigning conditional probabilities to each branch and quantifying the outcomes.

The quantification of environmental exposures following a release often relies heavily on distribution, including dispersion modelling, although event tree analysis can also be an important tool here. Understanding the risks of harm following exposure, beyond the reference to environmental criteria, requires a more detailed evaluation of physical, chemical or biological damage and reference to health-based assessment criteria that account for the toxicological consequences of exposure. Selecting the right tool, in the right circumstance and for the right purpose requires both:

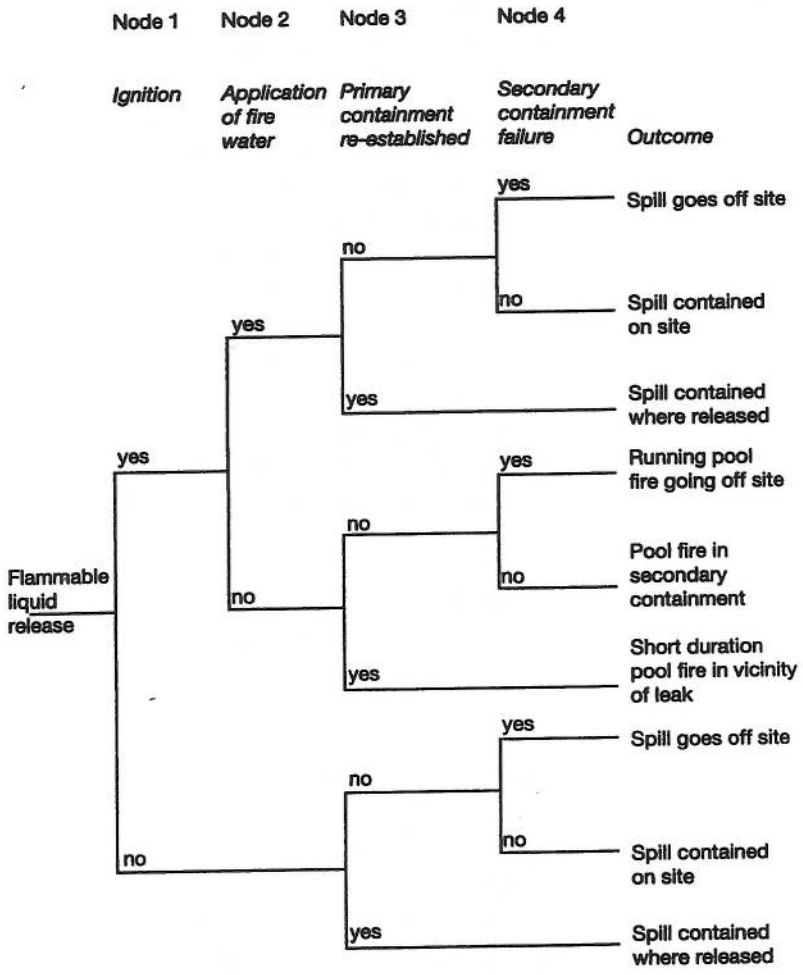


Figure 10.4 Example event tree for the release of flammable liquid from a process facility

- selection of the appropriate level (tier) of sophistication as needs, complexities, priorities and data allow; and, within this,
- selection of the appropriate tool with reference to the type of risk being studied.

Complex risks may require a range of tools at various tiers of sophistication in order to manage the uncertainties inherent to the problem. Often there is insufficient data to be certain about what one is dealing

with. Models are inherently inaccurate and/or incomplete and one may not know what changes will take place in the future. It is important to be aware of these uncertainties when carrying out a risk assessment. A series of software packages are available for dealing with uncertainties in conceptual models, specific data and decision uncertainty, but in applying these and expressing risks quantitatively it is essential not to assume a level of precision in the analysis that cannot be substantiated. The following are practical pointers that can help when dealing with uncertainty (Environment Agency, 2000).

- It is best to concentrate on the 'big picture' before getting into the detail and to avoid a complex analysis of an issue unless you are sure it is important.
- Try to communicate where the greatest uncertainties lie. For example, you might be confident in the permeability of a landfill liner that is in good condition, but very uncertain as to whether the liner is likely to be torn or damaged.
- Be honest about uncertainties. Use 'what if' questions, to explore the importance of uncertainty to the final assessment of risk (sensitivity analysis).

Evaluating risk assessments

Many environmental professionals find themselves in the position of commissioning, evaluating or reviewing the risk assessment work of experts. This can be daunting in that they may feel in unchartered professional territory and the complexity of many assessments can often obscure the key aspects relevant to managing the risk. Below are some key principles.

- *Involve others.* The risk assessor needs to understand the context of the decision being made and the full range of factors that might influence it. There may be a variety of audiences for the output and both stakeholders and the public may wish to have the opportunity to help frame the questions the assessment addresses, and input knowledge. Involving the audience early on and throughout the process may assist in gaining acceptance for the approach and in getting a wider buy-in to the final decision, though it would be naïve to expect this as given.

- *Good problem definition is essential.* What is the environmental setting? What are the spatial and temporal aspects of the problem? Which aspects will the risk assessment address and which will it not address? This can often be set out schematically, or using a diagram often referred to as a conceptual model. Involving those with an interest in the risk assessment output at this stage is essential.
- *Taking a stepwise approach to the risk assessment is vital.* The identification of hazards, the assessment of exposures and the estimation of risk and the subsequent evaluation of the significance of the risk follow a logical sequence: What is at risk and what is it at risk from? What and how might it happen? How large will the consequences be and how probable are they? What criteria will be used to judge their significance? How significant are the probabilities and consequences and how certain is the assessment of probability and consequence?
- *Be prepared to review the analysis.* As the risk assessment proceeds, one often discovers new information that necessitates a revision of one's previous assumptions. Assessments that allow for iteration are useful because they facilitate review, may help avoid the incorporation of systematic bias and ensure that the risk assessment process is developmental rather than being treated as a 'black box'. In practice, all risks are dynamic in time and space, so changes to the 'risk profiles' of all operations should be expected.
- *Risk assessments should be fit for purpose.* Detailed quantitative work will not be required in every case and many potential risks can be screened out early on using a sound logic based on the 'source–pathway–receptor' concept. Allowing for different tiers of sophistication of analysis ensures that a sound logic is established before progressing to quantitative assessment and, consequently, that resources are focused on the higher-priority, more complex risks. An important aspect of 'tiering' is ensuring that a defensible justification is provided for risks screened out and that the remaining risks are carried over into the next tier of analysis. At any point, the assessor may need to revisit the justification for screening a risk issue out.
- *The assessment–management interface.* In practice, there is an iterative exchange of information throughout between risk assessment and management, simply because certain practical management measures may often be anticipated or known quite early on in the assessment. Some frameworks explicitly emphasize a distinction between the risk analysis and assessing the significance of the risk. Communicating with, and involving, others is essential throughout.

- *Practicality*. Risk assessments should not be overly complex, but guide the practitioner through the various steps and considerations. It should not 'force' a level of analysis that is disproportionate to the risk. Throughout, the assessor should practice an approach to risk assessment that is commensurate with the supporting science.

Hot topics and future trends

Future trends in the assessment of environmental risk are likely to see its continued expansion to more strategic levels of assessment (programmes and plans of activity) and to the comparative assessment of many risks within an individual assessment (comparative risk analysis). We can expect greater use of probabilistic techniques as these become more accessible and the current demand for greater openness in the process continues. With respect to technical developments, the practice of environmental exposure assessment continues to develop with an increasing interest in environmental exposures within the home environment. There is a growing awareness of the episodic nature of many environmental exposures whereas exposure has historically been often oversimplified as constant in space and time. There are important implications here for acute exposure and the potential overestimation of chronic risk.

Beyond methodological developments, issues receiving increasing attention include the practice of corporate environmental risk management and the maturity of risk management within organizations, the implementation of risk-based environmental regulation, the role of citizens in risk-based environmental decision-making and the relationship and tensions between risk management and the precautionary principle.

We have moved on a long way from where risk assessment was used as the basis for justifying a course of action, to recognition that assessing risk is a prerequisite to designing a good decision. Managing risk has become an essential business requirement. From embedding good corporate governance within organizations through to the management of individual projects and assets (Figure 10.5), the ability to understand, communicate, assess and manage risk is now a mainstream activity. Environmental risk management is playing its part in what is increasingly viewed as the integrated, enterprise-wide activity of business risk management.

(after Prime Minister's Strategy Unit, 2002)

Figure 10.5 The risk hierarchy from strategic to operational risk, applied here to the water utility sector

As organizations become more proficient in managing risk, their organizational capability develops. Corporate maturity in risk management may be reflected in accreditation schemes such as the environmental management systems series (EMS) 14001 and their recent updated versions (ISO 14001:2004 and ISO 14004:2004). Holding accreditations of these standards demonstrates a capability to pursue a 'plan–do–check–act' management loop and infers a capacity to implement institutional learning within a framework of continuous improvement. Researchers and practitioners are now investigating the use of 'maturity models', developed initially in the software industry, for assessing how far along the journey from novice to expert organizations have come in managing their business risks (Hillson, 1997). Initially these have been employed in the offshore industry, but the advances made in risk management capability maturity models more widely within health and safety regulation have direct application for the operation and regulation of land-based installations with environmental permits.

Environmental regulators are showing increasing interest in both risk-based regulation and self-regulation, under which the capability of operators to actively manage risk is being assessed with implications for the amount of regulatory attention given to sites and operators. Environmental regulators have an inherent interest in organizational capacities to manage risk where companies operate multiple sites at home and abroad. The plant level monitoring of risk management

capability provides a valuable reality check on corporate statements on risk management. The operator pollution risk appraisal (OPRA) schemes introduced for environmental regulation of the process sector in the UK offer one example of how the inherent hazards associated with unit processes and operator performance at individual sites can be assessed to provide an overall risk profile for operators, process sectors and regions.

Within the stakeholder society, the risk assessments that support decisions on the licensing of new chemicals and processes find their way increasingly into the public domain, either through the regulatory process or through legal challenge. Historically, many of these reports would have been hidden from public view, but their recent accessibility has made available to many the complexities and uncertainties of environmental risk assessment. Risk assessment itself has become contentious, in part perhaps because some see its use as a means of justifying an action that may pose harm to the environment, rather than as a tool to identify what protection is required. Many have expressed unease over the number of assumptions used, the seemingly rigid approach adopted and the lack of opportunities for critique and broader engagement. New, inclusive paradigms for risk-informed environmental decision-making have been developed in response and participatory approaches to problem definition are being explored in the literature.

One of the key tensions recently has been the relationship between adoption of the precautionary principle and risk assessment, two approaches to decision-making that have erroneously been pitched against one another. In practice, the 'principle' requires an analysis of the significance and uncertainty of a hazard being realized, in order to inform the decision on whether to act now or defer action and monitor. It therefore requires an assessment of risk so that it can be applied.

Conclusion

Managing environmental risk is complex because the environment is dynamic, open and complex in its make-up and still relatively poorly characterized. One needs to be cautious, therefore, in applying risk analysis tools not to assume greater knowledge than one has available. This said, there is tremendous value to be gained in using environmental risk assessment to prioritize management action. Because environmental decisions invariably involve people and items they value

(landscape, river quality, ecosystems), application of risk assessment and the setting of priorities will always be contentious. In a democratized decision-making environment, environmental risk analysts face the challenge of undertaking and communicating their analyses, whilst managing the demands for assessment processes to be more open and accessible to lay audiences.

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RISK MANAGEMENT CAPABILITIES – TOWARDS 'MINDFULNESS' FOR THE INTERNATIONAL WATER UTILITY SECTOR

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ABSTRACT

Public health protection must be the primary goal of a drinking water utility; delivered through supplying safe drinking water. For complex multi-utilities, this goal may come under pressure from the need to manage a plethora of business risks. We describe a risk management maturity model for assessing the capacity of utilities to manage business risks and comment on the importance of 'mindfulness' as a prerequisite for effective risk management.

1 INTRODUCTION

1.1 A risk management imperative

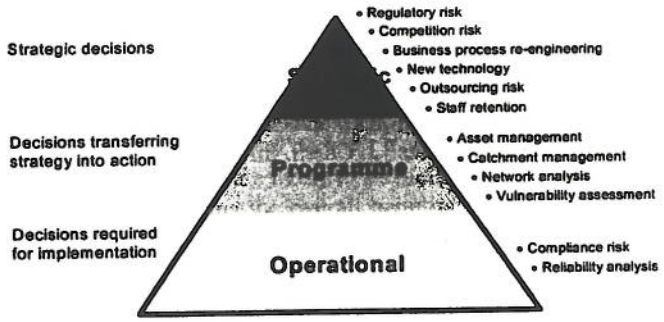

Figure 1 *The risk hierarchy applied to the water utility sector*[1].

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From embedding corporate governance, through to the management of individual assets, the ability to understand, communicate, assess and manage risk has become a mainstream business activity. Many of the larger water utilities have begun integrating their responsibilities for financial control alongside their risk management programmes, including those that exist for asset management and regulatory compliance (Figure 1).

The water industry is witnessing a significant shift in the approach to risk management to one that is increasingly explicit and better integrated with other business processes. This is clearly, in part, a response to the asset management (financial and environmental regulation), public health (drinking water safety) and environmental protection (*e.g.* catchment management) agendas but may also represent a growing recognition that the provision of safe drinking water deserves to be treated as a 'high reliability' service within society and subject to the sectoral and organisational rigours and controls inherent to operations in the nuclear, offshore and aerospace industries. These sectors have learned important lessons and developed significant literatures on the implementation of safety cultures, much of which is transferable directly to the water sector as it progresses with the implementation of risk management

This paper deals with the application of maturity models within the international water utility sector. The research is relevant to the subject of water emergencies because it explores the preparedness, or resilience, of organisations to foresee, prevent, manage and withstand adverse risks. Our research has been conducted as part of a larger study for the American Water Works Association Research Foundation (AwwaRF) on risk analysis strategies for better and more credible utility decision-making[2]

1.2 Risk analysis in the water sector

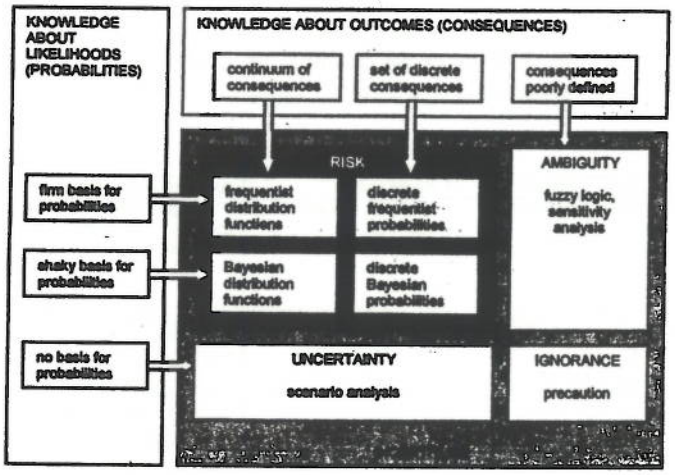

Figure 2 *Approaches to addressing uncertainty, risk and ignorance in decision-making (redrawn from Stirling[6])*

Notwithstanding the increasing application of risk assessment tools in the water utility sector[3, 4] there are many approaches to managing uncertainty in organisations[5] ranging from the use of standards, engineering judgement and good practice through to embedding company values and corporate cultures to safety and risk. Risk analysis plays an important

function in decision-making where the probability of a hazard being realised is significant and uncertain and where the outcomes, or consequences are reasonably well understood (Figure 2).

The water sector has made excellent progress towards setting its goal of "providing wholesome, safe drinking water that has the trust of customers" within a risk management context, most recently through the preparation of revised WHO drinking water guidelines that promote a risk management approach[7]. There remain challenging implementation issues to be addressed, however. For example, following the types of incident reviewed by Hrudey and Hrudey[8] it is becoming accepted that risk analyses need to extend their reach beyond engineered systems and view management (system) and human (people) factors as equally central to effective risk management [9,10].

1 CAPABILITIES IN RISK MANAGEMENT

2.1 Risk assessment is not enough – developing capabilities in risk management

Risk assessments do not guarantee risk reduction. Left with their recommendations not implemented, they are a hollow gesture that may only serve to increase legal liability after failures occur. Managing risk competently, wisely and by targeting the risk critical elements of a system for maximum risk reduction is what counts. To understand the organisational competency in risk management, we must look to the *capability* a utility possesses in risk management. Because most water companies manage risk by virtue of the routine provision of safe drinking water, we are generally concerned then with the relative *maturity* of their capability[11] in risk management, rather than its presence or absence *per se*. Practically, we are concerned with their ability to act wisely and to anticipate when things might go wrong and act quickly in a preventative fashion.

A capability maturity model (CMM) is a management tool used to assess the degree of wisdom with which an organisation competently performs the key processes required to deliver a product or a service (Table 1).

N	maturity	mode / style	process characteristic and effect
5	Optimised	Adaptive, double loop learning	The organisation is 'best practice', capable of learning and adapting itself. It not only uses experience to correct any problems, but also to change the nature of the way it operates.
4	Managed	Quantified, single loop learning	The organisation can control what it does in the way of processes. It lays down requirements and ensures that these are met through feedback.
3	Define	Measured, open loop	The organisation can say what it does and how it goes about it but not necessarily act on its analyses
2	Repeatable	Prescriptive	The organisation can repeat what it has done before, but not necessarily define what it does.
1	Ad hoc	re-active	Characterises a learner organisation with complete processes that are not standardised and are largely uncontrolled
0	Incomplete	Violation	Incomplete processes, criminal or deliberate violation tendencies

Table 1 *Interpretation of maturity levels*

The degree of wisdom is represented by levels of maturity. Level 5 (high) organisations exhibit 'best practice'. They are capable of learning and adapting and they use experiences to correct problems and change the nature of the way they operate. Level 1 (low) organisations are learner organisations with non-standard and largely uncontrolled processes.

CMM has its roots in the field of performance measurements[12, 13] and quality management developed in the 1970s[14, 15]. The most widely referenced CMM is that developed by the US Software Engineering Institute to assess the software design capability of software houses[16]. One of the strengths of the CMM approach is its broad applicability and this is leading to increasing numbers of CMM models in other sectors[17, 18]. Capability maturity models can be used both as an *assessment* tool and as an *improvement* tool. Both approaches are used in practice.

Risk management (there are various paradigms; Figure 3 indicates one such approach for environmental risks) can be viewed as a 'service' most organisations undertake on behalf of their internal and external stakeholders to ensure business continuity and the delivery of corporate objectives is not adversely threatened.

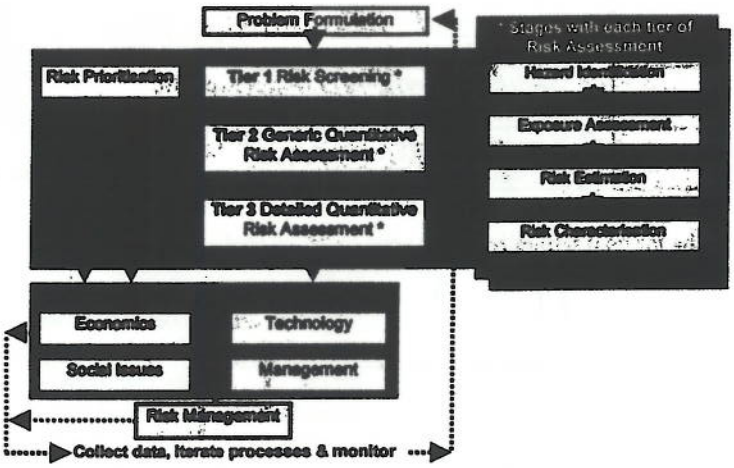

Figure 3 *Example risk management paradigm*[19]

Many water utilities seek to improve the processes involved with managing their risks and see this as an effective means of reducing exposure and improving risk-based decision making within their organisations. Understanding one's own risk management maturity has value in that it may (i) assist organisations in formalising their appetite for risk; (ii) help formalise and make more explicit the role of the group risk manager; and (iii) provide the opportunity for a 'climate' check on the implementation of risk management procedures on the ground within the organisation; thus acting as a check on corporate level statements on risk.

Our research at Cranfield University[20,21,22] has developed and piloted a risk management capability maturity model (RM-CMM) for the international water sector (Figure 4). There are 5 levels of capability that build on ideas from the theory of action and the concept of single and double loop learning[23]. Single loop learning occurs when

risks are detected and the product or service is amended, thus permitting the organisation to carry on its present policies or achieve its present objectives. Double-loop learning occurs when risks are detected and managed in ways that involve the modification of an organisation's underlying norms, policies and objectives. Being able to manage the risks to your organisation extends beyond the ability to perform the risk analyses and options appraisal set out in Figure 3. There are key processes such as the ability to establish the organisational appetite for risk through setting risk acceptance criteria, and the ability to integrate risk management across business functions that are also important and reflect the wisdom (maturity) of approach (Figure 3).

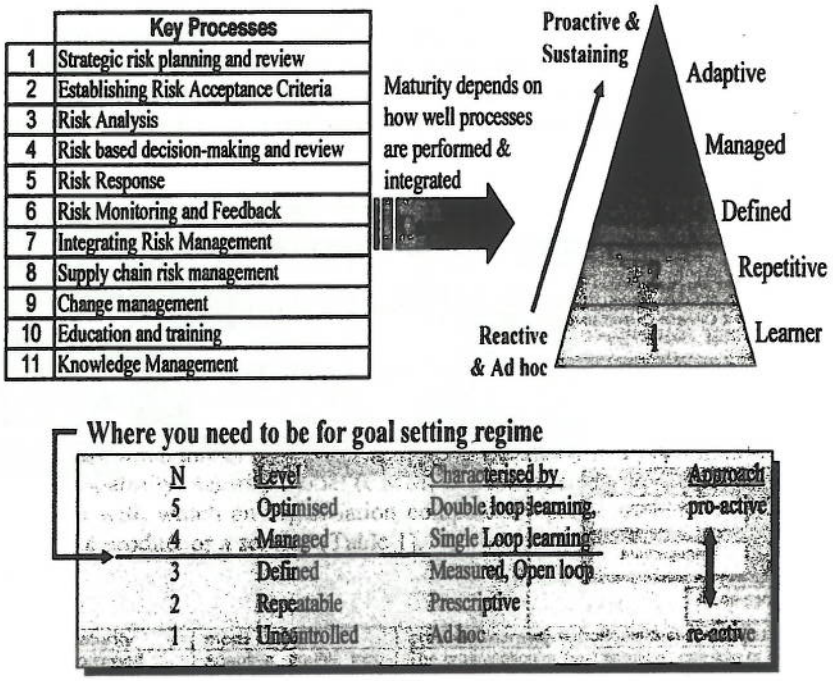

Figure 4 *Overview of the risk management CMM*[22]

The practical value of codifying this into an assessment model for water utility risk managers is in establishing the basis for risk improvement plans – structured and targeted action plans for better risk management within companies. The RM-CMM approach seeks to elicit where, on the ladder of improvement a utility wishes to be by reference to the importance of the risks it manages, and then to identify through critical analysis where the utility is on the ladder. An organisation's maturity in risk management can be schematically represented as snapshots of their current status[22]. The requirements to move between 'rungs of the ladder' (*i.e.* the levels of Table 1) provide the basis for risk management improvement plans within individual companies.

2.2 Applying the tool in practice

A preliminary RM-CMM framework has been developed and piloted within a number of water utility companies collaborating in the AwwaRF project for self assessment and review. The framework remains to be refined on the basis of initial responses from users. However, the initial responses offer insights into the risk management practices and cultures within the water utility sector. In summary, there is a growing capability, generally characterised by Level 3 of the RM-CMM. The pilot capability profiles returned by six organisations are summarised in Figure 5.

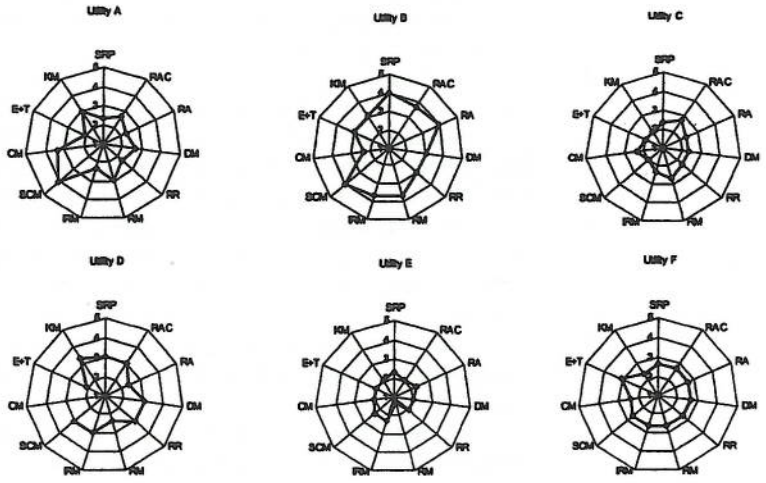

Figure 5. Capability profiles for 6 water utility companies[22]

Key for risk management processes:

SRP	Strategic risk planning and review of business goals
RAC	Establishing risk acceptance criteria
RA	Risk analysis
DM	Risk based decision-making and review
RR	Risk response
RM	Risk monitoring and feedback
IRM	Integrating risk management
SCM	Supply chain risk management
CM	Change management
E&T	Education and training
KM	Knowledge Management

Our initial observations indicate:

1. That most of the risk management processes reported are at a Level 3 or below, with most organisations at or becoming defined (Level 3) in terms of their risk management processes.
2. The transition to Level 4 capability is difficult because it implies that key management practices must influence decision making. This in turn implies that analysis is carried out early enough for it to influence decision making and that companies invest effort in effective response to risk. There appears to be widespread difficulty in transforming risk analysis and monitoring outputs into formats that inform decision makers.
3. The range of different methodologies used for risk analysis by water companies is limited, suggesting that there is a need for training in assessment methods and competency improvements.
4. Verification of risk management processes (the monitoring of residual risk) is often weak and validation activities often absent.
5. Risk monitoring is a core process but its practice appears surprisingly weak. One reason may be that organisations do not consider monitoring as a process in its own right but rather as validation of prior decisions (see 4 above, however).
6. The true integration of risk management with other core business processes appears some way off. It would appear that the interfaces are not fully understood, perhaps because of disciplinary barriers among technology, health and financial managers.
7. There appears to be only limited engagement of stakeholders in the risk management process, both internal (*e.g.* cross functional groups) and external (*e.g.* regulators).
8. An inability to measure and communicate the value (both tangible and intangible values) of risk management processes appears to have restricted corporate buy-in.
9. In many cases, organisational appetites for risk, in terms of tolerances, are weakly defined, often cited as a 'Board level issue'. Lack of risk acceptance criteria can adversely impact on risk response decision making.
10. An emphasis on individual business units 'owning' the processes has in some cases led to a proliferation of what are often disparate risk management initiatives, creating a barrier to integrated risk management.
11. Although senior and executive management have generally 'bought in' to the central role of risk management in utility operations, communicating its status throughout the company is proving somewhat difficult. 'Making it [risk management] part of the mindset' is often cited as the core function of the risk management team.

These are valuable findings. They suggest that most organisations have moved beyond the reactive state of Level 2 maturity for the range of risk management processes. However, the three core constraints they face in attaining full Level 3 status and beyond are:

- reaching the appropriate level of definition of their processes, *i.e.* identifying the tasks, activities, inputs and outputs of which they are comprised;
- the ability to enable these processes, *i.e.* establishing procedures for their initiation and providing the necessary resources;
- absence of a 'learning culture', which often proves to be the key constraint in proceeding beyond Level 4. On current performance this appears to be largely beyond the immediate control of corporate risk management teams.

2 DEVELOPING A RISK MANAGEMENT CULTURE

3.1 Getting the culture right – towards 'mindfulness' in the water utility sector

Much has been written on safety culture in the light of organisation accidents since the 1970s, much of it coincident with good risk management practice. Developing a risk management culture that is sustaining and continues to learn and improve in face of the inevitable peaks and troughs of organisation performance requires[24]: leadership, procedures, an appetite for conservative decision-making where safety it put first even under pressure; a culture of sharing reported close calls [*near misses have been described as inaccurate, more like "near hits", we use close calls later*]; good communication at the appropriate level, an open, learning organisational culture able to benchmark itself against the best-in-class, systematic competency checking, effective management of organisational change and the ability to prioritise.

Disasters and incidents have deeply-rooted causes[25, 9] that are often a combination of technical failures, an incapacity to manage change and of the underlying values within, or market forces acting on an organisation; as catalogued for waterborne outbreaks by Hrudey and Hrudey[8]. They are often a failure to convert hindsight into foresight and typically occur[24] when there is a loss of institutional foresight and corporate memory, in the face of strong market pressures for efficiency gains, when there are considerable elements of outsourcing, where organisations fail to maintain their status as an 'intelligent customer', with loss of internal technical expertise and particularly during, or following periods of business re-engineering. Cost pressures, priority-based working and changes that are rushed are all circumstances that can generate accidents. For organisations to become resilient and mindful, they must be able to anticipate and circumvent threats to corporate objectives and manage severe pressures and conflicts between performance and the risks that threaten it. Modern management culture sets a strong impetus on doing more for less ('lean') and on maintaining business continuity, and middle managers may find it difficult to challenge this philosophy in 'managing up' risk issues to the executive management or Board. When they do, risks that are not easily quantified in monetary terms may receive restricted air time at Board meetings and lie dormant within the organisation as latent causal factors[25]. It is clear from the prior art that leadership and management are key to establishing the right culture in terms of the expectations and example that are set, or not.

But how do organisations to develop a risk management culture without having first to suffer a major accident? How do we force ourselves to ensure risk issues are treated seriously? And how can we usefully process the volumes of risk information gathered by risk managers so as to make sense of it for accident/incident prevention? When should executive managers listen to the challenge from below? Above what threshold should they act? And are risk managers arguably an additional source of risk because, in taking institutional responsibility for coordinating risk assessment and management, they absolve others of their individual responsibilities for risk management? These are critical organisational questions germane to the organisation practice of risk management and requiring additional research. They remind us that managing risk requires wisdom and reflection, and that preventive approaches are creative and forward-looking. Best in class organisations are mindful about risks to their operations.

Weick and Sutcliffe[26] characterise 'mindfulness' in organisations that (i) are preoccupied with failure and the root causes of it; (ii) are reluctant to (over)simplify; (iii)

are sensitive to operations; (iv) committed to resilience; and (v) are deferential to expertise. We propose that for water utilities seeking to develop mindfulness[27]:

- informed vigilance is actively promoted and rewarded;
- there exists an understanding of the entire system, its challenges and limitations is promoted and actively maintained;
- effective, real-time treatment process control, based on understanding critical capabilities and limitations of the technology, is the basic operating approach;
- fail-safe multi-barriers are actively identified and maintained at a level appropriate to the challenges facing the system;
- close calls are documented and used to train staff about how the system responded under stress and to identify what measures are needed to make such close calls less likely in future;
- operators, supervisors, lab personnel and management all understand that they are entrusted with protecting the public's health and are committed to honouring that responsibility above all else;
- operational personnel are afforded the status, training and remuneration commensurate with their responsibilities as guardians of the public's health;
- response capability and communication are improved, particularly as post 9-11 bioterrorism concerns are being addressed; and
- an overall continuous improvement, total quality management (TQM) mentality pervades the organisation.

3 CONCLUSIONS

Our conclusions are drawn from a series of extended interviews with risk managers within the utility sector and our initial piloting of the RM-CMM.

(1) Risk analysis is widely applied within asset management for assessing the likely condition, lifetime and projected management costs of asset maintenance and replacement. At the strategic level, however, risk and values are intimately linked and there appears to be little explicit expression of the risks utilities are prepared to accept and statements on those consequences that will not be allowed to occur. This is complex territory for many organisations and for water utilities depends, in part, on their private, public or corporatised legal status and corporate objectives.

(2) The promotion of water safety plans under revised World Health Organisation guidelines[6] is driving a more integrated approach to risk identification and analysis from catchment to tap[2]. Implementation will require sound and effective knowledge management.

(3) Along with many sectors, their remains a tendency to view risk assessment as an end in itself, rather than as the evidentiary analysis and input to a management tool for identifying company exposure and opportunities for innovation – the value of risk management requires greater advocacy in organisations.

(4) The provision of safe drinking water has not been historically viewed as a high reliability sector (as has aerospace and the nuclear sectors). This said, failure to adequately manage risk in a climate of 'efficiency gains' and 'optimisation', with risk analysis often being used to justify such actions, may leave the sector exposed to the types of organisational disasters we have witnessed with the fatal outbreak in

Walkerton, for example – attention to the *implementation* of risk management culture is required.

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Benchmarking Risk Analysis Practice in the International Water Sector

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Abstract Risk analysis in the water utility sector is fast becoming explicit. Here, we describe application of a capability model to benchmark the risk analysis maturity of a sub-sample of eight water utilities from the USA, the UK and Australia. Our analysis codifies risk analysis practice and offers practical guidance as to how utilities may more effectively employ their portfolio of risk analysis techniques for optimal, credible, and defensible decision making.

Keywords analysis, benchmarking, governance, management, risk.

Introduction

The provision of safe, reliable drinking water, the overarching goal of the international water utility sector (AWWA *et al.*, 2001), is arguably well within the bounds of the developed world's science, technology, and financial resources. Nevertheless, water quality related outbreaks remain depressingly prevalent (*e.g.* Hrudey and Hrudey, 2004), with their causes ranging from technical failures through to lapses or even criminal negligence on the part of operating or managerial staff. Risk analysis can help prevent such failures through proactively identifying and assessing the mechanisms through which they may arise. This concept of *preventing failure through understanding failure* extends beyond the design and operation of a water supply system to encompass the full range of utility functions (*e.g.* from plant operations to strategic investment; Figure 1.1).

Figure 1.1 The risk hierarchy (adapted from Prime Minister's Strategy Unit, 2002).

Indeed, the introduction of water safety plans, codes of good corporate governance and the debate on self-regulation are promoting a shift in the approach to risk analysis to one increasingly explicit and integrated with other business processes. Risk analysis now extends beyond its traditional preserve in occupational health and safety and public health protection to embrace corporate level decision making, asset management (Booth & Rogers 2001; Lifton & Smeaton 2003), watershed protection (IMPRESS Management 2002; WHO 2003; Lloyd & Abell 2005) and network reliability (Stahl & Elliott 1999; Stevens & Lloyd 2004). When supported by initiation criteria and formal procedures, using personnel with appropriate skills, experience, and resources, risk analysis can provide utilities with benefits ranging from an improved understanding of treatment reliability to an explicit appreciation of

project financial risks (MacGillivray *et al.*, 2006a). Applied inappropriately, whether due to ill-defined procedures or deficient institutional capacities, risk analysis is not a subset of risk management but its panacea.

As such, a reasonable research question is: how can we assess and improve organisational competencies in risk analysis? In this paper, we report on the application of a maturity model to benchmark risk management within the international water utility sector, focussing on the findings relating to risk analysis.

Research scope

Before proceeding, it is necessary to explain what we mean by risk analysis and risk management. Risk is widely accepted to consist of a combination of probabilities and consequences. A more pragmatic approach is to consider risk as the potential for deviation from desired outcomes (*e.g.* business objectives, design intentions). We consider risk management to be a series of processes for identifying, evaluating and responding to these uncertainties. Risk analysis involves the identification and assessment of risk. Given the varying contexts within which risk analysis is applied, we view the juxtaposition of both the technical and managerial aspects of the prior art as central to providing a well-rounded examination of its application within the sector.

Methods - risk management capability maturity model

Capability maturity models (Paulk *et al.*, 1993) codify industry practice so distinctions can be made between organisations and improvements made. Our risk management capability maturity model (MacGillivray *et al.*, 2006b) adopts five levels of maturity, from "learner" to "best practice." Its design has drawn on wide-ranging literature reviews, structured interviews with utility managers and prior knowledge of maturity modelling in similar utility sectors. The model includes, in part, an evaluation of the extent to which risk analysis, as one feature of an organisation's capability to manage risk, is defined and controlled *as a process*. Attributes describing the maturity of any process within risk management, including risk analysis, and the specific descriptions of maturity levels 3 (L3) and 4 (L4), as they refer to risk analysis, are in Table 1.1.

Table 1.1 Basic descriptions of the key attributes characterising risk analysis maturity.

Attribute	Attribute description	Attribute at level 3: Risk analysis The defined organisation - the organisation can say what it does and how it goes about it.	Attribute at level 4: Risk analysis The managed organisation - the organisation can control what it does in the way of processes. It lays down requirements and ensures that these are met through feedback.
Scope	The execution of key practices, and the breadth of process implementation across the organisation.	A defined, documented process is in place containing criteria, methods and guidelines for the identification, assessment and evaluation (with respect to acceptance criteria) of a broad range of risks across core business areas, guided by a risk register. The organisation is conversant with and goes beyond the regulatory requirements for risk analysis.	A controlled process is in place containing detailed criteria, methods and guidelines to manage the identification, assessment, evaluation (with respect to acceptance criteria), establishment of causality and linking (common cause and dependant) of risks at all levels of the company and across all functional boundaries of the business, guided by a company-specific risk register.
Integration	The level of process embedment within the organisation.	Procedures are in place to initiate risk analysis processes.	Risk analysis is initiated automatically as part of core business processes (e.g. periodic business risk assessments).
Verification and Validation	Verification refers to ensuring that the process is being performed correctly, validation refers to ensuring that the correct process is being performed.	Basic mechanisms are in place to verify that risk analysis is performed as required, largely reliant on lagging indicators. The expertise for validation is generally lacking.	Verification and validation systems are in place to verify the efficiency of risk analysis activities and to validate their expediency (e.g. the organisation tracks that tools and techniques are being used correctly and that the correct tools and techniques are being used).
Feedback and Organisational Learning	The manner in which feedback, both internally and externally sourced, is collected and used to question and revise processes.	The risk analysis tool suite is reviewed and modified on an event-driven basis.	Feedback is actively used to improve the execution of risk analysis (e.g. gaps identified and risk analysis tools and techniques improved in response).
Stakeholder Engagement	The process of engaging stakeholders, both internal and external, with the purpose of leveraging the process.	Risk analysis processes generally reside within the responsible unit, with limited cross-functional or external consultation.	Risk analysis processes generally reside within affected disciplines, and stakeholders work together to define and implement an integrated approach to risk analysis, capitalising on synergies and collective knowledge.
Competence	The organisational qualities and abilities, both implicit and explicit, which influence process performance.	Detailed knowledge of risk analysis resides only within the responsible unit.	Most involved staff exhibit a good level of competence in the selection and application of risk analysis tools and techniques, and have access to support from internal or external expert risk practitioners.
Resources	Extent and use of resources (e.g. people, pounds and tools)	Adequate resources are provided in support of risk analysis, with both qualitative and quantitative tools and techniques available.	Sufficient resources are provided in support of risk analysis, a portion of which is made available for R - D for risk assessment. A broad range of qualitative and quantitative tools and techniques are available and applied, including methodologies for aggregating and comparing risks.
Documentation and Reporting	Documentation and reporting of risk information.	Risk analysis outputs are compiled and disseminated in a format that supports decision-making.	Risk analysis outputs are compiled and disseminated in a clear, concise and actionable format that supports real-time decision-making, and their reporting is co-ordinated with other risk reporting mechanisms (e.g. risk status updates).

Results and discussion – observed risk analysis practices

We have applied the risk management capability maturity model to the water sector in the US, the UK Canada and Australia and, for a sub-sample of eight utilities providing high quality data, have captured common, good and best practice in risk analysis. Benchmarking comprised three components: self-assessment by questionnaire; semi-structured interviews; and document analysis. With respect to risk analysis, contributors to this sub-sample were described as being at either L3 or L4, though we do not suggest this reflects risk management capability for the sector as a whole. A key finding of our research is that risk analysis is not best viewed as an overarching process, but rather as a series of discrete processes within

which distinct analysis methodologies are applied, which themselves reside within organisational functions. We therefore discuss our observations on a function-specific basis.

Process engineering

A prerequisite for process definition (L3) is that the application of risk analysis techniques is guided by formalised procedures – a practice intended to ensure the consistency and rigour of analysis. We observed this within process engineering in one utility, where a technical guideline had recently been devised for the application of hazard and operability studies (HAZOP). HAZOP systematically evaluates the process and engineering intentions of new or existing facilities in order to identify the hazards that may arise due to deviations from design specifications (American Institute of Chemical Engineers, 1992). Typically, a carefully selected team examines a process (*e.g.* disinfection) subdivided into "nodes," at each node, the team applies guidewords (*e.g.* low) to process parameters (*e.g.* ozone levels) to identify ways in which the process may deviate from its design intention, before evaluating the causes and consequences of the deviation. The logic of process definition is that specifying the stages in the design process for the application of HAZOP, proceduralising the tasks and activities central to its execution, and providing staff with the requisite expertise (*e.g.* through workshops), creates a process infrastructure that supports its execution beyond the tenure of experienced staff. This is particularly important in an industry characterised by regular restructuring and high levels of staff turnover.

Business planning

We now turn to discuss the strategic approach to risk analysis which focuses on "business risks", *i.e.* those primarily non-technical risks with the potential for causing deviation from high-level business objectives. Within one utility, we observed this to be proceduralised within the second of two business planning workshops. The first addressed the market and competitor environment, including: social, technological, environmental, economic and political (STEEP) analysis; strengths, weaknesses, opportunities and threats (SWOT) analysis; strategic objectives; and strategic options. From this, the "strategic direction" was set for each business area, which served as the initiation point for the risk analysis workshop. Here, the outputs of the previous workshop, allied with brainstorming and knowledge of historic risk analyses, informed the identification of risks to achieving business objectives (*e.g.* in finance: impact of adoption of International Accounting Standards). A qualitative risk ranking matrix was then applied to assess their potential impact and likelihood of occurrence.

However, in common with the remainder of our sub-sample, this strategic risk analysis tended to rely more upon expert judgement rather than being underpinned by extensive data analysis. One manager opined that as their strategic risk portfolio tended to evolve over time and with the perceptions of management, a predefined strategy of data collection to support its analysis was not pragmatic. As such, the role of internal audit and the risk management group in facilitating and providing quality assurance (L4) of these workshops, observed within one utility, is critical to ensuring that strategic risk analysis provides utilities with an improved understanding of the risks that they are seeking to manage, rather than simply being an exercise in fortune telling blindly undertaken to satisfy corporate governance regulations. In another utility, quality assurance had historically encompassed the use of a "professional support group" – comprised of experts drawn from multiple disciplines (*e.g.* legal, insurance, finance, environmental and quality, health and safety) who were independent of the risk analysis process – to peer review the strategic risk analysis.

Asset management

Balancing risk and resources has long been an implicit component of asset management, and is becoming increasingly explicit owing to growing pressures for utilities to exhibit financial self-sufficiency, meaning that they can no longer seek to over-engineer facilities with the presumption of screening out technical risk (MacGillivray *et al.*, 2006a). A risk-based approach to asset management requires an integrated, systematic process drawing upon a

broad range of methodologies for the identification, analysis and prioritisation of assets-at-risk, from the process to the component level (*e.g.* Booth and Rogers, 2001). Within one utility we observed the undertaking of failure mode, effects and criticality analysis (FMECA) studies across their water supply systems. FMECA is an engineering technique that tabulates failure modes of equipment and their effects on a system (American Institute of Chemical Engineers, 1992). The failure mode describes how equipment fails (open, closed, on, off, leaks, *etc.*); failure effect is determined by the system's response to the equipment failure. Its application allows the utility to identify and prioritise risks across their asset portfolio (*e.g.* various mains, raw and treated reservoirs, treatment works *etc.*), enabling them to focus attention on the most serious threats to system performance. We observed that their procedures for undertaking and updating FMECA studies were initiated on a cyclical basis. The interviewee highlighted the value of this requirement, noting that prior to its introduction, supported by a central asset risk register, risk analyses were not regularly updated, instead being performed for a specific purpose at decision making points.

We further observed mechanisms for ensuring procedural compliance and proving quality assurance of risk analysis in recognition of its central role in shaping capital investment programmes. This was driven by a desire to ensure consistency in application and to correct for analyst bias. Within one utility, whilst "experts in the field" regarding asset condition principally undertook the analysis, this was supported by a programme of facilitated workshops to ensure consistency. Additionally, the administrator of the asset database conducted spot check audits and was further responsible for the ongoing moderation of analysis outputs.

Drinking water quality management

The revised WHO guidelines (WHO, 2003) are promoting the implementation of water safety plans for water quality management from catchment management, through treatment, distribution and on to the tap. Central to this is the hazard analysis and critical control points (HACCP) methodology, namely the determination of "critical control points" whereupon risks can be monitored and reduced (Codex Alimentarius, 1993; Hellier, 2000). We observed the implementation of this approach within our sub-sample. In one utility, the process begins with the division of the water system into subsystems (*e.g.* catchment, treatment, distribution, *etc.*). Across each subsystem (*e.g.* catchment) hazard types (*e.g.* physical: turbidity and colour) and their associated causes (*e.g.* erosion) and driving events (*e.g.* landslip, storm) are identified and rated via a qualitative risk ranking matrix. Those deemed most significant were evaluated further for their critical control points (operational parameters describing the effectiveness of control measures designed to mitigate water quality hazards, *e.g.* ph residuals at and post disinfection). Assessors then identified the critical limits (*e.g.* 2000 cells/mL of cyanobacteria for taste and odour related hazards), monitoring programmes and corrective actions for each CCP.

We now highlight the subtle distinction between verification, which seeks to evaluate whether the process has been followed correctly, and validation (L4), which is concerned with whether the process itself is correct (*e.g.* validating the risk analysis methodologies). Both of these aspects were enshrined in one utility's application of a "common sense screen" at the end of their HACCP-based process. Here, if analysis outputs appeared at odds with experienced operational knowledge, the reason behind the "false" score was investigated, and either the process and score adapted where appropriate.

The practical lessons

So what does this mean for utility managers? How can they assess their current maturity in risk analysis and identify practical steps to improve? Given that risk analysis is best treated as a function specific, not overarching discipline, we suggest that they gather representatives from their various functional areas and ask them "the four questions."

What methodologies do you apply to identify and assess risks?

A self-explanatory question, but care should be taken to delve deeply, as the authors have experience of utility engineers viewing risk analysis methodologies as something that "the corporates" apply, neglecting to consider their own use of HAZOP.

Have you defined how these methodologies are applied and supported?

Specifically, this seeks to determine whether: initiation criteria are formalised; procedures exist detailing how the methodologies are to be applied; and whether the requisite resources (*e.g.* data inputs, skills) are predefined and available. As we have noted, this creates a process infrastructure which ensures consistency and stability of execution.

Do you verify that risk analysis is undertaken, and undertaken correctly?

This seeks to establish whether risk analysis is *controlled* as a process. Ensuring that risk analysis is undertaken as required can be attained through, for example, supervisory "sign off" of completed assessments. Ensuring that risk analysis is undertaken properly (*i.e.* quality assurance) may be achieved through peer reviews. Where HAZOP is applied, for example, questions for the reviewers to pose may include: did the analysts work their way through the HAZOP study systematically, or did they overlook important scenarios, components and process flows; were all stages and operating modes of the process considered (*e.g.* start-up, shutdown and transitioning to partial operation); and was adequate time spent on the analysis.

Do you know whether your risk analysis process is valid?

In our experience, this is the most difficult question to answer. Regardless, managers should not shy away from examining whether, for example, the application of HACCP within drinking water quality management constitutes good practice, or if recourse to quantitative methodologies is justified. Validation appears a weakness of the sector, and managers should not be distracted by justifications as to why staff *think* that their process is valid, but instead focus on whether objective evidence exists. Methods for validation include external audits, benchmarking, or statistical techniques in the case of quantitative methodologies.

Conclusions

Our benchmarking results provide utility managers, chief finance officers and regulatory officials with valuable insights into the developing risk management culture within water utilities and a systematic understanding of good risk analysis practice. Of course, there is a trade off between the investments required to become leading-edge in risk analysis and the benefits to be obtained. Risk analysis remains a largely expert discipline, and many organisations are more comfortable with their historic implicit approaches. However, this does not absolve them of their obligation to understand how mature their risk analysis processes are, and how they may be improved. Only then can the cost-benefit implications of progression up the maturity scale be evaluated.

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ESTIMATING POLLUTANT REMOVAL REQUIREMENTS FOR LANDFILLS IN THE UK: III. POLICY ANALYSIS AND OPERATIONAL IMPLICATIONS

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ABSTRACT

The policy analysis and management implications for achieving landfill equilibrium status within a sustainable timescale (decades rather than centuries) are presented based on modelled results reported previously. Until relatively recently, timescale estimates suggested that equilibrium or landfill completion could be achieved within 40-60 years i.e. the same order of magnitude as financial provision for aftercare. However results of modelling in this study (reported in previous paper) suggest that timescales may be considerably longer (many centuries in some instances) suggesting that financial provision may be inadequate. The role of the most promising and available waste treatment technologies and strategic waste management options in contributing towards achieving equilibrium status are discussed. Results suggest that a re-examination of techniques for accelerating landfill stabilisation, including aerobic and bioreactor landfill, is warranted.

Keywords: Equilibrium, completion, emissions, municipal solid waste

INTRODUCTION

This work presents the final part of a series of three companion papers. The first manuscript presented a benchmark study of leachate modelling and reviewed treatment technologies likely to form the basis of meeting the biodegradable municipal waste diversion targets of the Landfill Directive [1] in England and Wales. The second manuscript presented model development [2]. Landfill pollutant removal is intrinsically linked with achieving environmental equilibrium status. Equilibrium is defined here as that state when emissions from a landfill site occur at a rate that allows sufficient natural attenuation in the surrounding environment to prevent environmental harm, so management is no longer required. To embody the principles of sustainability, equilibrium can only be achieved when the management period (post-closure when the site has ceased accepting waste for disposal) is measured in decades rather than centuries. Landfills must remain under management control until the surrender of a landfill permit or licence is accepted by the regulator. Surrender is a site-specific determination and it can only be accepted if a landfill has stabilised physically, chemically and biologically to such a degree that the undisturbed contents of the site are unlikely to pose a pollution risk in the landfill's environmental setting (landfill completion) [3].

POLICY AND OPERATIONAL IMPLICATIONS

Sustainable Landfill

Large-scale modern engineered landfill sites, developed for groundwater protection, are now a common aspect of the waste management system in many countries. Despite this, they are comparatively new, with their development only starting in the 1980s. Consequently such sites, that predominantly contain untreated wastes, are a long way from achieving landfill completion or equilibrium status. One measure of landfill sustainability, an aspect that the EU Landfill Directive [4] does not explicitly consider, is the timescale required to achieve landfill equilibrium. Consideration of landfill sustainability requires an understanding of complex landfill processes that are responsible for stabilisation. There are two main methods of achieving sustainable landfill; flushing *in situ* wastes or pre-treating waste to produce residues that meet set criteria prior to disposal. Current pre-treatment techniques do not produce residues capable of meeting stabilisation criteria [5].

Site-specific landfill leachate measurements provide

some indication of landfill processes, but recent modelling is starting to provide an understanding of the factors that control leachate quality [6]. An increased understanding of waste streams that disproportionately affect leachate quality may suggest a change in management practice is required (e.g. waste segregation, diversion, development of additional pre-treatment techniques) so as to bring forward the achievement of equilibrium. This could ultimately increase the sustainability of landfill.

Strategic Waste Management Options

Whilst raw municipal solid wastes (MSW) managed within a site allowing a moderate amount of leachate flushing, may be close to achieving equilibrium status, the requirements of the Landfill Directive [4] will make this option unavailable for the majority of sites as pre-treatment is a prerequisite of the Directive. This result is contrary to predictions made in the early 1990s [7-9] when it was recognised that measures have to be taken to enhance landfill degradation processes else degradation was likely to take many centuries for landfills to meet trigger concentrations. Combusting raw MSW in incinerators will meet the waste diversion targets, but the effect of combustion and the concentration of non-combustible fractions would appear to make equilibrium status more difficult to achieve. Processing of ash (either artificially or naturally via carbonation) reduces the level of emissions of some heavy metals such as lead and zinc, but results in a significant increase in the sulphate emission.

Coupled with the problems of landfilling the ash, there is the issue of the disposal of air pollution control (APC) wastes and fly ash which may be classified as hazardous wastes. It is unlikely that APC waste from the majority of incinerators will meet the current hazardous waste acceptance criteria (WAC), and an additional waste pre-treatment will be needed for these wastes (or an alternate means of disposing of them needs to be found).

Treatment technologies such as mechanical biological treatment (MBT) followed by intensive composting may provide a means of getting close to the objectives. However, the hydraulic conductivity of MBT residues may make it difficult to recirculate the fluids or introduce irrigation within the landfill, meaning that they will remain at low liquid/solid (L/S) ratios for extended periods. This technology does also remain highly dependent upon the feed stock entering the process, and there is little experience in the UK in managing variations in plant feed stock.

Results of this study (not reported here) supported the notion that it is leachate and not landfill gas (LFG) that will be the rate limiting process for achieving equilibrium status. In all cases the LFG emissions fell below a manageable production rate prior to leachate reaching the requirements of equilibrium status. In some cases this was marginal but in such scenarios, the management option that best suited the requirements of rapid stabilisation included moderate flushing of the landfill to wash leachable contaminants from the landfill and at the same time optimise the rate of gas generation (in order to degrade the organic carbon as soon as possible).

Flushing of Wastes

The waste management industry has discussed the concept of the flushing bioreactor for many years, and the majority of practitioners believe that it is fundamentally workable provided there are large volumes of water available. Flushing rates in excess of 2000 mm y^{-1} of equivalent infiltration have been reported [10] and such rates may be needed to achieve stabilisation (but perhaps not be achievable) for landfills in excess of 50 m deep. Some hydraulic properties of waste change dramatically with depth [11]. The scenarios that we examined here concentrated on relatively thin waste deposits (circa 20 m) but with considerably lower flushing rates. The modelling assumed that during the operational period there is infiltration of 250 mm y^{-1} from rainfall, falling to 50 mm y^{-1} upon capping of the site. For the flushing scenarios, there is an assumed further addition of 200 mm y^{-1} for the MBT, raw MSW and one of the stable non-reactive hazardous waste options, and 500 mm y^{-1} for mechanically sorted organic residues (MSOR), incinerator bottom ash (IBA) and the other stable non-reactive hazardous wastes scenarios during the period of active management. The choice was dictated in part by the results of the non-flushed model results for each waste residue. There was an assumption that if the liquid being recirculated is leachate (rather than water) it should have undergone at least some basic treatment to remove high concentrations of organics and ammoniacal nitrogen. Sulphate and chloride removal would not normally be an issue for raw MSW or MBT residues as these leachates would be unlikely to reach solubility limits for these species, but could do so if concentrations were allowed to build up. The reality is that additional infiltration of the order of 200 mm y^{-1} would be readily achievable from run-off available from capped areas for the majority of sites in the UK. Additional infiltration amounting to 500 mm y^{-1} would be geographically more restrictive. Flushing as a means of accelerating the stabilisation of landfilled waste has been advocated for many years [10] and research continues to demonstrate that it can serve to shorten the aftercare period considerably. However, there is no real incentive for the waste industry to invest in such practice. It seems that the recent revision of financial provisions was a missed opportunity to provide that incentive. It might have been possible to introduce a two or three tiered system with lower amounts of money set aside at sites where accelerated stabilisation measures were installed.

In the case of IBA landfills, the leachate would be quite different from that found in the more organic sites that we are familiar with. Leachates from these landfills will be largely inorganic and contain primarily metal salts. Alternate leachate treatment technologies will be required and the recirculation

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of treated leachate could be more problematic since the removal of sulphate will be needed to avoid saturation of these salts.

In many respects, the easiest way to achieve higher flushing rates would be to postpone the installation of a cap until equilibrium status was achieved. However, for wastes that are likely to require any form of landfill gas control, such an option is not viable. It may be an option for incinerator bottom ash (IBA) wastes as there is little evidence that the ash generates landfill gas, and odour should not be an issue. This might be a function of the site geometry as a deeper landfill will require a larger degree of flushing or a longer management time to achieve the required L/S ratio, but the depth of the site is unlikely to have a pronounced effect on the gas generation rate and the time to reach equilibrium status in respect of gas. The option of removing a cap at the end of the gassing phase of a landfill may remain, subject to the regulatory requirements for minimisation of leachate production.

Removal of the cap at this stage would be similar to maintaining a flushing rate at 250 mm y^{-1} and could then proceed as a flushed site for a further 40 years or so, at which time it would achieve equilibrium status. Thus, this management scenario would not require re-circulation of leachate, nor would it require collection and injection of water specifically to achieve the flushing rates. The resultant time to equilibrium status would be extended by around 30 years, but would be significantly shorter than if the cap were to remain in place.

Furthermore, the liner performance can be expected to be better during the first century of its operation as the degradation due to loss of antioxidants is unlikely to occur within this period [12]. One issue that would make this option less favourable is the disturbance of what would have been a restored landform for some 30 years or so.

The time disjoint between achieving what is modelled as equilibrium status and the maximum groundwater impact probably remains one of the major obstacles to the practical use of this work. It will require pragmatic regulation in order to issue a closure certificate for a landfill that still contains contaminants at 10 times the water quality standard. This could be further compounded by the fact that most waste permits will require a specific leachate head to be maintained. In order to approach the sort of conditions that might occur when equilibrium status is approached, there may need to be a planned gradual increase in leachate level so that the site reaches some degree of hydraulic equilibrium as well as chemical equilibrium with its surroundings.

Leachate Strength at Equilibrium Status

It was envisaged that the research would indicate a leachate strength at which equilibrium status could be shown to have been achieved and, along with other tests and monitoring data, allow a completion certificate to be issued for a site. The work undertaken here showed that the relationship between leachate strength and equilibrium status is far from linear. Where a site meets our definition of equilibrium early on, then the concentrations of leachate within the site that satisfy equilibrium will be higher than where the site meets the requirements later. This is simply a function of the degradation of the liner and capping systems where there is an expectation that these systems will see degradation with advancing age. This is compounded by the fact that those sites that will need an extended aftercare period will also have to continue to manage leachate to a quality that is less polluting than one where the aftercare period is shortened due to selective processing or flushing.

It has been suggested that the Inert WAC C_0 values (initial eluate from the percolation test prCEN/TS 14405:2003) for inert waste sites might have shown an indication of the leachate quality at the point of equilibrium. It was therefore worth comparing the typical ranges obtained from this study (albeit that they varied due to time dependency issues) with the WAC values for inert waste landfills. A comparison of the leachate concentrations and the inert C_0 values is shown in Table 1.

These results indicated that while there is a generalised relationship between the formal C_0 values for inert wastes and those derived from this study, the relationship is not always strong enough to be relied upon. This conclusion follows that of the time dependency issue; although there are a number of cases where the leachate concentrations need to fall well below the inert WAC C_0 values for inert waste sites (e.g. copper, lead and chloride). This is in part due to the way in which the C_0 values were generated, being a combination of modelling, rounding up/down and a comparison with leach test data from common waste streams that are deemed to be inert.

Ammoniacal Nitrogen

It is clear that certain species drive the time periods required to achieve equilibrium status. Prior to this research it was thought that ammoniacal nitrogen would be a governing factor given its high concentration in raw MSW leachates and low environmental threshold. While the modelling undertaken did not indicate that ammoniacal nitrogen was a major problem, it is recognised that some MSW leachates contain considerably more ammoniacal nitrogen than those modelled. It is of some comfort that the MBT compost process removes a large amount of ammoniacal nitrogen and fixes the organic nitrogen in other less mobile forms.

While this is to an extent reassuring, there remain a significant number of current landfills within the UK where ammoniacal nitrogen will continue to be a notable issue for many years. In addition, the modelling in this study assumed a composite liner. Where clay liners are used, it is likely that a greater flux of ammoniacal nitrogen will result and that this may still be an issue that affects the attainment of equilibrium status. What is surprising is the lack of commercial development of the research that has shown benefits

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Table 1. Comparison of inert WAC C_0 values and leachate concentrations at equilibrium status.

Component	Raw MSW	MBT & MSOR	Incinerator bottom ash	C_0 (percolation test) from inert WAC
	mg l^{-1}	mg l^{-1}	mg l^{-1}	mg l^{-1}
As	0.03	n/a	n/a	0.06
Ba	n/a	n/a	n/a	4
Cd	0.01	0.018	0.008	0.02
Cr	0.8	0.8	n/a	0.1
Cu	0.25	0.4	0.2	0.6
Hg	0.002	n/a	n/a	0.002
Mo	0.3	n/a	0.2	0.2
Ni	0.2-2.5	0.25	n/a	0.1
Pb	0.08-0.13	0.13	0.03	0.15
Sb	0.008-0.01	n/a	0.01	0.01
Se	0.03-0.04	n/a	n/a	0.04
Zn	0.75-0.8	0.8	n/a	1.2
Chloride	960-1230	430-1480	720-980	450
Fluoride	3.5-5.4	n/a	n/a	2.5
Sulphate	860	400-1100	350-1050	1500
NH_4	n/a	40-530	n/a	n/a

n/a – not available, generally because the leachate was at equilibrium status within 3 yrs and would therefore be below the C_0 value. Ba, Se and fluoride were not modelled.

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associated with the injection of nitrified leachate back into the waste mass. Work by Burton and Watson-Craik [13] has shown that the introduction of nitrate into waste results in the denitrification of the leachate (resulting in the formation of nitrogen gas) and a substantial reduction in the nitrogen load within the landfill.

Ammoniacal nitrogen is likely to be much more of a consideration with regard to surface waters in instances where specific landfill sites are at risk of spilling over (the bathtub effect). This can occur as a result of continued integrity of containment coupled with the waste being saturated. Our modelling thus far has not included emissions to surface water, which could form a separate study.

Accelerating the Achievement of Equilibrium: Air Injection

In a similar vein work has been undertaken, particularly in Germany and Italy, relating to the injection of compressed air into landfills that are in their methanogenic stage. Conventional landfill disposal encourages waste decomposition processes that operate anaerobically. This study has reported that modelled predictions suggest that landfill completion may take centuries, based on modern highly engineered landfills. This raises the question of sustainability for both operational landfills and the landfill legacy i.e. sites that are no longer licensed or permitted, some of which pre-date regulation. Many of these latter sites are ex-local authority landfills that are often relatively shallow and are slowly degrading with considerable pollution potential remaining. This treatment affords an opportunity to accelerate the stabilisation process for organic waste aerobically and potentially return sites to market for redevelopment in a timely fashion.

Whilst the benefits of aerobic or semi-aerobic landfill have been clearly demonstrated, including full-scale studies in Spain and Canada, many practitioners are sceptical of the benefits and are concerned about the risks such as gaseous emissions and entry of oxygen into a landfill that could cause fires. Other uncertainty surrounds the optimum point at which to begin aeration and the effect of aeration on leachate parameters.

Cossu et al. [14] reported the full scale stabilisation of part of a landfill (for rail construction purposes) by the injection of compressed air over a 140 day period. A marked drop in methane generation occurred and presumably an aerobic composting process was established. The study did not report the affects on the leachate quality during this period, but it would be expected that there would be a reduction in ammoniacal nitrogen production and a fall in BOD and COD, accompanied by a reduction in TOC levels. Work by Purcell and Walker [15] showed that on a pilot scale, the forced aeration of green waste and shredded biodegradable MSW can achieve a relatively stable residue within 6 months (aerox process). While the organic indicators (BOD, COD and NH_4) all showed marked reductions from the control cells, unsurprisingly the total heavy metal content of the waste remained virtually unaffected. The removal of some of the organic material will result in a long-term lowering of the TOC content of the waste and a subsequent reduction in the capacity to generate organo-metal complexes that form readily with some metals (especially copper).

While the aerox process was designed primarily as a

means of pre-treatment of organic wastes, the work by Cossu [14] showed that it is feasible to undertake forced aeration *in situ* on a landfill site scale. It may therefore be possible to speed up the stabilisation of wastes that are approaching the end of their methanogenic life and achieve equilibrium status at least for landfill gas. Certainly the application of forced air injection either at the beginning or the end of the landfilling process would remove certain trace organic species that remain problematical within biologically active landfills and pose a threat to groundwater quality. While a number of researchers are looking at this area of forced aeration of organic wastes, rate constants still remain to be generated so that these processes can be readily modelled and the effects predicted.

Controlling Inorganic Species

Depending upon the waste treatment and the applied technologies, different inorganic species appear to control the time taken to achieve equilibrium status. For conventional raw MSW, these are likely to be lead and chloride (with ammoniacal nitrogen at sites where biodegradation in the groundwater is unlikely, or above average concentrations exist). For MBT residues, these include lead, nickel, zinc, sulphate and chloride (but not ammoniacal nitrogen). For IBA the contaminants most likely to cause problems are antimony, cadmium, copper, molybdenum, zinc and chloride. As the ash undergoes carbonation, zinc and lead will cease to be an issue but will be replaced by sulphate.

Certain MSW waste streams contain high proportions of these contaminants and it might be worth considering whether the likely changes in waste management practices could result in an increased diversion of these waste streams from landfill. In the case of energy from waste mass burn (EfWMB), much of the organic and combustible fraction of the waste will be lost from the waste mass (primarily carbon in its many forms) although any metals in these fractions may well be retained. It is only when certain waste fractions are removed from a waste stream (as might happen in the sorting and mechanical treatment stage of MBT) that whole waste fractions will be removed from the final residue. Contaminants within the waste entering an EfWMB will be partitioned between the IBA and the APC and fly ash generated. Given the concentrating effects of combustion (in relation to non-combustible fractions) and the change in oxidation state that results in some metals becoming more leachable, it is not entirely surprising that IBA performs least well in the modelling undertaken.

Table 2 contains the percentage proportions of a selection of elemental contaminants in raw MSW. The figures take into account the composition of the waste fraction itself, and the relative proportion of that fraction within a typical household waste stream. It does not take into account the relative leachability of the contaminants from each waste

Table 2. Percentage distribution of specific elements in waste fractions.

Element	As	Cd	Cl	Cr	Cu	F	Pb	Hg	Ni	Zn
Paper and card	5.9	4.9	8.5	2.4	0.	**21.2**	1.8	5.3	4.1	1.9
Plastic film	2.0	2.5	3.7	2.8	0.1	3.0	8.6	1.1	0.6	1.0
Dense plastic	1.4	**39.9**	**44.3**	5.3	**20.7**	**14.9**	9.6	1.4	5.7	**14.0**
Textiles	0.5	0.4	0.4	0.3	0.8	1.2	0.10	0.4	0.8	1.0
Absorbent hygiene products	0.2	1.3	1.2	0.3	0.2	9.8	0.6	0.3	0.3	0.5
Wood	0.9	0.2	0.2	0.5	0.0	0.0	0.5	0.0	1.2	0.2
Combustibles	**14.6**	8.7	**21.3**	**16.9**	1.1	6.9	6.3	2.6	**4.4**	**15.7**
Non-combustibles	**18.1**	7.7	2.6	6.5	0.3	**23.7**	**20.4**	2.0	9.2	**4.2**
Organic	**13.3**	2.9	**11.6**	2.1	0.6	**13.4**	2.4	6.5	6.2	2.0
Ferrous metal	**29.9**	**19.7**	0.0	**47.7**	1.9	0.0	**14.7**	**77.6**	**23.6**	8.3
Non-ferrous metal	0.7	3.4	0.0	1.1	**20.8**	0.0	7.3	1.0	**11.6**	**13.6**
Fine material <10mm	11.4	1.1	1.2	2.1	0.3	3.4	5.9	1.9	2.6	1.5
Waste electrical & electronic equipment	0.0	0.0	5.0	**10.1**	6.8	2.6	5.9	0.0	7.7	6.1
Hazardous household waste including batteries	1.2	7.2	0.0	2.0	**45.7**	0.0	**15.9**	0.0	**22.0**	**30.0**
Batteries	0.3	1.3	0.0	0.3	16.3	0.0	5.0	0.0	5.4	8.0
Clinical waste	0.4	0.1	0.1	0.1	0.0	0.6	0.6	0.2	0.2	0.1
Paint/varnish	0.3	0.1	0.5	0.2	0.0	0.1	0.2	0.3	0.1	0.3
Oil	0.2	0.1	0.3	0.1	0.0	0.1	0.1	0.2	0.1	0.2
Garden herbicides & pesticides	0.3	0.1	0.5	0.2	0.0	0.1	0.2	0.3	0.1	0.3

Note 1 – values in bold represent greater than 10% of the total contribution of each element.
Note 2 – Columns sum to 100% down to specific hazardous household waste. [18]

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fraction nor does it consider any changes to the leachability through waste treatment or combustion. However, Table 2 could be useful as a guide for managing a specific site *e.g.* if cadmium is a concern, removal of the dense plastic waste stream could be a priority.

For MBT residues, we might expect that many of the contaminants associated with paper, plastics, ferrous and non-ferrous metals, and Waste Electrical & Electronic (WEE) goods will be removed. Given that for MBT issues remain with lead, nickel and zinc, it is of some concern that these elements are predominantly present within waste streams that should have been largely removed. With respect to lead, nearly 50% of the total lead in MSW should have been removed. For nickel the removal figure is 53%, and for zinc the figure is nearly 45% (see Table 2). Part of the reason why these contaminants remain a problem could be that much of the research on MBT residues comes from continental Europe, while the compositional data from MSW has been derived solely from UK waste streams. In addition, it must be remembered that MBT residues are likely to have a higher density than raw MSW and hence will contain a higher contaminant load within the same landfill volume. The fact that intensively composted MBT residues appear to have lower leachable metal content than less intensively composted MBT is not something that is readily understood, and may imply a fundamental difference in the overall performance of different MBT plants.

Organic Species

The understanding of the origins of some of the trace organics within leachate (which have not been modelled in this study) and landfill gas remains poor for many species. Certain trace organics such as mecoprop that is present in nearly all MSW landfills is probably one of the best understood, and is thought to originate from green waste (grass cuttings) and empty (or partially empty) herbicide containers. Mecoprop along with a number of other organic species appears routinely in leachate samples primarily because they do not degrade anaerobically; and they are not volatile and hence do not partition into the landfill gas phase.

There is a very clear advantage in subjecting these contaminants (in the waste that they exist in) to an aerobic degradation period prior to placing them in to a landfill. Other contaminants, such as heavily chlorinated solvents, will degrade only in anaerobic conditions. However, these groups of compounds tend to be more volatile and will partition into the landfill gas phase.

Measuring Equilibrium Status

One of the objectives of this work was to define a method for assessing when a site can be regarded as having achieved equilibrium status. This research has shown that this is a complex issue and one that will, in part, be based on the specific design of a landfill and upon its local hydrogeological regime. Furthermore, the criteria used to judge the impact on groundwater will almost certainly not be the Drinking Water Standard (DWS) that has been used for the comparative modelling that has been reported in this document. Under the Water Framework Directive [16] it is likely that groundwater quality criteria will be developed for specific groundwater bodies or classes of groundwater body. Furthermore, the revised Groundwater Directive [17] may include a change in the way the discharge of Listed substances is regulated. These may change the way completion will be judged and may have a marked impact on the completion time or equilibrium status of a landfill.

Leachate quality and an assessment of the hydraulic performance of a site, coupled with long-term monitoring data from the site remains the only viable means of assessing completion criteria at present. This will have to be addressed on a site-specific basis as it is clear that no uniform standard will work in each and every case.

For sites where flushing has been undertaken over the entire landfill area it is likely that much of the waste will have achieved a reasonably high L/S ratio, and while there are bound to be areas that have (due to short circuiting) received less flushing than others, on the whole, the residual emissions are likely to be acceptable. For sites where there has been less flushing, or flushing is restricted to certain areas of the site, then an investigation of the leaching properties of the waste may be warranted. The leach tests defined for the WAC characterisation testing will be appropriate tests, and the degree of variance between samples and comparison between the leach test data and existing leachate quality will provide an indication as to whether the whole site has reached equilibrium status or whether water flow through the waste has been channelled in very specific areas.

The fact remains that it is easy to measure leachate concentrations. What is needed is a means of measuring the flux of contaminants migrating from the site. Only when we are in a position to measure the flux can we properly judge the equilibrium status in a way that does not require a great deal of conservatism.

CONCLUSIONS

This study has examined the municipal solid waste streams that the UK will most probably generate following the implementation of the Landfill Directive requirements to reduce biodegradable waste from going to landfill and the requirements for waste pre-treatment. The properties of the residues undergoing the most likely processes were investigated via a literature search and an assessment made via modelling of the probable management times these residues would require within a landfill environment. A re-evaluation of these properties in light of emerging knowledge, for example on pre-treatment aspects, may show whether such aspects bring us any closer to equilibrium status or further from it.

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Each process investigated generates a residue that will need to be landfilled and there is a likelihood that at times the products generated by these processes (e.g. MBT compost, or refuse derived fuel (RDF) material) may be out of specification, or in quantities greater than the demand, and hence these may also need to be landfilled.

On the whole those processes that involve the combustion of wastes are shown to lengthen the period of time taken for the landfill to reach equilibrium status. This is partially due to the higher densities of the wastes resulting from combustion and hence the higher amount of metals and salts that can be disposed of within the same landfill void space. However, the same argument cannot be applied to intensively composted MBT residues which, despite their higher density, give the best performance waste residues considered. Interestingly, these MBT residues that result from intense composting perform as well as, but no better than, raw MSW except that they give the same performance while possessing a higher density, and therefore represent a better use of the void space within a landfill.

Leaching processes can be accelerated by the flushing of landfills with either recirculated, but treated, leachate, or the infiltration of additional volumes of water. Other processes that show promising results at full scale were discussed, including landfill aeration and recirculation with nitrified leachate.

The modelling was restricted to those processes that are readily modelled (even if the model parameters are uncertain). There remain a number of landfill processes and management practices (such as nitrate injection and air injection) that are the subject of interest world-wide but as yet have not been developed to the extent that the processes have rate constants. Air injection in particular, shows promising results in reducing the emissions from landfill with marked improvement in leachate quality. It is likely that modelling the effectiveness of these processes will be forthcoming in the very near future. Further work is required to examine more critically the sensitivity to baseline assumptions, such as C_o, hydrogeological settings and kappa values. This can only happen once more data values are available.

While this study does not provide the answers to how the landfill aftercare period may be shortened sufficiently to attain sustainable development criteria *i.e.* achieving equilibrium within decades rather than centuries, it does take a step in the right direction and identifies where significant progress can be made towards achieving sustainable landfill and equilibrium status. It is clear that until such time as landfill sites achieves this status, risk assessment will be required. A sensitivity analysis of the baseline assumptions and data underpinning the modelling work is required. This was beyond the scope of our study but it could lead to the development of equilibrium criteria. A full technical and economic reappraisal of techniques that demonstrably accelerate waste decomposition processes is justified on the basis of modelled results presented in this study.

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Wastes as Co-Fuels: The Policy Framework for Solid Recovered Fuel (SRF) in Europe, with UK Implications

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European Union (EU) member states are adopting the mechanical–biological treatment (MBT) of municipal solid waste (MSW) to comply with EU Landfill Directive (LD) targets on landfill diversion. We review the policy framework for MSW-derived solid recovered fuel (SRF), composed of paper, plastic, and textiles, in the energy-intensive industries. A comparatively high calorific value (15–18 MJ/kg) fuel, SRF has the potential to partially replace fossil fuel in energy-intensive industries, alongside MSW in dedicated combustion facilities. Attempts by the European standards organization (CEN) to classify fuel properties consider net calorific value (CV) and chlorine and mercury content. However, the particle size, moisture content, and fuel composition also require attention and future studies must address these parameters. We critically review the implications of using SRF as a co-fuel in thermal processes. A thermodynamic analysis provides insight into the technical and environmental feasibility of co-combusting SRF in coal-fired power plants and cement kilns. Results indicate the use of SRF as co-fuel can reduce global warming and acidification potential significantly. This policy analysis is of value to waste managers, policy specialists, regulators, and the waste management research community.

Introduction

Municipal solid waste (MSW) management is of strategic concern across Europe. MSW growth, in England, for example, of ca. 2% w/w in 2004–05 (*1*), is leading to implementation of a substantive program of policies and regulations targeted at decoupling economic activity from waste generation. A heavy reliance on landfilling makes meeting the targets for diverting biodegradable municipal waste (BMW), set by the European Union (EU) Landfill Directive (LD) (*2*), difficult. In 2005–06, England landfilled ca. 62% w/w of its MSW (*3*). To comply with legislation and manage waste as a resource, a strategic hierarchy is proposed that includes prevention, reuse or recycling, recovery in the form of energy, and disposal by landfilling (*4*). Energy recovery has established benefits, though arguably it may restrict opportunities for recycling or composting and results in specific emissions of concern (*5, 6*).

Mechanical–biological treatment (MBT) is an established technology to treat MSW in Germany, Italy, Austria, and The Netherlands (*7*). MBT is a generic term for a number of similar processes treating mixed MSW, or fractions of MSW, in order to gain value from waste through the recovery of metals and energy (*8, 9*). Several output streams are generated, including a compost-like digested material, a high calorific value (CV) fuel stream (15–18 MJ/kg), metals, and residuals. The high CV fuel stream typically comprises paper, plastic, and textiles. Being a waste-derived fuel, it can be used within the energy-intensive industries. In the UK, waste-derived fuels from MSW are termed refuse-derived fuel (RDF) or solid recovered fuel (SRF), depending upon the fuel's characteristics.

SRF is a new terminology. SRF is more homogeneous and less contaminated than the generic RDF. RDF has been historically used in industrial and boiler applications (*10–17*) and combustion studies for other waste-derived fuels such as tires, sewage sludge, and MSW exist. However, along with similar potential fuels (*18, 19*), there is currently market confusion over the incentives and legal position for SRF. This review aims to correct this and present evidence for the use of MSW-derived SRF as a co-fuel within energy intensive industries. We set out to inform policy makers in their decision making, energy users in reducing their operating costs and emissions, and the waste industry in its efforts to meet LD requirements.

Critical Review

Legal and Policy Framework. Policy and legislative developments often emerge in a piecemeal fashion and, with the benefit of hindsight, can appear poorly integrated. Waste-derived fuels are a case in point and their use is influenced by what we term "enabling" and "constraining" legislation (*19*). The current position is complex and, to many, is confused (Figure 1). The legal drivers encouraging the use of SRF as fuel include the LD (*2*), the Renewable Energy Directive (*20*), the Climate Change Levy (CCL) (*21*), the Substitute Fuels Protocol (SFP) (*22*), and the EU Emissions Trading Scheme (EU-ETS) (*23*).

The LD requires diversion of the biodegradable fraction of MSW and used tires from landfill. To meet the targets, an economic instrument, the Landfill Allowance Trading Scheme (LATS), encourages English waste disposal authorities to reduce their amounts of BMW destined for landfill (*24*). Tradable landfill allowances are allocated to each local authority. Waste disposal authorities with insufficient allowances need to increase their diversion rate, purchase additional allowances, or borrow forward, up to 5% of next year's allowance. Exceeding their allowance may result in the imposition of a penalty of 210 euros/t of waste (*24*). Furthermore, the UK landfill tax is increasing at an annual rate of ca. 5 euros/t to an anticipated peak at 56 euros/t, lending additional impetus for MSW treatment (*25*).

The Renewable Energy Directive (*20*) encourages the use of waste-derived fuels to facilitate European compliance with Kyoto targets. Countries that have ratified Kyoto have to reduce their greenhouse gas emissions or engage in emissions trading. In the UK, solar, wind, biomass, tidal power, and advanced waste treatment, such as gasification, pyrolysis, and anaerobic digestion, are eligible for Renewable Obligation Certificates (ROCs) (*6*). The biomass fraction of SRF may be eligible for ROC, if processed thermally at a dedicated power plant or co-fired power station (*6*). Under the Renewable

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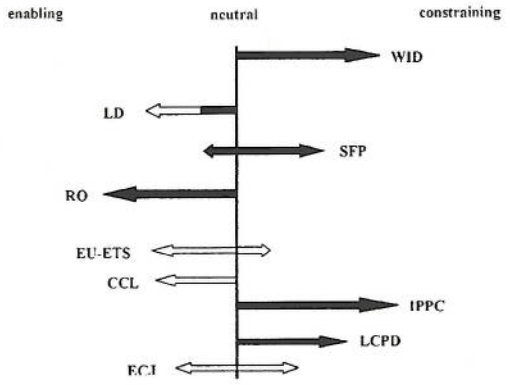

FIGURE 1. Relative influence of legislation and policies on the use of MSW derived SRF as co-fuel in energy intensive industries (solid arrow, direct influence; unshaded arrow, indirect influence).

Obligation Order, the electricity generator is paid a minimum of 45 euros/MWh_e in addition to the value of the wholesale electricity for power produced by the biomass fraction (*26*). According to a recently published draft by the Department of Trade and Industry (DTI) regarding the Renewable Obligation Order (2006), a waste-derived fuel can qualify for ROCs if 90% of the total energy is produced by its biomass content, rather than 98% (*27*). It is thought that the biomass fraction in MBT-derived fuel can be raised to 95% from an initial value of ca. 70% in mixed MSW (*23*). Therefore, this directive has a positive incentive on the utilization of SRF within energy-intensive industries.

The CCL (*21*) is a tax on the use of energy (not carbon) in all nondomestic sectors, except the transport sector, or on fuels used for the production of other forms of energy such as electricity generation or for nonenergy purposes. This is an economic instrument targeted at reducing greenhouse gas emissions. A discount of 80% on the levy, until March 2003, was granted to business sectors that agreed to improve their energy efficiency or reduce their CO_2 emissions. The discount since April 2003 has been dependent on their performance in doing so. In order to achieve set targets, industries require a substitution of conventional fossil fuels with those rich in biomass. MSW-derived SRF can be used along with other biomass fuels as replacement of fossil fuels.

The Substitute Fuels Protocol (SFP) relates specifically to the use of alternative fuels in cement kilns. The protocol, introduced by the environment regulator in England and Wales, the Environment Agency, sets out the principles and practices for carrying out trials of the use of substitute fuels in cement and lime kilns together with the associated regulatory requirements. In its revised form (*22*), relaxed emission limits for NO_x and particles have been permitted in cement kilns compared with those set for incinerators. Minimum limits on CV have been lifted, making lower-grade fuels suitable for burning. This means even though SRF produced from MSW may have lower CV than other waste derived fuels, such as tires and liquid solvents, it can be used in cement kilns. After the 2003 amendment, cement companies can get regulatory permission for burning in a single application rather than two separate applications, as was previously required, thus reducing the cost of investing in new fuel handling. In this sense, the SFP is facilitating as well as controlling the use of SRF directly.

The EU-Emissions Trading Scheme (ETS) (*23*) emphasizes the restriction of CO_2 emissions from specific industries. In this market-based trading approach, emission credits are allocated to power generators and energy-intensive industries to match their CO_2 output. In the first phase of the scheme (2005−2007) some industries, such as combined heat and power plants, cement manufacturers (having capacity greater than 500 t/d), coke ovens and refineries, iron and steel producers, glass and ceramics industries (capacities greater than 20 t/d), paper and pulp mills, and tile manufacturing industries have to manage their greenhouse gas emissions. In addition, any other sites combusting fossil fuel with greater than 20 MW_{th} (thermal capacity) also must comply. The implementation of EU-ETS has forced more than 1200 installations across 25 European countries to constrain their emissions within an annual CO_2 output, with a gradual reduction of allowances over time. Given this policy landscape, the utilization of low-carbon MSW-derived fuels is being doubly incentivized, in terms of diverting wastes from landfill and for renewable energy conversion. Power and heat producers prefer paper- and card-rich SRF due to the presence of a high proportion of biomass, as it is considered as carbon neutral (*28*) and provides a market value to SRF: (a) by reducing or eliminating the need to purchase EU allowances from the markets; and (b) by generating extra allowances for an end-user with enough existing credits, which can then be sold into the secondary market (*6*). The EU-ETS acts indirectly on the co-combustion of SRF. However, its potential influence may be both positive for, and limiting of, co-combustion since it may cause the increased use of other biomass fuels such as wood waste.

The statutes constraining the use of SRF as fuel include the Waste Incineration Directive (WID) (2000/76/EC) (*29*), the Integrated Pollution Prevention and Control Directive (IPPC) (96/61/EC, 1996) (*30*), and the Large Combustion Plant Directive (LCPD) (2001/80/EC) (*31*). The WID governs the operation of all energy-recovery operations from waste-derived fuels. It brings closer the requirements for incineration and co-incineration, but has created a divergence in the requirements for emission control. For example, air emission limit values for dust, NO_x, and SO_2 emissions are less stringent for cement kilns than for incineration facilities (*32, 33*). WID imposes the same limit values for the incineration and co-incineration of "untreated municipal waste". No clear meaning of the term "untreated" is offered. This can encourage SRF production which is more homogeneous and has a high calorific value, thus having a positive impact on the increase in pretreatments of residual waste. However, under WID, all existing installations may require an upgrade of their processes as well as pollution abatement equipment.

Integrated Pollution, Prevention and Control (IPPC) is the principal European environmental statute for large process plants. It requires best available techniques to protect the environment. All plants that thermally treat gases or solid fuels (produced from MBT processes) "with a capacity exceeding 3 t/h" are regulated by IPPC. In the UK, domestic transposition of this legislation, in the form of the Pollution, Prevention and Control (PPC) Regulations, specifies that all new and dedicated installations utilizing RDF/SRF (above 3 MW_{th} input) be regulated under IPPC, except cement kilns and power stations that are burning these fuels as a substitute for, or in combination with, primary fuel in the course of manufacturing or other operations. In the UK, a new facility intending to use SRF as fuel would require planning permission, an environment impact assessment, a permit under the PPC Regulations, a best practicable environmental option appraisal, and a waste management license. The LCPD governs large power plants (thermal output greater than 50 MW_{th}) that are required to reduce their sulfur and NO_x emissions by taking remedial measures. Therefore, the directive controls directly only larger plants.

Two recent European Court of Justice (ECJ) rulings (*6*) are also of importance. One (Case C-228/00) ruled that the use of waste as fuel in cement kilns is recovery rather than disposal, when excess heat is used in the process. Conversely, a second (Case C-458/00) ruled that burning waste in a

municipal incinerator, whether or not it reclaimed energy, should be considered as disposal. These judgements further reinforce the need for legal clarity. Figure 1 summarizes our assessment of the relative impact of legislation on the adoption of SRF co-combustion. The size of the arrow indicates the degree of influence of the legislation, while the position of the symbol to the right or left of the center line indicates the extent of constraining or enabling effect.

Composition of SRF and Design Considerations for its Use. SRF is prepared from nonhazardous waste and utilized for energy recovery (*34*−*42*). Appendix I in the Supporting Information provides a summary of its production and essential characteristics, including a discussion of recent moves through introduction of the European standard, CEN/TC 343 "solid recovered fuels", to lend consistency to SRF production. Different unit process options exist for energy recovery from SRF (*6*, *32*, *35*, *37*, *43*, *44*). Appendix II of the Supporting Information summarizes these options for the reader.

EU Experiences of MBT Processes Producing SRF from MSW. Several MBT processes exist hat have different preferences for the product output, including SRF, compost, and digestate. We review two MBT processes, the Ecodeco and Herhof processes producing SRF from MSW. Both employ bio-drying to stabilize the solid waste prior to extensive mechanical refining. SRF from the Herhof process is known by a trade name, Stabilat. In the Sistema Ecodeco process, shredded waste is converted into stabilized, sanitized, odor-free material in 12−15 days by bio-drying. During the biological process, the temperature is maintained between 50 and 60 °C. The material is then separated in different streams using various mechanical methods. This produces 50% w/w SRF (~ net CV of 15−18 MJ/kg), which is used in different energy-intensive industries. For instance, at the Corteolona site (Italy), SRF is fed into a fluidized-bed plant to produce electricity (9 MW_e) (*46*). Land requirements for plants having capacities of 60 000 tpa and 180 000 tpa are 15 000 m^2 and 35 000 m^2, respectively (*47*).

The Herhof process works on a similar principle. Here, residual waste is stabilized in 300 t capacity boxes. Air is passed through the base of the box and the waste is kept enclosed for 7 d. The dried material is mechanically sorted to separate various outputs. One, SRF, has a high CV of 17 MJ/kg (*48*). The fuel produced in the Dresden plant (Germany) is used for methanol production. Capital costs for smaller and larger plants are ca. 12 million euros and 36 million euros, respectively. Operational expenditure can vary from 22 to 75 euros/ton of waste.

Strategic Evaluation of SRF within Sustainable Waste Management. The generation and utilization of waste-derived fuels occurs within a strategic waste planning context in which local authorities (municipalities) seek to deliver sustainable waste management. Various appraisal tools are available to help contextualize the use of SRF. For example, Lee et al. (*36*) evaluated the performance of different residual MSW management options in terms of electrical yields. MBT-derived SRF showed optimal performance with electricity yields for SRF of 928 kWh/ton compared to 714 kWh/ton with incineration, the latter calculated on the basis of 25.4% thermal conversion. A sensitivity analysis revealed this value did not alter significantly with a change in waste composition. While calculating the electric yield of MBT-derived SRF, it was assumed that 50% w/w of the biodegradable fraction was converted into SRF and the CV of SRF was 16.5 MJ/kg. The efficiency of the generator was assumed to be 40%. However, the energy required to generate SRF using an MBT process was not taken into account in this analysis, though it is suggested that this is ca. 30 kWh/ton of input material.

Chackiath and Longhurst (*49*) evaluated waste technologies from a local authority perspective of national policy compliance aiming to minimize costs, promote technology acceptability, and reduce planning risk. Their technology assessment for municipal waste treatment in Greater London used a multicriteria analysis in which different technologies were assessed for (i) the track record in treating the specified waste; (ii) BMW diversion from landfills; (iii) quantity of waste disposed to landfills; (iv) timescales; (v) total expenditure (capital and operational); (vi) revenues; and (vii) land take for the facility. MBT with SRF was the preferred option to treat residual MSW.

The performance record of a technology is important in investment decisions because many of the statutory waste management targets have to be met immediately. A technology's "bankability" (i.e., its ability to attract financial investment from banks based on its likely operational performance) is a critical factor. BMW diversion is a crucial factor in the EU because if BMW diversion does not meet statutory targets, it now incurs financial penalties as explained above. The delivery time taken from design to commissioning is a further important factor. Longer times result in non-compliance with targets. Total expenditure including capital and operational costs, revenues, and land requirement are the other criteria to assess the feasibility of the process. Anaerobic digestion and composting were assessed (*49*) for source-separated organic waste (a mixture of green, kitchen, and food waste), whereas, other technologies, such as, MBT with SRF, MBT with anaerobic digestion, MBT with compost-like material, energy from waste, and advanced treatment technology were assessed for residual MSW. The analysis revealed that MBT with SRF is the preferred current option to treat residual solid waste. The capital cost of all MBT treatment methods was the same (23 euro m). However, the operational cost was least for MBT with SRF (48 euro/t) compared to other MBT and thermal processes. Also, design to commissioning time was lower (3 years) compared to that of other energy recovery options (typically ca. 11 years).

The Borough of Telford and Wrekin (*50*) carried out a best practicable environmental option (BPEO) study for their municipal waste strategy (2005−2021). Views from public, industry, and community groups were elicited and preferences were assigned to different options. An MBT process performed the best among the options studied, followed by incineration. This study may assist waste management decision makers, but market availability, the use of digestate/compost, regulatory change, and environmental permit feasibility must be considered before reaching any decision (Table 1).

Energy and Mass Flow Modeling. For this analysis, a mass and energy flow analysis (*19*) was performed with the objective of assessing the technical and environmental performance of SRF in two co-combustion scenarios: (1) co-combustion with coal in a coal-fired power plant for power generation (assuming 2 GW power station, SRF 10% of input on dry solid (DS) basis); and (2) co-combustion in a cement kiln for using power and/or heat (CHP) (assuming 300 kt DS/y coal consumption, SRF 20% of input on DS basis). Compositional data for coal and SRF are presented in Table 2.

The thermodynamic model performed energy and mass balances for incineration, steam generation, and electricity/power generation. The energy consumed during transportation was not taken into account. In addition, any need for fuel drying was eliminated as SRF is used in combustors as received. Fuel mixtures containing coal and SRF were assumed to be added directly to the combustion chamber (Figure 2) with either the combustor generating direct heat (dotted line arrangements after combustor) at 50% thermal efficiency or steam (solid line) (30% efficiency) to generate a 90% efficient generator to produce electricity. It was assumed the exit temperature of hot gases released from the

TABLE 1. Performances of Different Treatment Options Observed in the UK

option	rank		
	Lee et al. (*36*)[a]	Chackiath and Longhurst (*49*)	Municipal Waste Strategy for Borough of Telford and Wrekin (*50*)
landfill	-	-	7
energy from waste	3	4	2
MBT (fuel)	1	1	1
MBT (anaerobic digestion)	-	2	3
MBT + compost-like-output	-	3	-
autoclave	-	-	4
anaerobic digestion	4	-	-
composting	-	-	6
advanced treatment technology	2	5	-
landfill (where electricity generated)	5	-	-
export	-	-	5

[a] Performances were based on electricity yields.

TABLE 2. Elemental and Proximate Analyses Data for Coal and SRF

fuel	C (%DS)	H (%DS)	O (%DS)	N (%DS)	S (%DS)	Cl (%DS)	moisture content (% as received)	ash content (% DS)	volatile matter (%DS)	calorific value (MJ/kgDS)
coal (*19*)	74.9	4.6	7.3	0.6	1.1	0.3	7.1	9.4	31.5	30.49
SRF[a]	47.1[a]	7.1[a]	29.4[a]	0.7[a]	0.24[a]	0.6[a]	15.0[a]	10.9[b]	82.06[b]	21.2[a]

[a] Values from ref *3*) have been converted into % DS basis. [b] From practical experience.

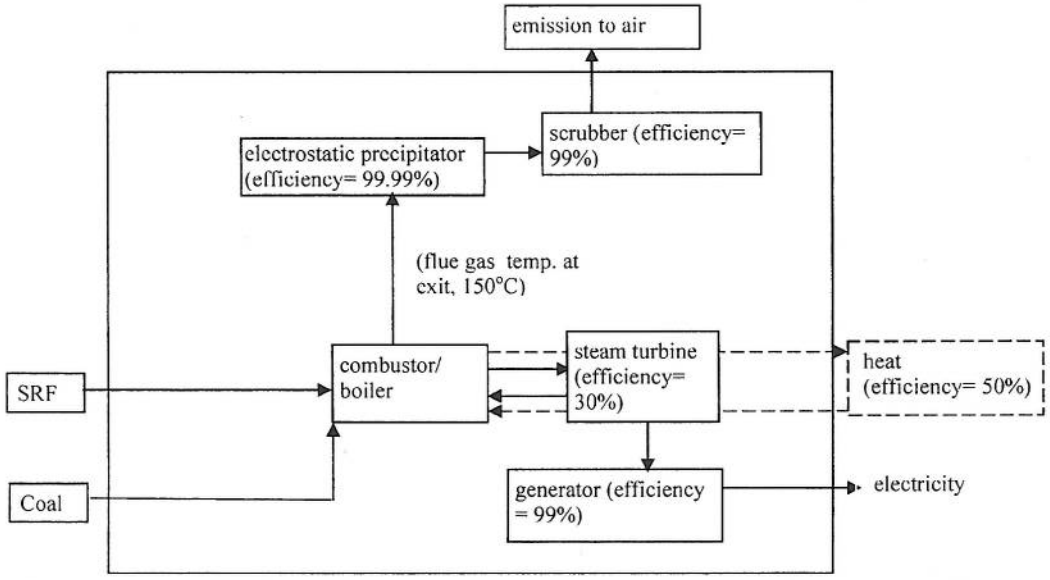

FIGURE 2. Co-combustion scenarios for a pulverized fuel coal power station boiler (solid arrow) and cement kiln (dotted arrow).

combustor/boiler after combustion was 150 °C. The flue gas stream then passed through an electrostatic precipitator and a scrubber for removing dust and gases (SO_2 and HCl), respectively.

Data on the fuel feed rate, moisture content, ash content, and elemental composition were used as inputs for the thermodynamic models. To ensure complete combustion, 30% v/v excess air was supplied to the combustor. From the model inputs, fuel consumption, heat loss, electricity production, heat availability, flue gas emission, and ash production were measured. It was assumed that all sulfur and chlorine present in the fuel mixture were converted into SO_2 and HCl. In this analysis, 6% nitrogen from fuel was converted into NO and N_2O in a 1:1 ratio (*19*). Using these results, the effect of SRF on the power/heat production, potential greenhouse gas emissions, net effect on acidification (in terms of SO_2), and potential contribution to winter smog were evaluated (Table 3) by comparing the model output for co-combustion with that for coal alone.

TABLE 3. Incremental SRF Impacts (Values Are Normalized per kg DS SRF)

co-combustion facilities	electricity (kWh)	global warming (g CO_2 eqvt.)	acidification (mg SO_2)	winter smog (mg dust)
coal-fired power plants (2 GW capacity)	−0.870	−2468	−192.4	+0.661
cement kilns (300 kt/y capacity)	−1.466	−2471	−192.4	+0.614

Electricity/heat production decreases due to the lower calorific value and higher moisture content of SRF. Heat loss in removing the moisture reduces the boiler efficiency.

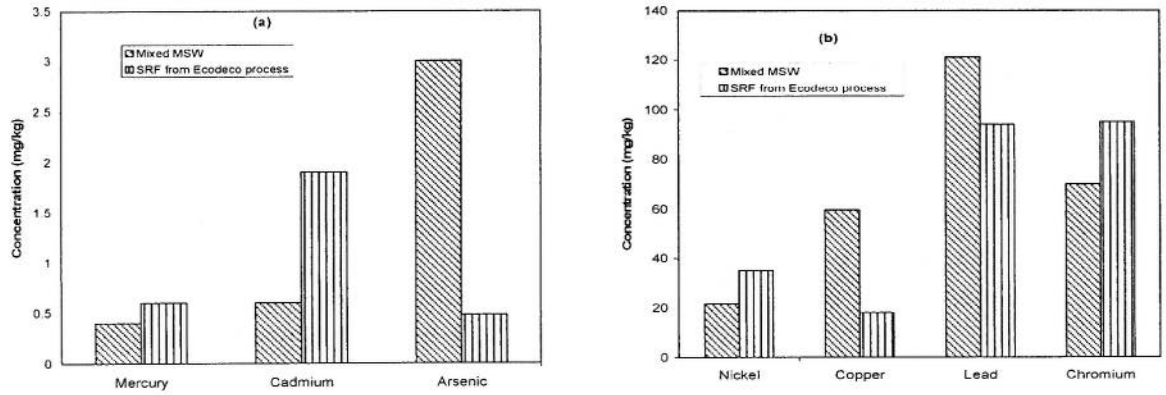

FIGURE 3. Comparison of heavy metal contents between mixed MSW and SRF (from Ecodeco; *60*)

However, the global warming effect was found to be reduced significantly. This is due to the presence of biomass-derived material (ca. 70% w/w) in SRF. A reduction in acidification potential was observed due to a lower sulfur content in SRF (0.24% w/w compared to 1.1% w/w in coal). However, a projected increase in winter smog potential was observed due to the higher ash content in SRF. The analysis illustrates the trade-offs in substituting SRF for coal and the relative benefits that can be secured. A reduction in electricity can be compensated for by the lower SRF cost. Good quality SRF having a CV > 20 MJ/kg and chlorine content < 0.5% w/w can be available at a cost of −5 to 10 euros/t to the cement industry (*26*). Oxford Economic Forecasting (*51*) speculate that cement production could increase by 22.7% between 2002 and 2012, further enhancing the demand for SRF.

Discussion

Legislation on the definition of waste and, specifically, the point at which materials exit the chain of utility has been a recurrent constraint on our progression toward a resource management economy. As illustrated for biosolids (*19*), an absence of clarity can result in lost opportunities to secure the benefits of energy recovery from waste. With energy costs rising steeply in Europe amid concerns around the security and diversity of supply, the need to diversify the fuel mix and release biomass fuels, such as SRF, to the market is pressing. Recognizing this, the European Commission is seeking to clarify the legal situation on waste used as fuel and is collating case studies on industry byproducts that become waste, a commitment made in the Commission's 2005 waste thematic strategy. Below, we offer insights into the opportunities for the use of SRF and a rationale in each case.

It is believed that power plants, the cement industry, industrial boilers, and dedicated incinerators could be potential end-users of SRF in the UK. Of these, cement production is highly energy intensive. Fuel accounts for 30% of total operating costs (*52*) and the sector is a major generator of CO_2. The use of SRF as a co-fuel would be a significant step toward sustainable integrated waste management (*53*, *54*), especially as SRF produced from say, the Herhof process, emits less carbon per unit of electricity production compared with conventional fossil fuels (*55*). Unresolved issues related to SRF include its reproducible homogeneity in terms of the net CV offered, the gaseous and heavy metal emissions, and storage of the material. Mechanical waste separation can improve homogeneity (*56*) and for end users, the material must be dry and stabilized, so that odors and the energy requirement for driving off moisture are minimized, and the material must be friable and uniform for easy handleability.

An assessment of the environmental impacts of RDF production and use was explored using a life cycle assessment (LCA) methodology (*32*). In the study, use of RDF in brown and hard coal power plants, cement plants, and MSW incineration plants was compared. The analysis suggested the greatest impacts were likely to be from emissions of mercury and cadmium at cement works and brown-coal-fired plants. Several pilot plant studies with co-combustion of RDF with wood chips, coal, and peat suggest the increase in NO_x, HCl, particulate matters, and heavy metals (Cu, Cr and Pb) (*10*−*11*, *13*). The alkaline environment in the kiln neutralizes acid gases (HCl and SO_2). The use of such fuels also reduces net CO_2 emissions significantly, but can promote NO_x emissions in coal-fired power stations if NO_x abatement equipment has not been installed (*57*). Emission control for NO_x and SO_x is needed by installing selective catalytic regeneration (or staged combustor or low NO_x burners, depending upon boiler configuration) and flue gas desulfurization techniques. This would incur additional installation costs but gate fees and revenues may compensate. The chlorine content in waste-derived fuels is much higher than that in fossil fuels. Reliable information about the fate of chlorine species and Na, S, and K is required (*58*). For example, a study of the release of HCl from combustibles in MSW during incineration found the main source of inorganic chlorine was food waste and the major portion of organic chlorine was present in rubber and plastic (*59*). Though the organic chlorine in wood, paper, and textiles is small, even wood and textiles contribute significantly to HCl production.

SRF obtained from the Ecodeco process possesses a heavy metal content substantially less than the UK specification for substitute waste-derived fuels in cement kilns (*6*, *60*), though Hg, Cd, Ni, and Cr contents were higher in SRF than mixed MSW. On the other hand, Pb and As were found in much lower quantities in SRF (Figure. 3).

Other researchers have undertaken technology assessments of SRF. Maunder and Haggard (*61*) discuss project-specific technical, environmental, and regulatory risks for securing finance to implement different waste processing technologies, including composting, anaerobic digestion, advanced thermal treatment, and MBT. Despite not being a fully proven technology in the UK, most MBT facilities did not present a substantive process risk. Their study suggested the key risks associated with the availability of markets for MBT outputs (like SRF) can be eliminated by establishing short-term contracts (3−5 years) rather than the current 20−25 year arrangements with local authorities.

The economics of any utility process is affected by the geography of a country (logistics), the waste "catchment" (volume), and the scale and rate of supply of the conventional fuel (materials flow). If suitable facilities are available to make use of waste-derived fuel and conventional fossil fuel is in short supply, then alternative fuels clearly become more

viable (*32*). Local market conditions dramatically affect the feasible use of RDF/ SRF (such as gate fees, transportation costs, and low cost of landfilling). In some situations, mono-combustion of the RDF/SRF may be advantageous; for example, if two or more MBT facilities construct a single dedicated facility for fuel combustion. However, financial viability will be affected by the price for treating the fuel in dedicated facilities or sending the fuel to industries such as cement manufacture and revenues from the sale of energy (*62*).

For thermal waste treatment, public acceptability is critical and public engagement (*43*), where the benefits and impacts are discussed early on, is now expected. As MSW-derived fuel appears to not have the same negative image to incineration, cement industries are using it in place of fossil fuel (*45*). Kakaras et al. (*63*) are studying SRF as coal substitute in the electricity generation sector. To date, their results indicate that the co-combustion of SRF could be a feasible and environmentally beneficial process.

Moving to a resource management economy requires the clarification of conflicting statutory instruments. The waste management and power generation sectors are respectfully cautious adopters of new technology and change because of the need to secure disposal routes and the supply of electricity. Further, the economics of alternative fuel use are marginal, and constraining legal burdens, even where there is accompanying facilitating legislation, can tip the balance against their use. Strong market incentives and regulation are required that provide clear market signals to the combined objectives of reduced carbon, environmental protection, and resource efficiency.

This review has illustrated the benefits that can be secured through the utilization of SRF in the energy-intensive industrial sectors and the legal complexity that faces plant and environmental managers in these industries. The role of the research community is, in part, to provide greater certainty on the performance characteristics of SRF and its production. Our own work is focusing on the process optimization of SRF and monitoring gaseous pollutants, ash, and heavy metals emissions during pilot plant scale co-combustion studies.

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Supporting Information Available

Appendices I and II summarize the composition of SRF and design considerations for its use. This material is available free of charge via the Internet at http://pubs.acs.org.

Abbreviations

MBT	Mechanical–biological treatment
MSW	Municipal solid waste
CV	Calorific value
LD	Landfill Directive
BMW	Biodegradable municipal waste
RDF	Refuse-derived fuel
SRF	Solid recovered fuel
IPPC	Integrated Pollution Prevention and Control Directive
LCPD	Large Combustion Plant Directive

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ARTICLE

Benchmarking Risk Management Within the International Water Utility Sector. Part I: Design of a Capability Maturity Methodology

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ABSTRACT Risk management in the water utility sector is becoming increasingly explicit. However, due to the novelty and complexity of the discipline, utilities are encountering difficulties in defining and institutionalising their risk management processes. In response, the authors have developed a sector specific capability maturity methodology for benchmarking and improving risk management. The research, conducted in consultation with water utility practitioners, has distilled risk management into a coherent, process-based framework. We identified eleven risk management processes, and eight key attributes with characterise the extent to which these processes are defined, controlled and institutionalised. Implementation of the model should enable utilities to more effectively employ their portfolio of risk analysis techniques for optimal, credible and defensible decision making.

KEY WORDS: Maturity model, risk, analysis, management, water, sector

Introduction

Financial restrictions, regulatory pressures and sectoral restructuring are encouraging water utilities to move from technically inclined, risk-averse management approaches towards more commercial, business-oriented practices (MacGillivray *et al.*, 2006a). Many within the industry, spurred

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on by developments in international regulation and guidance, are promoting a business-wide approach to risk management as a means to ease and exploit this transition (e.g. Lifton and Smeaton, 2003; Miller, 2005; Lloyd and Abell, 2005). Whilst the sector has made good progress towards setting its stated goal (AWWA *et al.*, 2001) of providing wholesome, safe drinking water that has the trust of customers within a risk-based context (Pollard *et al.*, 2004), there remain barriers to the implementation of risk management. These can be categorised as business-related, the challenge of embedding risk management within organisational cultures and decision-making processes (e.g. Pollard *et al.*, 2004; Howard and Lourens, 2005); and technical, relating to the selection and application of risk analysis tools (e.g. MacGillivray *et al.*, 2006a). Our research addresses the former; the premise being that the tools and techniques for risk analysis are sufficiently developed, yet lacking is the organisational capacity to employ these methodologies for more optimal, credible, and defensible decision-making.

The authors propose that the dominant cause of this capacity deficiency is the difficulty inherent in establishing, defining and controlling risk management processes. This is perhaps because the sector's approach to implementation has centred on adherence to risk management frameworks. These are essentially standards describing the fundamentals of the prior art and the interrelationships between its core elements (e.g. Hamilton *et al.*, 2006). Here, we are not concerned with frameworks for drinking water quality management (e.g. NHMRC, 2001; WHO, 2002), widely accepted and applied within the sector as a means of placing public health protection within a risk-based context, but with those corporate-level frameworks intended to foster an integrated approach to risk management (e.g. COSO, 2004; Canadian Standards Association, 1997; Council of Standards of Australia, 1999). These latter frameworks have been instrumental in transforming the discipline from the preserve of engineering and finance functions towards a business-wide paradigm. However, a number of criticisms may be offered. Critically, although they typically embrace the concept that risk management is comprised of processes, their treatment of the discipline focuses on organisational structures and procedures. They often fail to address how the core tasks and activities of risk management may be defined and controlled as processes. Furthermore, although they have evolved beyond prescribing static requirements towards embracing the concept of continuous improvement, too often this is addressed as an afterthought rather than as an explicit component of these frameworks. As such, the water sector has lacked methodologies on which to base risk management improvement initiatives, suggesting that enhancements may often be isolated and that their associated benefits can neither be replicated nor extended throughout organisations. Finally, whilst typically generic in nature, these frameworks are often representative of the large, financially-oriented firms where their application predominates.

To address these shortcomings, the authors have developed a sector-specific risk management capability maturity model (RM-CMM), a vehicle for benchmarking, implementing and improving the *processes* that comprise risk management. In this paper we review the field of capability maturity modelling. We then describe the research methodology adopted in the design of our model, before discussing its development, structure and practical definition. A companion manuscript (MacGillivray *et al.*, 2006b) describes the model's application in a benchmarking of eight utilities within the international water sector.

Risk Management in the Water Sector

The water industry is undergoing a significant shift in its approach to risk management to one that is increasingly explicit and better integrated with other business processes. Risk management strategies and techniques traditionally applied to occupational health and safety and public health protection are now seeing broader application for asset management (Booth and Rogers, 2001; Lifton and Smeaton, 2003), watershed protection (IMPRESS Management, 2002; NHMRC, 2001; WHO, 2003) and network operation (Stahl and Elliott, 1999; Stevens and Lloyd, 2004). Beyond this operational context, utility managers are increasingly concerned with managing the risks inherent to corporate level decision making. Critical issues include decisions on outsourcing asset maintenance; billing and monitoring; the management of change; staff retention; the long-term viability of investment decisions; and the management of external interfaces with regulators and "competing" utilities (MacGillivray *et al.*, 2006a). Pollard *et al.* (2004) report that the organisational hierarchy that exists even within "flat" utilities requires that these risks are actively managed at strategic, programme and operational levels (Figure 1). Typically, there are split accountabilities for these risks such that the chief financial officer/financial director and Board have overall responsibility, supported by an internal audit or control function for the management of strategic risks; executive and senior management address programme level risks (e.g. asset management, maintenance planning); and operational (e.g. site) managers bear responsibility for operational risks (e.g. treatment plant performance).

Water utilities must employ a range of techniques to evaluate and consider these aspects alongside one another, devising business and operating strategies that prioritise resources on the basis of risk. Here tensions may arise from the explicit risk trade-offs inherent to running a commercial water utility, such that the industry's overarching goal of public health protection is placed in conflict with narrower financial interests. Critically in this regard, the transition to an explicit risk management philosophy within the sector is reflected in recent revisions to the World Health Organisation's (WHO, 2003) Guidelines for Drinking Water Quality. It is this overall context that drives the need for an increased capability to manage risk.

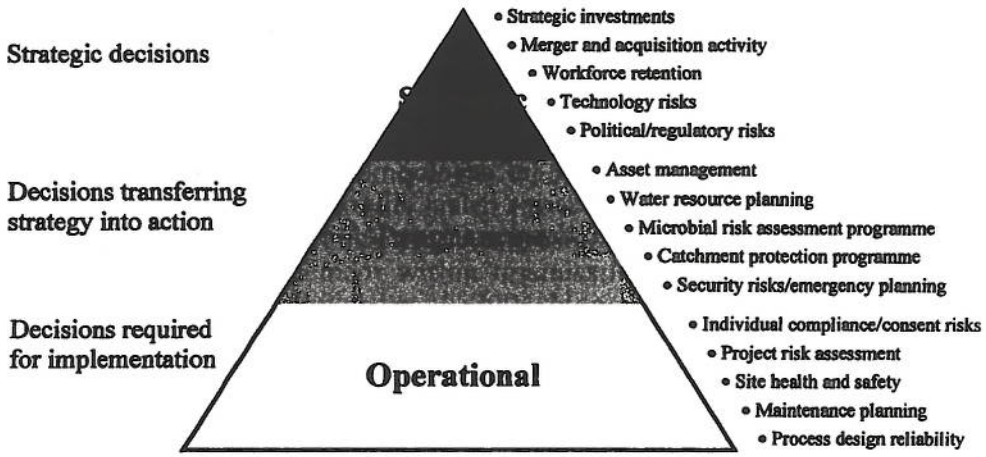

Figure 1. The risk hierarchy (adapted from Prime Minister's Strategy Unit, 2002)

Overview of Capability Maturity Modelling

A capability maturity model (CMM) is a simplified representation of an organisational discipline (e.g. software engineering, risk management) that distils industry practices into a coherent, process-based framework. These models are constructed according to maturity levels, from learner to best practice, which are characterised by the extent to which the processes are defined, controlled and institutionalised. The field's origins can be traced to the "quality revolution" of the 1970s (e.g. Crosby, 1979) and to the field of management performance measurement. The CMM methodology was first articulated by the Software Engineering Institute (SEI), whose seminal model (Paulk *et al.*, 1993) explored the design capability of software development organisations. The capability maturity modelling concept is finding increasing acceptance in academia and industry. Notable applications include software and systems engineering (Paulk *et al.*, 1993; Software Engineering Institute, 2002a), workforce development and management (Software Engineering Institute, 2002b), offshore design safety (Sharp *et al.*, 2002), reliability engineering (Strutt, 2003), and construction (Sarshar *et al.*, 2000). Capability models enable organisations to establish their current level of process maturity and identify the steps necessary to progress to a higher level, building on their strengths and improving on their weaknesses. They may be used for benchmarking purposes, enabling organisations to compare themselves against other companies in their sector and beyond. This may be done at the corporate, functional or business unit level. Similarly, they may be used to assess the capabilities of key suppliers and partners.

Recently, a selection of risk management capability maturity models (e.g. IACCM, 2003; RMRDP, 2002) have been developed. We believe that these models insufficiently reflect the basic principles of capability maturity modelling. The most critical point is that they are not explicitly

process-centred. Furthermore, they do not closely reflect the clear distinctions between maturity levels as set out by the SEI and developed further by subsequent researchers, instead characterising risk management maturity on a graded scale of good-to-bad practice. Of course, the CMM approach is not the sole means for improving risk management, and these critiqued models have found support within industry. Thus, we do not imply that the IACCM and RMRDP models are without value, indeed their simplicity and modest time demands may prove attractive to many organisations. However, our development of the RM-CMM is not an extension of these models, but rather a novel application of capability maturity modelling to risk management in the water utility sector.

Rationale of Research Methodology

The tailoring of existing maturity models to a new discipline and sector is not a simple mapping exercise (Sarshar *et al.*, 2000). Here, the core principles of maturity modelling were abstracted and recreated in a form specific to risk management within the water utility sector. Design of the research methodology (Figure 2) was informed by the authors' previous experience in maturity modelling within similar utility sectors and drew upon the CMM literature, particularly Sarshar *et al.* (2000). The methodology is designated "testing-out research" (Starke, 1995). Here, the aim is to explore the limits of previously proposed generalisations and to specify, modify or clarify their content (Starke, 1995). This form of research must be conducted under real world conditions, where the kind of control present in laboratory conditions is neither feasible nor justifiable. The lead author, in concert with a steering group of four expert practitioners, designed the model in collaboration with partner water utilities. Key development inputs included literature reviews of risk management and capability maturity modelling, structured scoping interviews with eleven water utility professionals from five countries, prior knowledge of maturity modelling in similar utility sectors, and past experience within the water sector.

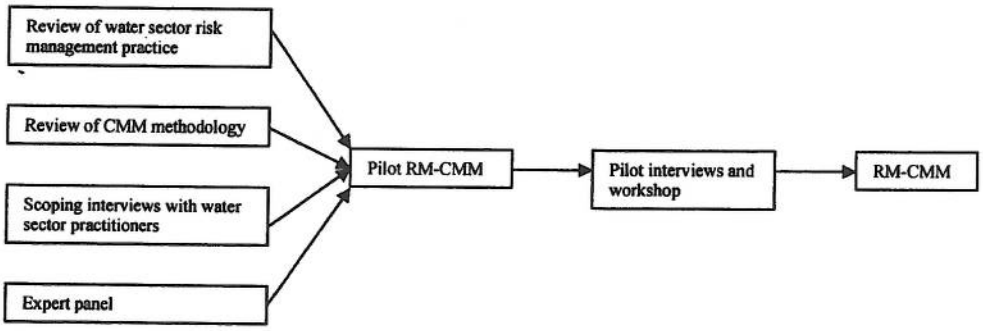

Figure 2. Research methodology for design of RM-CMM

Given the qualitative nature of the research, verification and validation mechanisms were adopted. The purpose of the expert steering group was to verify that the model accurately codified risk management in line with the principles of maturity modelling. Furthermore, feedback was sought from three water utilities to ensure that the model reflected the practical realities of managing risk in the sector. This took the form of one workshop and two interviews conducted after sharing the pilot model. This piloting sought to validate the model's architecture (e.g. are the right processes included, are they adequately characterised, are the key attributes relevant, etc.) and to clarify its terminology. The model remains under research. The authors have recently tested the model through a benchmarking exercise and two industrial case studies. These applications will provide data of intrinsic value to both the industrial and academic communities, and will serve as a means for evolving the model towards a state compatible with industrial ownership.

Risk Management Capability Maturity Model

Model Overview

The RM-CMM is designed to measure and improve risk management processes. Hence it is process-based rather than focussing on specific outcomes or deliverables. It is increasingly accepted that continuous process improvement is based on a series of small, evolutionary steps, rather than revolutionary measures (Paulk *et al.*, 1993). The RM-CMM organises these steps within evolutionary plateaus, or maturity levels, which lay successive foundations for continual process improvement. Figure 3 illustrates the model architecture.

Risk Management Maturity Levels

Setting sensible goals for process improvement requires an understanding of the difference between mature and immature organisations (Paulk *et al.*, 1993). We have developed descriptions of five maturity levels that characterise organisational behaviours in both risk management overall and for each constituent process. These levels were derived by abstraction from existing CMMs describing different disciplines (Paulk *et al.*, 1993, Software Engineering Institute, 2002a, 2002b; Sharp *et al.*, 2002; Strutt, 2003; Sarshar *et al.*, 2000), contextualisation of which was supported by reviews (MacGillivray *et al.*, 2006a, Pollard *et al.*, 2004; Hamilton *et al.*, 2006) and scoping interviews. It is important to understand what these levels represent in practice, as they are central to assessing the maturity of an organisation. Below we describe the overarching maturity hierarchy. Note that at a given level of maturity, the positive characteristics from preceding levels remain.

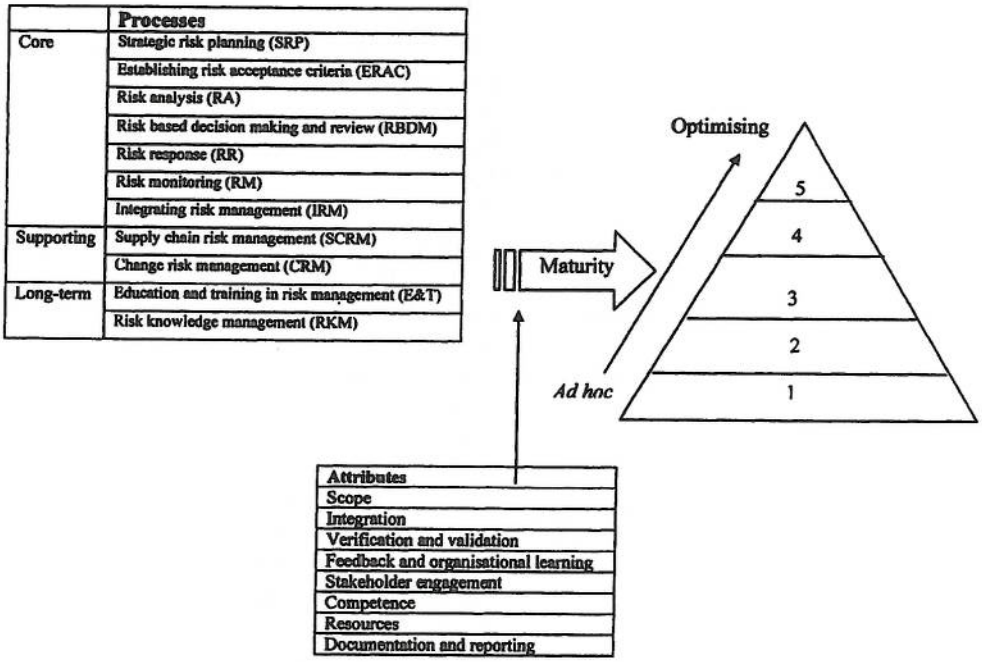

Figure 3. Overview of the RM-CMM (after Strutt *et al.*, 2005)

Level 1 – Initial. L1 organisations practice a largely *ad hoc* approach to risk management, possessing no formal risk management processes and often exhibiting limited knowledge of relevant standards or regulatory guidelines. Thus, they are largely reliant upon individual heroics for the active management of risk. L1 organisations are likely to be small water providers based in isolated rural areas where resource constraints prevent the staffing of utilities with dedicated water professionals.

Level 2 – The repeatable organisation. L2 organisations understand that they have risks that require formal management, and have established basic risk management processes for this purpose. However, these processes are ill-defined and poorly institutionalised, limiting their capacity to influence organisational actions. Furthermore, the scope of risk management is narrow, generally restricted to addressing mission-critical risks and areas required by regulation (e.g. occupational health and safety, water quality). Hence, at L2 the active management of risk tends to be influenced less by explicit risk management processes than by the repetition of activities and practices that have worked for the organisation before. In a technical context, this places a premium on accepted standards of performance and codes of practice (e.g. engineering standards; accepted best practice) which, if adhered to, provide high degrees of control. This is a pragmatic approach in familiar and well-characterised situations where uncertainties and system vulnerabilities are well understood.

However, this mind set is vulnerable; when mistakes are made they do not learn – failures are repeated as well as success. Whilst L2 organisations often have a reputation for achieving reliable, cost-effective water supply, they are very vulnerable to change, whether organisational, technical or commercial. This, allied with deficient organisational learning, is a common theme across many recent water quality related outbreaks in affluent nations (Hrudey and Hrudey, 2004).

Level 3 – The defined organisation. The key characteristic of the L3 organisation is the definition and implementation of risk management processes across core business areas. This is achieved through establishing process "enablers". Enablers include the policies, procedures and frameworks that guide risk management activities (i.e. who does what and when), and the provision of adequate training, funding and tools in support of these activities. Several scoping interviewees described their recent definition of risk management processes. Drivers for this included: a desire to balance the role of "brainstorming" and "judgement" in risk management with more methodological, standardised and objective approaches; the need to "institutionalise" risk management; and obligations to exhibit good corporate governance to shareholders and regulators. In essence, definition seeks to formalise existing implicit approaches to risk management. This is most notably illustrated in the sector's increasing adoption of the "water safety plan" approach, which codifies good practice in the identification, assessment and control of hazards to water quality.

Definition creates an environment in which risks are methodically identified, analysed, responded to and monitored. In a technical context, L3 maturity is required where systems are characterised by greater levels of uncertainty and the potential to deviate from routine operation. This is increasingly common, as the trend towards utility self-sufficiency means that management can no longer seek to "over-engineer" facilities with the presumption of screening out technical risk (MacGillivray *et al.*, 2006a). Here, optimisation of plant, network and process design and operation requires a capacity to assess, understand and respond to what is driving the risk from or to the plant, process or network. However, at L3 the efficiency and quality of risk management processes are variable, stemming from limitations in their verification, validation and feedback mechanisms (the "evaluators"). These limitations restrict organisations' ability to track and therefore control their risk management processes, which are thus characterised as "open loop."

Level 4 – The controlled organisation. The key characteristic of the L4 organisation is a structure which not only enables their risk management processes but also evaluates and ensures their effective execution (closing the open loop of L3). The scope of these processes reach throughout the organisational hierarchy and across all functional boundaries. Evaluating refers to the implementation of verification and validation mechanisms to

provide feedback on the status, quality, efficiency and expediency of risk management (e.g. ensuring procedural compliance, quality assurance, benchmarking etc.). The value of systematic verification was emphasised by one scoping interviewee, who noted that previously, free access to the corporate risk register was combined with an absence of peer review of risk assessments. This had allowed staff to "over-estimate their own pet concerns" and to assign risk reduction actions via the register to other staff "unbeknownst to them." These deficiencies were remedied through the introduction of formal procedures governing access and use of the register and the establishment of challenge procedures to provide quality assurance of risk assessments.

However, the L4 organisation tends to be hardwired and lacking in internal flexibility. This is reflected in that although a learning ethos exists, the manner in which L4 organisations learn is defined as single-loop (Argyris and Schön, 1978). This refers to learning where the emphasis is on improving techniques for executing processes, within the constraints of established process strategies. In other words, learning is directed towards making existing process strategies more effective. Single-loop learning tends to be present in organisations where goals, values, frameworks and strategies are taken for granted. This lack of capacity for deeper learning hampers their ability to make informed risk management decisions in rapidly changing and uncertain contexts. Additionally, L4 organisations are often unable to grasp the soft issues associated with human and organisational behaviour. This is a core weakness.

Level 5 – The optimised organisation. The key characteristics of the L5 organisation are its adaptability, flexibility and attention to human and organisational behaviour. The L5 mindset is one of deeper understanding, of an adaptive, learning organisation aiming to be best in class and always improving in the long term. Central to this is their capacity for both double (Argyris and Schön, 1978) and triple-loop learning. Double-loop learning involves questioning the norms, values and assumptions underlying the design of risk management processes, and is typically found in organisations where risk information is continually developed through a broad range of channels (e.g. experience, R+D, benchmarking, analysis, simulation, etc.). This information is openly shared, communicated and used to publicly test assumptions and beliefs. We define triple-loop learning as questioning and revising *broader* organisational structures and practices to optimise the capability of risk management processes (e.g. changing incentive structures to encourage knowledge sharing and collaboration between traditionally competing departments, etc.). The core enablers of triple-loop learning are an understanding of how human and organisational behaviour influence process capability, and organisational flexibility. L5 organisations are also actively engaged in the innovation, development and piloting of new ideas and technologies to optimise risk management throughout the organisation. From these efforts, best practices are identified and transferred throughout

the organisation. L5 processes are extremely efficient and there is a strong risk management culture, because of the long term investments made in developing processes and in training staff to participate in them.

Risk Management Processes

Our research identified 11 risk management processes (Figure 3). Strategic risk planning centres on developing the corporate framework for risk management. Hamilton *et al.* (2006) describe how these frameworks can introduce greater rigour, consistency and standardisation to the discipline. The researchers further note their potential for adaptation to suit "user needs." This final point is crucial, as our scoping interviews suggested that risk management frameworks were not simply shoehorned within utilities. Establishing risk acceptance criteria is perhaps the least understood aspect of risk management. Whilst our scoping interviews implied that internally developed criteria for evaluating the significance of risks were commonplace (risk ranking techniques), prior experience in similar sectors suggests that tolerability criteria are less prevalent and often externally imposed (e.g. ALARP criteria for dam safety). We address both of these aspects in the context of an internal process, as we propose that both are required to develop responses to risks in a consistent, objective and defensible manner. Risk analysis involves the identification and assessment of risk. We have previously reviewed (MacGillivray *et al.*, 2006a) its application in the sector at operational, programme and strategic levels. Here, our focus is not on the methodologies *per se*, but on their application. Supported by initiation criteria and formal procedures, using personnel with appropriate skills, experience, and resources, risk analysis techniques can provide utilities with benefits ranging from an improved understanding of treatment reliability to an explicit appreciation of project financial risks. Applied inappropriately, whether due to ill-defined procedures or deficient institutional capacities, risk analysis is not a subset of risk management but its panacea. Our inclusion of risk based decision making examines how organisations identify and evaluate solutions to manage individual risks. Clearly, risk analysis is of little use if the outputs are intended to placate regulators rather than inform decision making. Furthermore, one interviewee noted that an absence of criteria to evaluate decisions restricts objectivity (i.e. opinions dominate in decision making), and we further propose that it prevents the *ex ante* validation of decisions taken. Risk response is the implementation of risk based decisions. Although an argument may be forwarded that this lies outside the scope of our model as implementation processes are unlikely to be unique to risk based decisions (i.e. there will exist models for implementing capital or operational solutions, not models for implementing risk based decisions *per se*), it is included as decisions left unimplemented are hollow gestures. The model's treatment of these latter two processes is particularly relevant as risk management frameworks have historically focussed on the identification and assessment of risk, effectively

marginalising guidance on their practical management. Risk monitoring involves tracking the evolution of identified risks, and is included in recognition of their dynamic nature. Integration is the current focus of the risk management community. From the literature and our scoping interviews, two aspects were identified: embedding risk management within organisations; and enterprise risk management, where risks are managed with reference to the organisation as a whole, rather than in isolation or in functional silos. Illustrating the latter aspect, Lam (2003) contends that the traditional, fragmented approach, where companies manage risk in organisational "silos," is ineffective because risks are highly interdependent and cannot be segmented and managed by entirely independent units. As one scoping interviewee stated, "one of the challenges is...when [staff] are all using discrete [risk] tools which may have different terminologies, scoring systems and ways of presenting the outputs, my role is [to ensure] is a shared understanding and an ability to interpret the results of tools in a business-wide context." We introduce a third element of integration by abstraction from the systems engineering CMM (Software Engineering Institute, 2002a): integration of the risk management process interfaces (e.g. between risk analysis and risk based decision making).

Supply chain risk management addresses two components: the sourcing of components required to develop a product (e.g. chemicals) and the management of services provided by organisations throughout the supply chain. The latter element is of particular significance to the sector owing to the increasing utilisation of outsourcing. However, one pilot interviewee challenged the inclusion of product risk, arguing it is effectively managed through adhering to quality accredited suppliers. However, it was maintained as the authors' prior research in the oil and gas industry indicates that many organisational failures can be traced back to minor and apparently insignificant services *and* components sourced from suppliers. Change risk management is abstracted from the reliability engineering CMM (Strutt, 2003), and involves identifying and managing the risk implications of organisational (e.g. business process re-engineering) and technical change. We justify its inclusion as a range of factors (e.g. globalisation, regulatory and market restructuring, novel technologies) are serving to fundamentally alter the context in which water utilities operate. Education and training – the development and maintenance of the competencies required to manage risk – is included as our scoping interviews suggested that risk management simply does not fit well into traditional company skill sets. Risk knowledge management may be considered as the collection, storage and access of the data underpinning *and* accumulated from the broader risk management processes, i.e. the input and output data. The latter aspect is drawn from our scoping interviews, which discussed various risk communication and reporting protocols and the use of databases for storing risk assessment outputs. We include the former aspect on the premise that in the absence of pre-defined data requirements, risk

data collection is likely to be *ad hoc* and largely restricted to the needs of business as usual.

There was some discussion amongst the authors as to whether research and development in risk management merited inclusion as a process. However, the pilot interviewees were resistant to this, with one considering it "not directly relevant," another stating that the tools and techniques of the discipline are sufficiently developed, rendering it a secondary issue. Although their experience within the sector confers validity to their arguments, they may nonetheless be considered somewhat short-sighted. A compromise was found through considering research and development not as a distinct process but as a defining characteristic of mature risk analysis, risk monitoring and risk knowledge management.

Key Attributes

We have identified eight key attributes (Fig. 3) which characterise process maturity. Scope is included as we propose maturity to be correlated with the scope of implementation (i.e. a well defined process restricted to engineering does not constitute high *organisational* maturity). Here, integration refers to the existence of initiation criteria and procedures for process execution. Although its treatment as both process and attribute constitutes double-coverage, this was felt appropriate given its prominence in the practitioner and academic literature. Verification mechanisms address procedural compliance and quality assurance of process execution, whilst validation determines whether the process itself is correct. Together, these mechanisms create process control, and provide the primary feedback inputs for organisational learning. The inclusion of organisational learning builds on prior research conducted by the authors in offshore design and safety (Sharp *et al.*, 2002) and reliability engineering (Strutt, 2003), although the underlying principle is drawn from ideas from the *theory of action* and the concept of *single and double loop learning* (Argyris and Schön, 1978). It is best illustrated by paraphrasing Dalrymple (2006), who notes that experience rarely provides lessons directly, but instead requires interpretation through the filter of preconceived theories, values and prejudices. Where these are impregnable, facts are weak things. The capacity to use experience to question and revise these preconceived notions constitutes double loop learning.

We include stakeholder engagement in deference to its prominent representation within risk management frameworks. However, our scoping interviews revealed a disconnect between academic and industrial perceptions of the appropriate role of *external* stakeholders within risk management, with the latter generally more resistant to their involvement. Explanations to support this stance included the need to preserve commercial confidentiality, concerns over possible conflicting objectives between stakeholders and organisations, and fears that stakeholder

representatives may lack specialist knowledge and hence "slow down" risk management. One interviewee described that whilst they developed emergency response plans for water quality incidents in conjunction with the public health regulator, they were resistant to bringing concerns about drinking water safety to the public domain owing to fears of press sensationalism. Another noted that they "don't so much consult stakeholders as expose the [risk] governance process to them [e.g. regulators or shareholder representatives] – they form an opinion of [its] adequacy or otherwise." That said, there was agreement on the importance of engaging internal stakeholders, on the premise that through engaging other departments, functions, and business units, organisations may avoid the silo mentality which has historically pervaded risk management, thus creating synergies through shared knowledge and expertise, the co-ordination of related work, *etc.* For example, one interviewee described the value of using "networks of participants" to provide input to capital investment decisions. Here, stakeholders have the opportunity to critique proposed options (e.g. for constructing a new treatment plant, staff involved in the design, operation and maintenance, costing, etc.). The inclusion of competency as an attribute recognises that risk management processes will prove ineffective if their execution lies outside technical or managerial skill sets. Indeed, many of our interviewees discussed their desire to maintain in-house competencies to manage risk in preference to relying on consultants. Resourcing encompasses the use of monetary, human and technical (e.g. analysis methodologies) resources. As one interviewee noted, "funding, manpower, and specialists" are particular constraints to effective risk management in smaller utilities. Process documentation and reporting is the final attribute. Notably, Deloach (2000) reflects that there is often a lack of organisational consistency in reporting formats for risk management, which he perceives as a barrier to "enterprise wide" risk management. More practically, one interviewee argued that in what remains a conservative industry, if risk information is not properly documented and accessible then staff will use this "as an excuse to ignore risk management".

Consideration was afforded to the inclusion of culture as an attribute, given its extensive discussion in the literature and our scoping interviews. However, this was rejected for two reasons. Firstly, culture is a notoriously difficult concept to define, let alone measure. Secondly, overt attempts to change culture, which in this context may be thought of as the values and beliefs held by employees that guide their actions in managing risk, are not only Orwellian, but likely to be ineffectual. Ineffectual, as the authors consider that employee values and beliefs are not intrinsic properties, but rather are conditioned by the environment within which they manage risk (i.e. the risk management processes). Thus, culture change is a consequence of process improvement, not a prerequisite.

Internal Structure of Process Assessment Framework

At the framework's core are a series of guideline statements which describe how each process is conducted at each level of maturity with reference to the key attributes. In support of this are process descriptions which also outline the key practices required to satisfy the process goals. As the guideline statements are largely devolved from the principles contained in the overarching maturity hierarchy, we do not dwell on their detail. However, by way of illustration, Table 1 depicts the assessment framework at levels 3 and 4 for risk analysis.

Internal Structure of Process Improvement Framework

This framework outlines the operational steps that utilities may take in order to implement their process improvement priorities as identified from application of the assessment framework. It was developed after receiving feedback that the assessment framework was at a layer of abstraction which restricted its ability to inform the development of improvement plans. The steps are grouped by process and maturity level, and are categorised according to actions to: perform base and advanced practices that satisfy the process goals (i.e. do the process); establish and define the process (i.e. structure the process); and enable and evaluate the process (i.e. institutionalise the process). Table 2 depicts the process improvement framework relating to progression from L3 to L4 in risk analysis.

Illustrating the RM-CMM

We have discussed the overarching maturity hierarchy, and introduced the risk management processes and those attributes which define their maturity. Here, we build on these foundations by illustrating what the model practically means within various organisational functions. Consider first risk analysis. The distinction between the *ad hoc* and the repeatable level is that in the latter, the application of basic techniques by experienced staff creates a degree of stability. In process engineering, this may entail the execution of hazard and operability studies (HAZOP) to identify and assess the potential for designs to deviate from specifications, whilst at L1 this potential would be addressed implicitly if at all. At L3, initiation points for analyses are defined (e.g. at the concept design stage), and formalised procedures detail the tasks, activities, roles and responsibilities for execution, creating a basic infrastructure that maintains the process beyond the tenure of experienced staff (who are depended upon at L2). At L4, verification extends beyond ensuring procedural compliance (L3) to address quality assurance of analyses, for example through technical peer reviews. Questions addressed may include: did the analysts work their way through the HAZOP study systematically, or did they overlook important scenarios, components and process flows; were all stages and operating modes of the process considered

Table 1. L3 and L4 process maturity in risk analysis

Attribute	Attribute at level 3: Risk analysis	Attribute at level 4: Risk analysis
Scope	A defined, documented process is in place containing criteria, methods and guidelines for the identification, assessment and evaluation (with respect to acceptance criteria) of a broad range of risks across core business areas, guided by a risk register. The organisation is conversant with and goes beyond the regulatory requirements for risk analysis.	A controlled process is in place containing detailed criteria, methods and guidelines to manage the identification, assessment, evaluation (with respect to acceptance criteria), establishment of causality and linking (common cause and dependent) of risks at all levels of the company and across all functional boundaries of the business, guided by a company-specific risk register.
Integration	Procedures are in place to initiate risk analysis processes.	Risk analysis is initiated automatically as part of core business processes (e.g. periodic business risk assessments).
Verification and Validation	Basic mechanisms are in place to verify that risk analysis is performed as required, largely reliant on lagging indicators. The expertise for validation is generally lacking.	Verification and validation systems are in place to verify the efficiency of risk analysis activities and to validate their expediency (e.g. the organisation tracks that tools and techniques are being used correctly and that the correct tools and techniques are being used).
Feedback and Organisational Learning	The risk analysis tool suite is reviewed and modified on an event-driven basis.	Feedback is actively used to improve the execution of risk analysis (e.g. gaps identified and risk analysis tools and techniques improved in response).
Stakeholder Engagement	Risk analysis processes generally reside within the responsible unit, with limited cross-functional or external consultation.	Risk analysis processes generally reside within affected disciplines, and stakeholders work together to define and implement an integrated approach to risk analysis, capitalising on synergies and collective knowledge.
Competence	Detailed knowledge of risk analysis resides only within the responsible unit.	Most involved staff exhibit a good level of competence in the selection and application of risk analysis tools and techniques, and have access to support from internal or external expert risk practitioners.

Table 1. (*Continued*)

Attribute	Attribute at level 3: Risk analysis	Attribute at level 4: Risk analysis
Resources	Adequate resources are provided in support of risk analysis, with both qualitative and quantitative tools and techniques available.	Sufficient resources are provided in support of risk analysis, a portion of which is made available for R+D for risk assessment. A broad range of qualitative and quantitative tools and techniques are available and applied, including methodologies for aggregating and comparing risks.
Documentation and Reporting	Risk analysis outputs are compiled and disseminated in a format that supports decision making.	Risk analysis outputs are compiled and disseminated in a clear, concise and actionable format that supports real-time decision making, and their reporting is co-ordinated with other risk reporting mechanisms (e.g. risk status updates).

Table 2. Steps for progressing between levels 3 and 4 in risk analysis

Domain	Improvement step
Process enablement	• Identify and allocate sufficient resources in support of risk analysis, updating them as necessary to reflect changing needs. • Identify key internal and external stakeholders (e.g. representatives of different functions or divisions of the business) and define their potential contributions (e.g. synergies from collective knowledge and advice, etc.) and requirements (e.g. involvement in assessing cross business impacts). • Establish mechanisms to involve identified stakeholders (e.g. cross-functional working groups).
Process evaluation	• Establish formal mechanisms (e.g. periodic reviews, audits, status reports, milestones, etc.) to verify that risk analysis adheres to its formal description, policies, and procedures, and is being performed efficiently. • Designate 'ownership' of verification to a responsible individual(s). The individual(s) is responsible for ensuring verification is performed, reviewing the findings, and recommending corrective action where necessary. Stakeholders should be involved as appropriate (e.g. staff not conforming to established procedures). • Define and collect measures to support verification of adherence and efficiency (e.g. task and activity checklists, cost of analyses, timeliness of analyses, etc.). • Establish formal mechanisms (e.g. periodic reviews, external advice, status reports, etc.) to validate the process of risk analysis. Candidates for validation include the methods and procedures for risk analysis (e.g. the tools and techniques applied) and the risk analysis outputs (e.g. do the analysis outputs inform decision making). • Designate 'ownership' of validation to a responsible individual(s). The individual(s) is responsible for ensuring validation is performed, reviewing the findings, and recommending corrective action where necessary. Stakeholders should be involved as appropriate (e.g. where changes to the tool suite or procedures are recommended, the process 'owners' would be involved). • Define and collect measures to support validation of risk analysis (e.g. internal assessments by decision makers of the value of risk analysis outputs, formal validation of risk analysis methodologies, etc.). • Establish mechanisms to compare in-house risk analysis with industry practice, making changes where appropriate (e.g. benchmarking initiatives, strategic information exchange, etc.).

(e.g. startup, shutdown and transitioning to partial operation); and was adequate time spent on the analysis.

We now consider risk based decision making in the context of occupational health and safety. Here, the initiating point is the receipt of risk analysis outputs (e.g. job safety risk analyses, plant hazard evaluations, etc.). These outputs, together perhaps with a predefined hierarchy of health and safety risk controls (e.g. engineering; administrative; and protective personal equipment) serve as the framework for identifying solutions to manage individual risks. Once identified, these solutions may be evaluated with reference to criteria including: cost, feasibility and risk reduction achieved. In contrast, at L2 maturity, decisions to manage risks are taken in isolation of a clearly defined framework and perhaps even in the absence of risk analysis outputs, and are hence focus upon replicating historic good practice. Thus, health and safety is under pressure when circumstances change, whether through the introduction of new technical processes or modifications to work practices.

Finally, consider education and training in risk management. Here, a repeatable process may focus on workshops, where the concepts of risk management are introduced to staff on an as required basis, supported by on the job training. Further, there is an absence of clear criteria dictating when and to whom training should be delivered. An additional weakness is the inability to define the required competencies for effective risk management. Without these, on what basis are training programmes designed, how are the appropriate means of delivery selected (e.g. classroom training, workshop, on the job, etc.), and how can the efficacy of training be evaluated? These weaknesses are remedied at the defined state.

Model Application

The RM-CMM has a range of potential applications, including:

- Self-assessment or external evaluation (voluntary or audit) of risk management maturity at the corporate, business unit, functional and project level;
- Use by management and technical staff as a reference model for designing and implementing a risk management improvement initiative;
- Evaluation of potential suppliers'/contractors'/partners' risk management maturity prior to selection.

The model can be implemented either as a self-assessment procedure or by external audit using independent verification authorities. It is felt that the latter, in most cases, gives greater credence to the results of an assessment. However, internal assessments are often more useful when using the model as an improvement tool rather than as a measurement tool. The companion paper (MacGillivray *et al.*, 2006b) describes in detail the self-assessment methodology.

Conclusions

We have described a risk management capability maturity model, a vehicle for benchmarking and improving risk management within the water sector. We have addressed the model's theoretical and empirical foundations, overviewed its architecture, and illustrated its practical definition. Implementation of the model should assist utilities to more effectively employ their portfolio of risk analysis techniques for optimal, credible, defensible decision making. A companion paper describes its application to benchmark eight utilities within the international water sector.

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ARTICLE

Benchmarking Risk Management Within the International Water Utility Sector. Part II: A Survey of Eight Water Utilities

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ABSTRACT Risk management in the water utility sector is fast becoming explicit. Here, we describe application of a capability model to benchmark the risk management maturity of eight water utilities from the UK, Australia and the USA. Our analysis codifies risk management practice and offers practical guidance as to how utilities may more effectively employ their portfolio of risk analysis techniques for optimal, credible, and defensible decision making. For risk analysis, observed good practices include the use of initiation criteria for applying risk assessment techniques; the adoption of formalised procedures to guide their application; and auditing and peer reviews to ensure procedural compliance and provide quality assurance. Additionally, we have identified common weaknesses likely to be representative of the sector as a whole, in particular a need for improved risk knowledge management and education and training in the discipline.

KEY WORDS: Maturity model, risk analysis, risk management, water sector

Introduction

Risk Management in the Water Utility Sector

The water sector is witnessing a significant shift in the approach to managing risk to one that is increasingly explicit and broad in scope. Risk

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management strategies and techniques traditionally applied to occupational health and safety and public health protection are seeing application to corporate level decision making, asset management (Booth and Rogers, 2001; Lifton and Smeaton, 2003), watershed protection (IMPRESS Management, 2002; Lloyd and Abell, 2005; WHO, 2003) and network reliability (Stevens and Lloyd, 2004; Stahl and Elliott, 1999). This is in large part a response to the corporate governance, asset management, public health and environmental protection agendas, and represents a growing recognition that the provision of safe drinking water deserves to be treated as a "high reliability" societal service, subject to the sectoral and organisational rigours and controls inherent to the nuclear, offshore and aerospace industries (Pollard *et al.*, 2005). However, it is not the presence of risk management *per se* that governs the value derived, but its relative maturity of implementation within a utility. We have developed a capability maturity model for benchmarking and improving the *processes* that comprise risk management (MacGillivray *et al.*, 2006a). Here, we report its application to benchmark within the international water utility sector, the purpose of which was to identify good risk management practices and explore how they may be defined and controlled within organisational processes.

Risk Management Capability Maturity Model (RM-CMM)

Our companion paper (MacGillivray *et al.*, 2006a) describes the development of a RM-CMM for the water utility sector. The model is a prescriptive codification of water sector risk management practice, within a process-based maturity hierarchy. The model was developed by abstracting the principles of capability maturity modelling observed in other disciplines, including software and systems engineering (Paulk *et al.*, 1993; Software Engineering Institute, 2002a), workforce development and management (Software Engineering Institute, 2002b), offshore design safety (Sharp *et al.*, 2002), reliability engineering (Strutt, 2003), and construction (Sarshar *et al.*, 2000). This was achieved through literature reviews (MacGillivray *et al.*, 2006b; Pollard *et al.*, 2004; Hamilton *et al.*, 2006), structured interviews with water utility managers, and prior knowledge of maturity modelling in similar utility sectors. We identified eleven risk management processes (Figure 1). These processes are separated into five maturity levels, from learner to best practice. These maturity levels, characterised by reference to key attributes (Figure 1), reflect the extent to which each process is defined, institutionalised and controlled. It is important to understand what these levels represent in practice as this is crucial to assessing the maturity of an organisation. Whilst the precise definition of the maturity hierarchy is process specific, a generalised description is provided in Table 1.

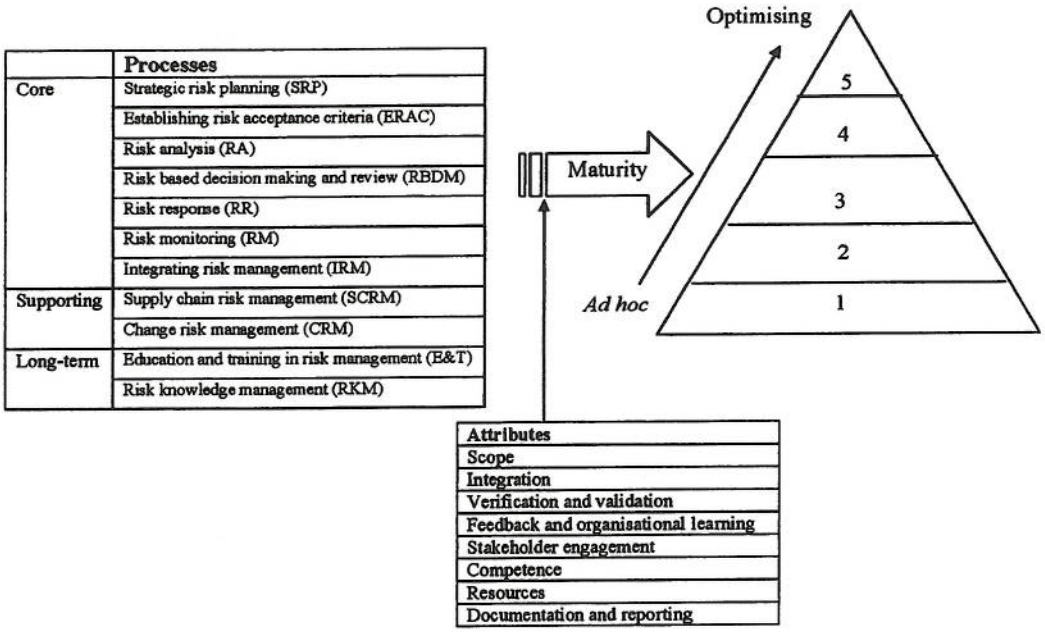

Figure 1. Overview of the RM-CMM (after Strutt *et al.*, 2005)

Methodology

Eight water utilities from the UK, Australia and the USA participated in this study. This was supplemented by the participation of an electricity utility regarded as best practice in risk management. However, an incomplete questionnaire return prevented its maturity assessment, and we restrict its discussion to key observations. The sample is intended to reflect good risk management practice, hence we do not suggest that our analysis is representative of the sector as a whole. The scope of analysis varies by utility, and includes organisational, business unit, and functional perspectives (Table 2). Sample selection drew upon existing industrial contacts and was further informed by prior reviews (MacGillivray *et al.*, 2006b; Pollard *et al.*, 2004; Hamilton *et al.*, 2006) of the academic, practitioner and grey literature.

A survey-type research design was adopted, whilst the research methods included questionnaire, interview and textual analysis. The questionnaire was comprised of a series of statements characterising the undertaking of each risk management process at each maturity level. These were responded to on a four point scale (fully agree; generally agree; partially agree; and disagree), with space provided for supporting comments. Process maturity was determined according to the highest "degree of fit"; a measure of the average level of agreement with the guideline statements at each maturity level for each process. The interview and textual analysis was concerned with identifying the specific risk management practices undertaken within

Table 1. Generalised representation of the process maturity hierarchy

Maturity level	Process Characteristics
Level 5 – Optimising	The process is a continual, explicit component of organisational activities, forming part of the 'culture'. Feedback is actively used to improve both the philosophy and execution of the process, and the adaptation of organisational structures and practices to optimise its ability to undertake the process (double loop learning). Management continually establishes measurable targets for process improvement, with systems in place to verify their achievement and to validate the means through which they are pursued. Active innovation, development and piloting of new ideas and technologies to optimise the process.
Level 4 – Controlled	Verification mechanisms extend to provide quality assurance, and are supplemented by the capacity for process validation. Feedback is actively used to improve process execution, albeit within the constraints of existing process strategies (single loop learning). Broadly spread competencies enable the process to reside within affected disciplines, although stakeholders work together to achieve an integrated approach, capitalising on synergies and collective knowledge. Sufficient resources are available, with limited internal R&D.
Level 3 – Defined	Process scope exceeds regulatory requirements, extending across core business areas. Documentation details procedures, criteria, methods and guidelines for process undertaking, whilst basic audit mechanisms verify compliance. Feedback limitations restrict process evolution to learning from 'events' (open loop learning). Processes reside within the responsible unit, with limited cross-functional or external consultation. Adequate resources in place.
Level 2 – Repeatable	Basic process in place, focused on meeting regulatory requirements and addressing 'mission-critical' risks. Initiated reactively, often in response to an event or situation. Limited capacity to evolve based on experience.
Level 1 – Initial	No formal process; *ad-hoc* approach. Reliance on individual heroics. Limited awareness of regulatory requirements or relevant standards.

the sample and correlating these with our model (e.g. how, practically, is risk analysis defined and controlled as a process). Semi-structured interviews were undertaken with each assessor following receipt of the questionnaire. The interview methodology was developed, tested and refined within a separate industrial case study. Interviews were conducted by phone, recorded, and subsequently converted into transcripts. These transcripts were returned to each interviewee, providing them an opportunity to comment. Finally, a range of pertinent supporting company documentation

Table 2. Sample characteristics

Descriptor	Respondent*	Unit of study	Scope of analysis
Utility A	Corporate risk manager	Corporate	Water supply, sewerage services and electricity distribution
Utility B	Water quality manager	Corporate	Water supply and sewerage services
Utility C	Water quality manager	Corporate	Water supply and sewerage services
Utility D	Corporate risk manager	Corporate	Water supply
Utility E	Asset manager	Corporate	Water supply and sewerage services
Utility F	Corporate risk manager	Corporate	Water supply and sewerage services
Utility G	Asset manager	Business unit	Water supply
Utility H	Water quality manager	Function	Drinking water quality management
Utility I**	Corporate risk manager	Corporate	Electricity transmission and distribution

*Respondent denotes the interviewee; in most cases, the questionnaire was undertaken in consultation with other staff.**Data limitations prevented the maturity evaluation of Utility I.

was requested from each participant. Those made available included risk management policies and frameworks, risk analysis procedures and techniques, and water safety plans.

Given the qualitative nature of the research, mechanisms to validate our findings were adopted. This was achieved through sample anonymity and triangulation. Anonymity removed the potential for conflicts with the fundamental goal of adding to the body of knowledge (as opposed, e.g., to the participants' desire that the findings reflected positively upon their organisation). Triangulation sought to balance the lead author's principal analysis of the questionnaires, texts and interview transcripts with a blind scoping analysis conducted by a co-author. Additionally, each respondent was offered the opportunity to comment on all statements within the paper referring specifically to their utility. Diverging perspectives were resolved through consensus.

Results and Discussion

Figures 2 and 3 illustrate the sample process maturity profiles. Detailed discussion of these levels may be found in our companion paper. Here, we do not dwell on the maturity profiles as our scoring methodology is arbitrarily rather than scientifically derived and the sample is not intended to reflect the sector as a whole. We restrict ourselves to the following observations. The sample profiles are relatively mature for the core and supporting processes of risk management, in contrast to the long-term processes of education and training in risk management and risk knowledge management. Two explanations are offered. Firstly, the attention and resources dedicated to the design and execution of processes is correlated

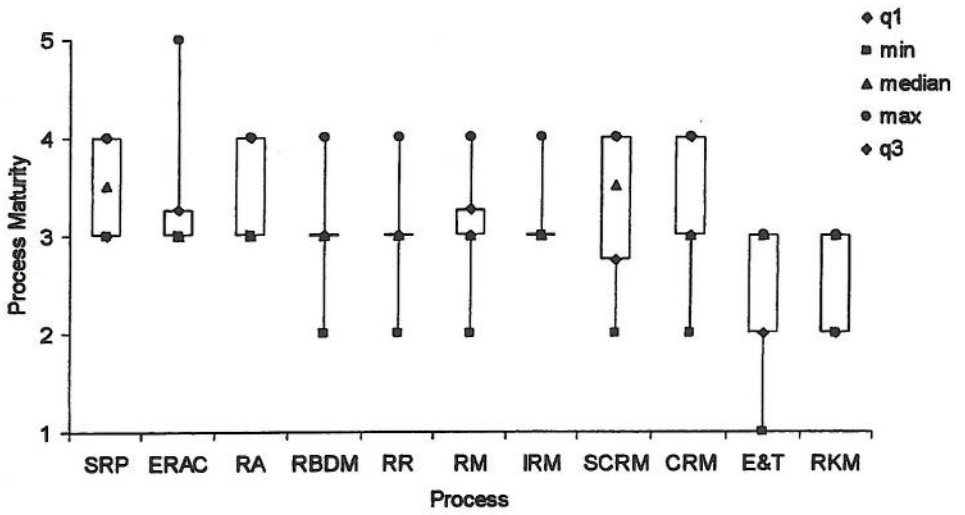

Figure 2. Boxplot of the sample risk management process maturity by self-assessment

with their perceived criticality. Secondly, the long-term processes receive limited treatment within the academic and practitioner literature, leaving utilities bereft of guidance. The maturity of the supporting processes – supply chain risk management and change risk management – is particularly high. The strength in the former is likely a function of the increasing level of outsourcing within the sector. Similarly, we propose that mature change risk management is driven by evolving regulatory and governance structures and the commonality of internal restructuring.

We now discuss the observed risk management practices on a process-specific basis.

Strategic Risk Planning

Here, we observed an even spread of our sample between L3 and L4. Strategic risk planning is primarily concerned with the development of a risk management framework. In essence, these frameworks were observed to set out the rationale, procedures and responsibilities for the discipline. At L3 and L4, we observed that their development may be characterised as the evaluation and adaptation of external risk management standards. For example, one manager described how the forbearer of their corporate-wide risk management framework was an adaptation of an occupational health and safety management system, which has evolved drawing upon the AS/NZS: 4360 (Council of Standards of Australia, 1999) standard and broader experiences of the sector. Another described how they were "trying to use the rationale, the basis of the COSO (COSO, 2004) standard, but the methodology is one that's been developed by us." We may consider the vetting of these frameworks (e.g. by the Board, internal audit, etc.) as a form

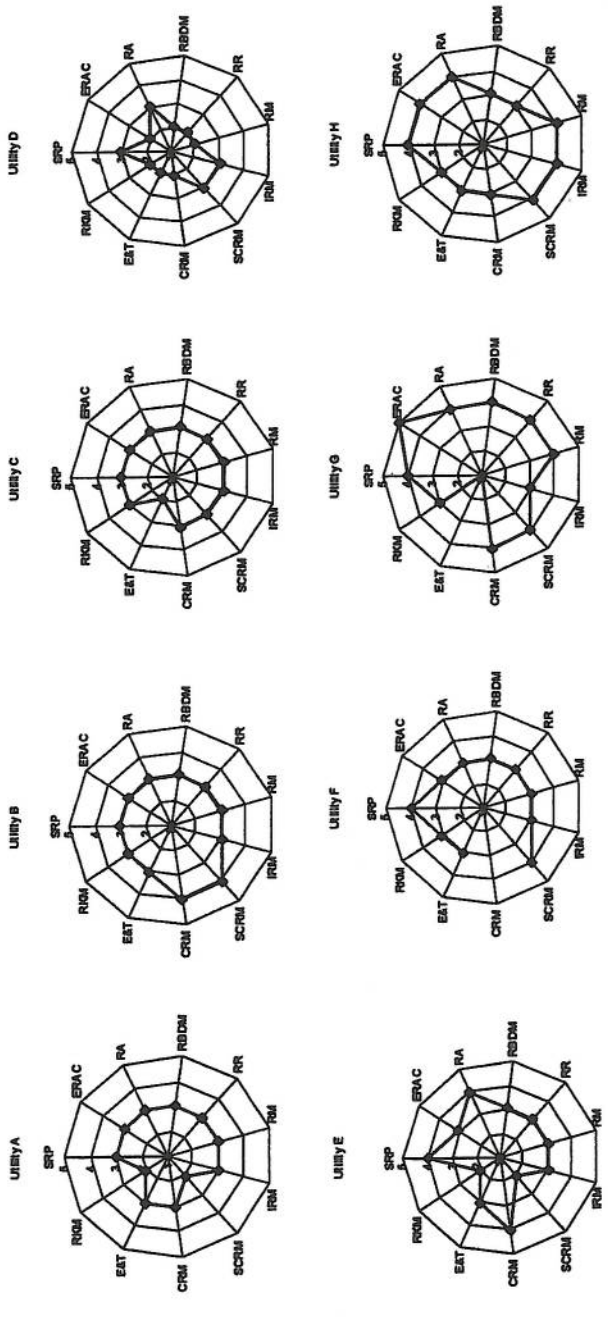

Figure 3. Spider diagrams of organisational maturity by self-assessment

*Red indicates uncertainty arising from incomplete questionnaire data.

of *output* validation, however, it was unclear whether the *process* by which they are developed, or more precisely adapted, is subject to oversight.

Establishing Risk Acceptance Criteria

This process involves the development of criteria for evaluating the tolerability and significance of risk. Here, we observed five L3 organisations, and one each at L2, L4 and L5. At L2, risk acceptability is largely set with reference to regulations and standards. Expanding on this, the L2 manager stated that "the corporate risk appetite is primarily perceptual and based upon broad guidelines established by upper management, the Board, external auditors, stakeholders and bond-holders."

An observed L3 practice was the allocation of risk tolerability criteria in operational and financial areas. These included design standards informed by hazard and operability (HAZOP) analyses; operating and maintenance practices informed by reliability modelling; as low as reasonably practicable (ALARP) criteria for evaluating dam safety risk; the use of risk-based criteria to determine raw water treatment requirements; and risk-adjusted discount rates applied within financial analysis models to balance investment returns with uncertainty. However, it appeared that the processes through which these criteria are established reside within organisational functions (e.g. engineering, finance) and thus lie outside the remit of the corporate risk manager. As one manager noted, tolerability criteria may exist "within discrete areas of the business...but they exist as islands with no...overlaying risk management policy or strategy."

Further, we observed the development of risk ranking techniques which outline the criteria by which organisations assess the significance of risk both at the corporate level and, in some cases, specific to organisational functions such as asset management. Tolerability criteria were often embedded within these techniques (e.g. low risk: manage by routine procedures; high risk: management response required). These techniques were typically derived from risk management standards. Observed adaptations included the alignment of consequence criteria with corporate objectives (e.g. environmental, financial, etc.); the tailoring of impact descriptors; and the assignment of costs to impact categories.

Risk Analysis

Here, five utilities were evaluated at L3, three at L4. Risk analysis involves the identification and assessment of risk. Our sample indicates two distinct categories of risk analysis: a generic strategic technique; and a series of discrete methods applied in operational areas. The former may be characterised as the application of qualitative risk ranking techniques to analyse the risks inherent to managing a water utility as a business. The latter included a raft of industry standard and best practice tools, both qualitative and quantitative. Those observed included HAZOP studies;

hazard analysis and critical control points (HACCP) evaluations; failure mode, effect and criticality analyses (FMECA); and Monte Carlo simulation of financial variables.

A prerequisite for process definition (L3) is that the application of these techniques is guided by formalised procedures – a practice intended to ensure the consistency and rigour of analysis. Regarding strategic risk analysis, best practice may be described with reference to the electricity utility. Here, a range of risk identification techniques are available, and their selection depends upon "the depth and breadth of activities under review and the extent to which the business context is new." Listed techniques include strengths, weaknesses, opportunities and threats (SWOT) analysis; scenario analysis; value chain analysis; benchmarking; control self assessments; audit reports; etc. Risk categories are used as a further prompt for identification (strategic, regulatory, financial and operational). It was common practice across our sample to assess strategic risks via a combination of expert judgement and, where available, historic data to determine a range of parameters (e.g. probability, consequence, development time, triggers, control design and usage, etc.). The electricity utility's use of the Delphi technique (Dalkey and Helmer, 1963) in risk assessment is notable. Here, facilitated discussions and iterative anonymous voting were applied to generate expert consensus. The method's explicit recognition of human judgment as a legitimate input is particularly valuable where data is limited. Furthermore, characterised as it is by group participation, anonymity and feedback loops, it minimises bias and dogmatism (i.e. reduces the reluctance of staff to abandon previously stated views). A caveat: it appears that in many cases strategic risk analysis tends to be as one manager stated "shepherded by the corporate risk team" rather than guided in a mechanistic manner. This contrasts with the more procedural approach adopted operationally (e.g. in occupational health and safety), and perhaps reflects the perceived value of creativity in strategic risk analysis.

A further observed L3 characteristic was the use of criteria for the selection *and* application of risk analysis techniques. The strategic risk ranking tools were typically initiated within business and strategic planning as well as on an *ad hoc* basis as new risks arise, whilst various nodes (e.g. the concept design stage for application of HAZOP) served as initiating criteria for the various operational methods. Observed selection criteria included the use of financial thresholds to delineate the application of Monte Carlo simulation from simple checklists to evaluate financial risk within programme management. Basic verification mechanisms are a further L3 characteristic. This is reflected in one utility's requirement for supervisors to review risk assessments of minor construction and maintenance works prior to "sign off." Similarly, one manager highlighted the role of their "systems certification process" in ensuring procedural compliance. Here, a taskforce "conducts certification audits, checking the business practices of each system, making sure that they're in concert with our way of doing business; one element of which is that they're doing risk assessments and that they're

doing it properly." Another interviewee described a tri-partite approach to auditing. Here, in addition to external auditing by their parent company, "internal audit come in every year, to check that we're process compliant by drilling down from risk reporting at the highest level, right down through identification, assessment...also as a [risk management] team, we do our own local audits to make sure that people are up to speed...and [we] tackle non compliance." The importance of such checks and balances was highlighted by one participant's contrasting of the inconsistencies surrounding their locally managed sanitary surveys with the consistency of their centrally managed barrier surveys. Furthermore, several managers related concerns that analyst bias may lead to distortions of risk analysis outputs. Whilst underscoring was the most commonly noted threat, one manager revealed that their adoption of a risk-based capital investment programme has led to a significant likelihood of asset managers "over-egging" their analyses to attract greater funding for their regions. To address this, verification should extend to audit the quality of analysis undertaken.

This enhanced role for verification was observed at L4, as reflected in one utility's "quality assurance consistency checks" within asset management. Here, risk analysis outputs and their underpinning assumptions were systematically reviewed and challenged by a multi-disciplinary team of experts. The interviewee noted that the value of this procedure extends beyond quality assurance of analysis outputs to highlighting common errors in applying the methodology itself: "we've had some problems with people using [the methodology], some were misinterpreting it, we spotted this from the data and [the consistency checks]. Some asset managers score the probability of an asset failing, some score the probability of an asset failing and [leading to a defined] impact; the latter is what we want." We now highlight the subtle distinction between verification, which seeks to evaluate whether the process has been followed correctly, and validation, which is concerned with whether the process itself is correct (e.g. validating the risk analysis techniques). Both of these aspects were enshrined in one utility's application of a "common sense screen" at the end of their water quality risk analysis process. Here, if analysis outputs appeared at odds with experienced operational knowledge, the reason behind the "false" score was investigated, and the process and score adapted where appropriate.

Although engagement of a broad range of stakeholders is characteristic of L4 maturity, broad internal stakeholder engagement was characteristic of each utility's approach to strategic risk analysis, which was typically conducted within cross-functional forums. However, the engagement of external stakeholders appears to occur on a far more selective basis. One L3 manager commented that there were "no formal procedures for external risk reporting" and that, beyond the outcomes of security-related risk assessments, the "regulator has shown little interest". Two of the L4 interviewees expressed a greater recognition of the need to engage external actors in risk analysis, both where risks have high external stakeholder implications (e.g. political or environmental) and where expert guidance is required. In contrast,

one manager explained their reticence to engage external bodies by noting that "risk assessments are a risk for ourselves, if we identify something as a business risk, particularly if its environmental, hazardous, or regulatory, that's out there, if you don't address that, it's going to come back at you."

Finally, the sufficiency of resourcing within each L4 company was evidenced by their active research and development in risk analysis. One was researching the integration of predictive GIS tools with continuous and event-based monitoring data for application in catchment risk analysis. In contrast, one L3 interviewee highlighted resource constraints as a limitation: "one issue is the complexity of our analyses, we have ten water systems and thirteen catchments [which are] diverse in [size and] nature...for a small organisation that serves only about 15,000 customers, resourcing these sorts of studies is not easy."

Risk Based Decision Making and Review

Risk based decision making involves the identification and evaluation of solutions to manage individual risks. Here, six of our sample were evaluated at L3 maturity, with one each at L2 and L4. At L3 maturity, we observed procedures to ensure that risk analysis outputs explicitly inform decision making. These ranged from the integration of the risk analysis and decision making processes within strategic risk management workshops, to the risk analysts' role of briefing non-technical decision makers in operational areas. We further observed decision making frameworks. This is reflected in one utility's adoption of a predefined hierarchy of occupational health and safety hazard control measures: elimination (does the work have to be done); substitution (can it be done in a less hazardous way); engineering controls (isolation, containment); administration (procedures, trained staff); personal protective equipment (respirators, helmets); and warning signs. This structures the identification of solutions. In a more generic context, the electricity utility categorizes risks by the extent to which their exposure can be managed: controllable (e.g. financial or health and safety risks) and influenceable (e.g. competition, regulation). Seven "risk treatment" options are then applied to structure the identification of solutions: retain; retain but change mitigation; increase (risk exposure is increased, for example, where the current controls are not cost-effective); avoid (e.g. withdrawal from a business area); reduce likelihood; reduce consequences (e.g. through emergency preparedness); and transfer (e.g. through insurance or out-sourcing). However, inherent in many risk assessment methodologies is a decision making structure. Consider one utility's catchment to tap methodology. Here, the assessment links hazard type (e.g. physical – turbidity and colour) to their causes (erosion) and to events (landslip, storm). Clearly, by identifying the underlying mechanisms through which hazards are realised, rather than simply evaluating their probabilities and consequences of occurrence, the identification of preventative measures (e.g. stabilise gullies, isolate draw-off) is facilitated.

A further L3 characteristic is the establishment of objectives for risk based decisions. However as one manager stated "with the exception of large projects, the majority of the goal-orientation will focus on cost and physical output", rather than risk reduction. In contrast, one L3 utility adopted a goal setting regime for risk reduction at both the asset and strategic level. In the former, asset planners attached cost estimates *and* risk reduction targets to a range of potential capital, operating or maintenance strategies to address risks across their sites, which were then prioritised on the basis of risk reduction per pound spent.

Quality assurance of decisions, whilst characteristic of L4, was observed to an extent within each utility, ranging from the peer review format of cross-functional strategic risk management workshops to more formalised challenge processes. For example, one manager noted that a central role of their "executive leadership team" – comprised of the president, vice presidents and union leader – and "business owners' council" – comprised of business unit representatives – was to provide input to and at times critique risk management decisions taken at the corporate and business unit levels respectively.

Risk Response

Risk response is the implementation of risk based decisions. Here, six of our sample were evaluated at L3 maturity, with one each at L2 and L4. An L3 characteristic is the systematic allocation of responsibility, tasks, timescales, guidelines and resources for the implementation of risk based decisions; this was observed, e.g. within the development of "action plans." Within the electricity utility, these include a description of the: risks to be mitigated; business objectives threatened; required actions; risk champion; target date of completion; residual risk rating; cost estimate; ease of implementation; and what could go wrong. Returning to a more operational context, we observed emergency management plans detailing the procedures required to minimise the impacts of, for example, plant failure (check component connections, check for blockages, review raw water for turbidity, taste, odour and algae, etc.). In practice, we observed that implementation processes were often not unique to risk based decisions, i.e. there existed models for implementing capital or operational solutions, not models for implementing risk based decisions *per se*. Indeed, the electricity utility manager emphasised that his role as a risk manager was not to act as a "central policeman," and that implementation was a matter for individual business units and functions.

Risk Monitoring

The sample contains one L2, five L3, and two L4 companies in risk monitoring. The L2 interviewee characterised risk monitoring as "the

weaker part of our scheme; we don't do much beyond the quarterly reviews, the exception being some particularly critical risks."

Our sample indicates that risk monitoring may be partitioned into two tiers: the first involving the re-evaluation of risk analyses outputs, the second relating to the tracking of discrete parameters which describe the evolution of risks. The former was observed to occur by procedure at L3 and L4, through both cyclical requirements and event-driven initiators (e.g. changes to technical processes). The importance of such procedures was emphasised by one manager's revelation that prior to their introduction of a central asset risk register with clear requirements for cyclical reviews of analysis outputs, risk analyses were not regularly updated, instead being performed for a specific purpose at decision making points. Good practice was further illustrated in one utility's adoption of reporting protocols for communicating the results of strategic risk re-evaluations; here: co-ordinators reported on the evolution of significant exposures at monthly management meetings; significantly increased risks were escalated to unit directors within thirty six hours; and the risk management function reported to the Board on a monthly basis. We further observed verification of procedural compliance, most commonly achieved through risk register oversight.

One might argue that this first tier of risk monitoring is indistinct as a process from risk analysis, as the revision of previous risk assessments is an element of the feedback loop within the latter process. The distinct second tier was observed to be most prevalent within drinking water quality management and network planning and operation. In the former context, risk monitoring includes both the standard regulatory-driven tracking of primarily lagging water quality parameters (i.e. verification of water quality, e.g. coliform testing at customer taps), and, where the water safety plan approach is adopted, extends to include leading indicators devised in accordance with the HACCP (Havelaar, 1994; Deere *et al.*, 2001) model (i.e. operational parameters describing the effectiveness of control measures designed to mitigate water quality hazards, e.g. ph residuals at and post disinfection). It should be noted that HACCP has the inherent characteristics of L4 maturity. To illustrate, within one adopter we observed: weekly reviews supported by in-depth periodic audits to ensure compliance with the established monitoring protocol (i.e. verification: ranging from requirements to review online turbidity data to the calibration of analysis and measurement equipment); formal peer reviews of established operational parameters and their target and action limits (i.e. validation: exploring, for example, the rationale behind setting 2000 cells/mL of cyanobacteria as an action limit for controlling taste and odour related hazards); and annual reviews of the protocol taking account of modifications to processes, industry standards, regulatory guidelines and operating licenses (i.e. feedback mechanisms).

Integrating Risk Management

Here, seven of our sample were evaluated at L3, with one at L4 maturity. Our discussion is restricted to one facet of integration: institutionalisation.

Our model views institutionalisation as dependant on risk management "enablers" and "evaluators." Enablers include the provision of guidelines, procedures, systems, tools and training for the discipline (L3), whilst evaluators include verification, validation and feedback mechanisms (L4). We have explored these within the context of each individual process, here, we seek to evaluate whether this is a sufficient explanation.

Indeed, the influence of culture on institutionalisation, an aspect not explicitly represented within our model, was highlighted by several participants. One noted how staff perceptions ranged from "those going through the motions, to those more cognisant of how [risk management] supports the broader organisational processes." The participant further noted the importance of engaging and empowering operational staff in creating a risk management culture. Here, this took the form of expert practitioners supporting front-line staff to fulfil their risk management obligations (e.g. jointly conducted risk assessments) and actively seeking and considering their feedback in revising existing processes (e.g. adapting risk evaluation criteria to reflect operational expertise). We further observed that a prerequisite for cultural change is commitment from executive and senior management, which is often dependent on external events. One manager noted that "[the risk management team] have finally got the attention of our organisation; early on we couldn't get much dignity...then a series of events occurred in the [United States] which made risk assessment more important, which resulted notably in the Sarbanes Oxley legislation, we have several members of our board who are very much attuned to that...once we got top level buy in, the rest followed." Similarly, one participant reflected that "Enron, Barings...showed that companies can go under if their controls fail, [whilst] Railtrack showed that companies could lose their [license to operate]. [Another] wake up call was the idea of corporate manslaughter; [this] made us focus our efforts on...assets with low likelihood of failure but high consequence, for example critical reservoirs."

Supply Chain Risk Management

This process addresses both the way utilities obtain the raw components required to develop products and the management of services provided by organisations throughout the supply chain (e.g. outsourcing agreements). Here, we observed two L2, two L3, and four L4 utilities. One L2 manager revealed that supply chain risk management was primarily "left to procurement," with formalised approaches to risk management tending to apply only to larger, discrete projects. Similarly, one L3 interviewee stated that risk management was only explicitly involved in supply chain management in relation to products and services critical to their continued operation, further noting that "although [we] evaluate, qualify and support [our] critical vendors and suppliers, this is not within the context of a formal risk based process." In contrast, within one L3 utility risk management was explicitly interwoven within procurement policies and procedures.

Inspection of their contracting and tendering policy revealed that in contrast to the traditional approach of selecting lowest cost suppliers once basic standards are met, a broad range of pre-qualification standards are applied as appropriate, including those that address risk explicitly (e.g. occupational health and safety, commercial risk, delivery risk) and implicitly (e.g. quality management accreditation). Furthermore, prior to binding acceptance, the probability of failure of the chosen tender to satisfactorily adhere to the contract, and the potential effects of such a failure, were formally assessed and reported.

We obtained limited data on the practices of those L4 utilities, however, we observed that one required all contractors to utilise a formal risk management framework, whilst another adopted criteria to ensure that the "risk attitude" of capital partners aligned with their own.

Change Risk Management

This process is concerned with identifying and managing the risk implications of organisational (e.g. re-engineering) and technical change. Here, we evaluated one utility at L2, and three each at L3 and L4. We observed the expected lack of process definition within the L2 utility, whose respondent noted that where changes to e.g. operating or asset standards are considered, "risk would be part of the decision making process, although the level of formality would vary". Regarding organisational change, the interviewee stated that "whilst the utility has a team dedicated to providing support and education for the implementation of business process improvements, it does not focus on the risk implications of change." At L3 and L4, we observed the undertaking of risk analysis to evaluate the expediency of planned technical changes; the use of SWOT analysis to evaluate the "business environment" for changes that may constrain utility operations and management; application of environmental impact assessments for projects that modify existing processes or introduce new processes, activities or equipment; and regular analyses and reviews of risks and interdependencies within organisational change programmes.

Education and Training in Risk Management

Here, we observed one L1 organisation, two at L2, and five at L3. An *ad hoc* approach was observed within the L1 utility, with no formal process in place to develop or maintain risk management skills and knowledge, and limited cognisance of the required competencies for effective undertaking of the discipline. As the L1 manager noted "we recognise we have an issue here...we took over one hundred people through risk training in 2000/01, [but we've] done nothing since...the next logical step was to cascade it across business...which we haven't." Emphasising the importance of this deficiency, he noted "we recognise some people have no knowledge of the [risk management] process, yet are expected to prioritise capital investment

on the back of it; [but the] only hint of training is when they get shot down at [the consistency checks]."

The defining characteristic of the L2 organisations was their limited process scope, with limited internal training in risk management (e.g. addressing occupational health and safety), supported by attendance of externally delivered courses for key managerial and operating staff (e.g. risk management conferences, HACCP training for operating staff). For example, one L2 utility's site induction procedures sought to ensure that staff understood site-specific hazards and the precautions required to protect their safety and the quality of service. These covered basic issues such as the isolation and lock out procedures required for machinery during maintenance works, site emergency procedures, confined space entry procedures, and the location of the first aid kit. This was supplemented by video-based training on: risk management planning for drinking water supplies; job safety analysis; and safety leadership. Indeed, this emphasis on "on the job" training was a common theme at L2, the logic perhaps being that staff learn best through real life, hands on examples, rather than lectures and presentations. As the electricity utility interviewee noted, "most of the education and indoctrination was [achieved] by running [risk management] workshops. At one time my staff were running forty to fifty workshops a year, so all the executives and managers were constantly exposed to this whole methodology of identifying, prioritising and mitigating risk; [towards the end], they'd come and borrow our anonymous voting equipment and run their own workshops."

Valuable insights regarding the formalisation of education and training may be gleaned from one L3 utility. Here, two dedicated risk management training packages were observed: an introductory course provided to key strategic members of the business, and a more comprehensive programme delivered to "team leaders". Of greatest interest is the latter, which was structured around a formal definition of the competencies required for effective risk management, ranging from an understanding of corporate governance to a grasp of the technical aspects of the risk assessment techniques adopted. Both packages were initiated by procedure, with oversight from local management and the risk management team to verify compliance. Furthermore, effective delivery of the process was verified through cyclical evaluations of the ability of staff to act on the training received. These evaluations partly underpinned succession routes, providing a strong catalyst for learning. Supplementing these programmes, *ad hoc* training workshops were provided by risk management staff on request.

In a more operational context, one L3 manager described how in addition to externally delivered HACCP training for key staff, internal training on the fundamentals of drinking water quality management focussed specifically on embedding the risk-based approach inherent in their operating and management principles. Furthermore, their post-incident analyses included an explicit evaluation of the *a priori* risk management strategy, which the interviewee emphasised breeds familiarity with the

methodologies and processes of risk management and, by focussing on real examples (or plausible scenarios), highlighted the practical implications of the discipline to front-line staff.

Risk Knowledge Management

Here, we observed three utilities at L2, and five at L3. Risk knowledge management may be considered as the collection, storage and access of the data underpinning and accumulated from the broader risk management processes, i.e. the input and output data. One L2 manager stated that input data requirements for risk management were not well defined, and noted that they "do not maintain detailed risk information beyond that which is accumulated during risk assessments or that inherent in the normal conduct of business." The interviewee assigned this to both a "resource driven inadequacy" and inadvertent constraints imposed by legislation: "in the public sector...we're subject to open records request...you don't want [your risk analyses appearing] in the newspaper the next day, how we store those documents and record our decisions is a strategy in itself, we try to limit circulation, which may be counter-productive to traditional risk management."

At L3, we observed procedures governing the use of software packages which serve as tools for the collection, storage and access of output data collected throughout the life-cycle of risk management. However, predefined strategies of input data collection were restricted to select operational risks, particularly those whose management was underpinned by formal analytical methodologies (e.g. reliability modelling), or, as one manager noted, subject to regulatory drivers (e.g. asset management, drinking water quality management). The electricity utility interviewee suggested that this is dictated by pragmatism, as "raw data requirements are fluid and evolve with the perceptions of management." However, we contend that in the absence of predefined requirements, risk data collection is likely to be *ad hoc*, and largely restricted to the requirements of "business as usual." Indeed, one manager described a reliance on "expert judgement; without senior experienced people, I'm not sure we have the data to underpin [risk management]". A further observed L3 characteristic was the lack of expertise for validation (i.e. to ensure that the correct data is being collected); to the extent that it is applied, it is informal and *ex-post*.

Conclusions

We have described the application of a capability maturity model to benchmark risk management within eight water utilities. The findings provide utility managers, technical staff, chief finance officers and regulatory officials with a systematic understanding of how to implement and improve risk management. This is timely work for a sector grappling to adapt to evolving regulatory and governance arrangements. Furthermore,

the research provides a basis for evolving the model from a prescriptive to a descriptive state, which will ultimately render it fit for industrial ownership.

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Communicating Understanding of

Contaminated Land Risks

SEPA

Sniffer
SCOTLAND & NORTHERN IRELAND FORUM FOR ENVIRONMENTAL RESEARCH

ENVIRONMENT AGENCY

ENVIRONMENT AND HERITAGE SERVICE

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Introduction

In common with many other countries, the UK has a legacy of land contamination arising from industrial development and related operational practices. Therefore, the UK is putting into place policies and legislation both to prevent future contamination from occurring and to ensure that appropriate action is taken to deal with existing contamination where it poses unacceptable risks to human health or to the environment.

Much land contamination has been present for long periods of time, for instance since the eighteenth century and longer. Not all of this contamination poses problems and some may only be of concern if the land is used for a particular purpose. Therefore, it may only be necessary to deal with some contamination when it is decided to use the land for a new purpose, for example to develop a former industrial site for housing.

Contamination can take a variety of forms, including chemical, biological and radioactive. It may impact upon health or the environment, ranging from toxic effects on humans or livestock, inhibition of plant growth, or explosive properties which may damage buildings. The distribution of contaminants in the UK is such that in many cases, it will not be isolated from the community. It may arise close to homes and schools, places of work or recreation, water supplies or wildlife habitats, roads and footpaths. Reflecting the fact that contamination may occur in a variety of places, it should be anticipated that a variety of people and organisations might have an interest in a contaminated site, whether contamination has been proven or is suspected. Contamination may affect peoples' perception of their local environment and it may affect use of land. Contamination may also have an impact on peoples' personal finances and their livelihood. However, different people and organisations will have different views, priorities and expectations about the situation, and in some cases these may conflict.

The environment agencies may be involved in ensuring that any unacceptable risks from contamination are appropriately managed. All regulatory staff will need to carefully assess how they anticipate and respond to the concerns, anxieties and expectations in a community that may arise in response to land contamination. Many things in life pose risks and it is not possible or practical to eliminate each and every risk. The same is true for contamination – it is not practical or financially viable to remove all risks from contamination and in some cases it is not technically possible to do so. However, the rationale for,

approach to and outcomes of, decisions about how much risk is posed; whether it is acceptable and if not; how best to control or manage it, are not easy to explain to third parties. In addition, different types and sources of contamination can provoke all sorts of anxieties that may sometimes seem at odds with the scientific or expert assessment.

Nevertheless, research and experience demonstrate that public perception and concerns are very real to those affected and do influence decisions about environmental management. Consequently, such concerns must be addressed seriously and with sensitivity as an integral part of any risk management programme.

Purpose of the Handbook

This handbook has been produced to provide a basic step-by-step guide to risk communication and relationship building with stakeholders in order to help anticipate and respond to concerns about contaminated land. It is the purpose of this handbook to encourage regulatory staff to incorporate best practice risk communication techniques into their work on contaminated sites. Officers of the regulatory agencies who may be involved in communicating risk from land contamination situations should read this handbook before embarking on communicating risk with stakeholders. This includes public relations professionals who have expertise in providing corporate communications. Public relations staff within the agencies should be included in the planning and implementation of a risk communication strategy. The handbook is applicable to all land contamination risk communication situations and whilst communication strategies should be site-specific, this handbook aims to prompt some of the questions and encourage the free-thinking required to assist the regulators to communicate risk effectively.

The process of assessing and remediating land contamination

In common with other countries, the UK uses a risk-based approach to identifying and managing contaminated land (see page 4). The advantages of this approach are that it is systematic and objective, and provides a consistent and defensible basis for considering uncertainties, discussing options and making decisions. The approach involves the following:

- Risk assessment - whereby risks are identified, estimated and evaluated, through carrying out desk studies, site investigation and interpretation of data to reach decisions on any unacceptable risks

- Risk management - which involves evaluating and selecting suitable remedial measures to reduce or control the risks identified as unacceptable, and then implementation on site of the selected remedial action.

Effective communication with all stakeholders, throughout the processes of risk assessment and risk management, is an integral part of the process of bringing land back into use.

Why is it important to communicate the risks arising from land contamination?

Decisions about contaminated land are not made on a purely technical basis. There will be a variety of regulatory, commercial, financial, legal and societal factors, which also affect how any particular contaminated site should be dealt with. This means that decisions about contaminated land can be complex, often including the need to resolve conflicting views. In addition, land affected by contamination is not just of relevance to the person who owns it. Land, its use and condition, plays an important role in the wider community. Therefore, decisions about contamination, whether to take remedial action and how best to implement remediation, can affect many people. It is important that any decisions about contaminated land are defensible and transparent. Community acceptance of decisions is very important if contaminated sites are to be managed successfully and effectively.

Because the wider community may be affected by the condition of the land within its area, it needs to be informed about any risks, which are thought to exist from contamination. Clarity of information and good understanding of what risks from contamination mean, play an important role in effective discussions between regulatory, scientific and interested parties. Communication with third parties in turn helps to inform the regulatory and scientific process, providing important elements of the context in which decisions about the site will eventually be taken.

Community acceptance of decisions requires explicit information about assumptions, value judgements, uncertainties and their effects on the decision, as well as technical information on the condition of the land. Ultimately any decision on whether a particular risk is acceptable, or not, is both a personal matter and subjective; credible regulation will recognise this and take into account the views, priorities and expectations of those parties affected, as well as those responsible for the situation.

SCHEMATIC OF THE APPROACH TO MANAGING CONTAMINATED LAND

Process	Risk Assessment	Evaluation and Selection of Remedial Measures	Implementation of Risk Management Action
Purpose	To decide whether or not a site poses actual or potential risks to human health or the environment	To enable choice on most appropriate and cost effective remedial action for the circumstances	To implement the selected remedial solution and demonstrate its effectiveness
How	By collecting data on sources, pathways and receptors and their relationships (pollutant linkages), then estimating and evaluating the risks associated with each pollutant linkage	By reviewing available options for remedial action and evaluating their suitability against technical, commercial and social factors.	By careful planning, design and procurement of resources to carry out the works required and by testing, monitoring and documentation to verify that objectives have been met.
Activities	• Desk study • Site reconnaissance • Exploratory and detailed site investigations • Development of conceptual model for site • Estimation and evaluation of risks	• Evaluate available options • Data collection, e.g. supplementary investigations, treatability studies if necessary • Preliminary design of solution	• Detailed design • Construction / implementation • Validation testing • Monitoring • Long-term maintenance
Possible Outcome	1. Proceed to evaluation and selection of remedial measures. 2. Exit Process if no pollutant linkages or no unacceptable risks exist, or if management context permits.	1. The selected remedial solution and preliminary/feasibility design details. Proceed to detailed design and implementation.	1. Successful management of unacceptable risks. 2. Need for on-going monitoring and maintenance to ensure effectiveness.

Reproduced from the Handbook of Model Procedures for the Management of Contaminated Land, Contaminated Land Research Report CLR11; DETR & Environment Agency (in preparation).

Understanding perceptions of risk

Where expert assessment may indicate tolerable levels of risk, community perceptions may be very different.

PERCEPTION IS REALITY

Any land contamination issue is likely to involve a range of considerations, for example:

- **Environmental impact to air, water and land**
- **Health considerations**
- **Economic impact (e.g. property values)**
- **Social impact (e.g. vulnerable people)**
- **Visual intrusiveness**

Communicating with interested parties about contaminated land is likely to involve discussing all of the above, different pollutants, their impact on health and the environment, any social and economic implications and views on assessments of how clean is clean enough, and how safe is safe enough?

Perceptions of the 'dangers' and wider issues posed by contamination will be influenced by a range of factors, and will be different for the various interested parties. For instance, some people are more likely to be concerned if vulnerable sections of the public, such as young children, are exposed to contamination. Some parties may perceive certain contaminants as more alarming than others, depending on their level of familiarity with the pollutant and its effects.

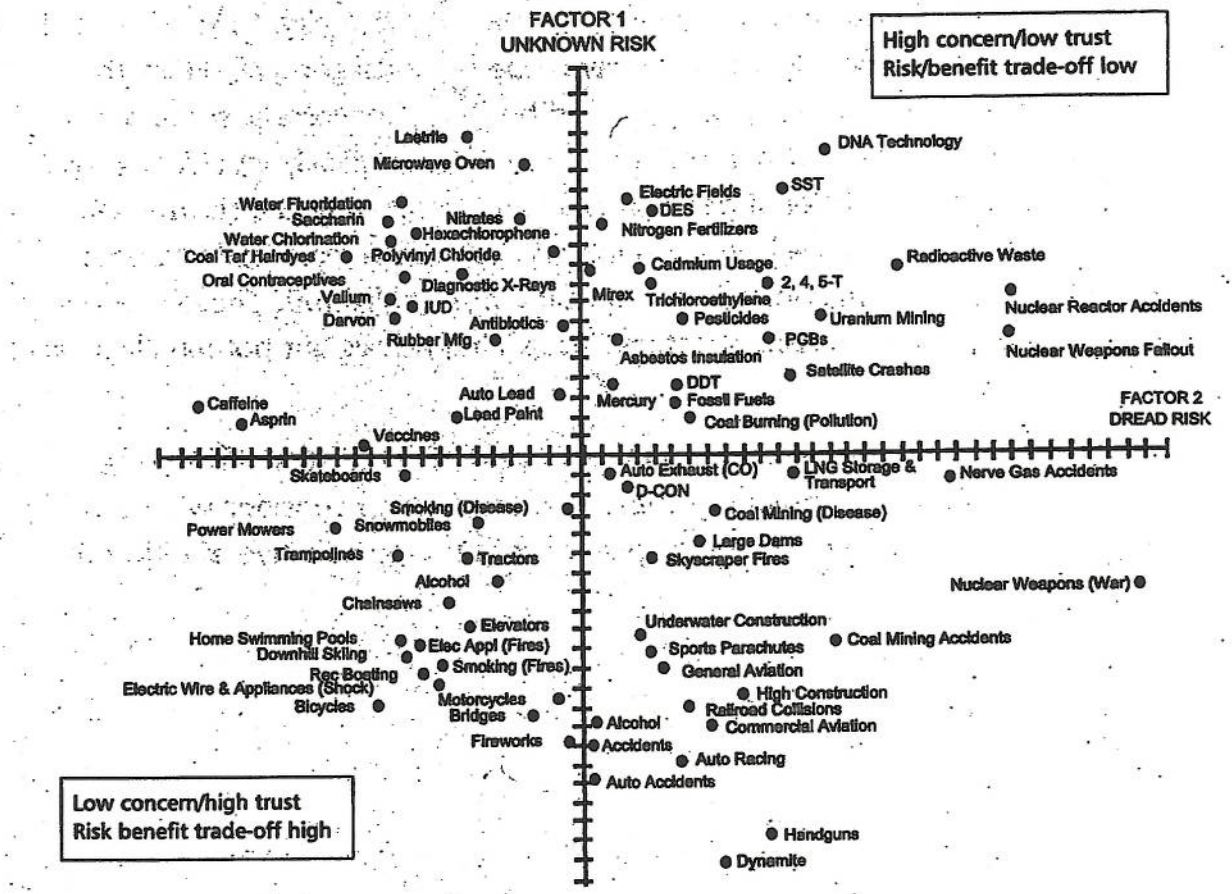
The perceptions of any individual will be influenced by their personal VALUES, LIFE EXPERIENCE, CULTURE AND BACKGROUND. Whilst you cannot influence any of these factors, you can try to take them into account when devising a communication plan.

The figure on page 7, based on extensive survey work, illustrates how a range of hazards are typically perceived based on degree of familiarity and degree of fear. Generally, the more familiar we are with the risks involved in an activity and the greater the degree of personal choice regarding exposure, for instance smoking, the less fear we feel. The less familiar we are with risks and the less control we feel over our exposure, such as risks posed by genetic engineering or vaccinations, the greater the perceived risk.

The following figure is helpful in setting a context for understanding the factors which incline people to fear and concern or otherwise. These factors include: levels of knowledge and familiarity with the activity, whether or not its impact is immediate and irreversible or otherwise, and whether or not the individuals or communities affected can exercise a degree of control over their exposure. Some of these hazards (shown in red) typically involve a high "dread" or "fear" factor, for example people feel they have little personal control. Here the personal risk/benefit trade-off is judged to be low. Conversely, some of the hazards in the bottom left quarter (shown in green) typically involve low fear and an assumed high level of personal control. In this case the risk/benefit trade-off is deemed to be high - or worthwhile. Some man-made hazards, with potentially catastrophic effects (purple), are highlighted. These tend to be judged differently from risks affecting isolated individuals but potentially in large numbers (orange).

Work by Syms (1997) shows that perceptions of environmental risk varies between different stakeholder groups. You may like to consider where on this diagram contaminated land would appear, from the perspective of different stakeholders.

FIGURE ILLUSTRATING A RANGE OF HAZARDS- FROM SMOKING TO GENETIC ENGINEERING- AND HOW THEY ARE TYPICALLY PERCEIVED BASED ON DEGREE OF FAMILIARITY, DEGREE OF FEAR



NOT OBSERVABLE
UNKNOWN TO THOSE EXPOSED
EFFECT DELAYED
NEW RISK
RISK UNKNOWN TO SCIENCE

CONTROLLABLE
NOT DREAD
NOT GLOBAL CATASTROPHE
CONSEQUENCES NOT FATAL
EQUITABLE
INDIVIDUAL
LOW RISK TO FUTURE GENERATIONS
EASILY REDUCED
RISK DECREASING
VOLUNTARY

UNCONTROLLABLE
DREAD
GLOBAL CATASTROPHE
CONSEQUENCES FATAL
NOT EQUITABLE
CATASTROPHIC
HIGH RISK TO FUTURE GENERATIONS
NOT EASILY REDUCED
RISK INCREASING
INVOLUNTARY

FACTOR 2

OBSERVABLE
KNOWN TO THOSE EXPOSED
EFFECT IMMEDIATE
OLD RISK
RISKS KNOWN TO SCIENCE

FACTOR 1

Adapted from Slovic, P (1987)

Anticipating the issues

It is possible to anticipate some of the issues and communication challenges posed by land contamination. These issues are likely to arise in response to:

(1) the PROCESS or steps taken during the technical aspects of risk assessment and risk management; and

(2) the CONTENT - language and subject matter - of risk assessment, which is not easily accessible to the non-expert.

Examples of Process challenges:

- Managing potential socio-economic impacts of contaminated land investigations e.g. 'planning blight'.
- Public cynicism that the process of site assessment is a search for an excuse not to remediate.
- Remediation may not address the problems perceived to be the major issues by the local community.
- Site investigations that require individuals to wear protective clothing may cause alarm to local residents.
- People will focus on time and costs, and will want to know that sufficient resources are being invested to produce a clear end result as soon as possible.
- Confusion over where authority for a decision lies.
- The land contamination risk assessment and management process may take months or years. Deviations from a timetable of remediation have the potential to create alarm.

Examples of Content challenges:

- Meaningful communication of risk assessment terminology to non-experts.
- Quantitative information needs to be provided in a transparent manner.
- Presentation of information when communicating is highly important, e.g. use of charts and diagrams, but care must be taken to be accurate and not distort information.
- People will be primarily concerned with risk outcomes or consequences as opposed to probabilities.
- Care should be taken to ensure that assumptions and uncertainties are clearly explained.
- Comparisons of land contamination risks with other risks should be approached with extreme caution so as not to trivialise the issues.
- Clear delineation of a site in order to fully identify potentially interested local parties.
- Sensitive handling of concerns prompted by remediation activities, such as traffic, dust etc.
- Land contamination issues arise within a local setting and will be highly influenced by local environmental conditions – some but not all of which will be familiar to all the stakeholders.
- Careful communication of site investigation findings. For example, a decision to take no further remedial action could be viewed suspiciously.
- Views and priorities of individuals and groups may change with time.

The following sections of this handbook outline 4-step process to communicating understanding of risk:

Step 1 When to Communicate

Step 2 Who to Communicate with – identifying stakeholders

Step 3 What to Communicate

Step 4 How to Communicate

Professional public relations expertise within the environment agencies can provide valuable advice, guidance and support and should ALWAYS be consulted on external communications.

"Lay people sometimes lack certain information about hazards. However, their basic conceptualisation of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments. As a result, risk communication and risk management efforts are destined to fail unless they are structured in a two-way process. Each side, expert and public, has something valid to contribute. Each side must respect the insights and intelligence of the other."

(P Slovic, 1987, Perception of risk, Science 236, 280-285)

Step 1 WHEN to communicate?

The communication process should be started early to ensure that maximum benefit can be gained. At the outset of a major project it is desirable to produce a communications strategy. Effective communication with the appropriate stakeholders will help build trust and understanding if it takes place as early as possible.

Communication takes time and effort, but the benefits gained when people are informed and have confidence in the risk assessment and remedial strategies can significantly outweigh the costs. Therefore, consider your communication approach at the beginning of a project, to give yourself maximum time.

Benefits of early dialogue

- Taking the initiative to communicate early provides you with the opportunity to explain the process and technical aspects of risk assessment and management. This in turn makes you more credible and accessible to external parties.
- Key parties will be able to share understanding of various positions, helping to anticipate and manage potential concerns in the future.
- Concerns can be expressed early on, rather than being pent up and exacerbated.
- Key parties will have had an opportunity to buy into the risk assessment process, which will be fundamental if they are to support the results.
- A relationship will have been initiated on reasonably non-controversial terms.
- The parties involved will know who to contact with concerns in the future, helping you to maintain control in the communication of key messages.
- Those involved may help you to identify other potentially interested parties that you may have over-looked.

Dangers of leaving communication too late

- Stakeholders will feel they are being delivered a *fait accompli* that they cannot influence.
- Stakeholders are more likely to feel that any communication is just a 'PR exercise', as they cannot genuinely affect the outcome.
- Stakeholders will not have had a chance to buy into the risk assessment process, and so more likely to challenge both the process and the results.
- Debate may have already occurred in the local media and/or amongst key groups. Your ability - and credibility - to control and communicate messages effectively will be more difficult to establish.

Communication is a continual process

Throughout the risk assessment and management of contaminated land, there will be an ongoing need to communicate with the stakeholders you have identified. This communication needs to be tailored to the groups or individuals concerned and could take on a variety of forms (see Step 4).

Be prepared to invest time and effort into ongoing communication and to critically assess whether your approach is effective and having the desired results. This can be done by seeking feedback and learning from your successes and failures. The simplest, quickest and most direct form of appraisal is to ask for feedback on stakeholder views before a public meeting and then reassess their feelings after the meeting. An overall appraisal of your communication strategy will provide valuable experience for colleagues who may be planning their own communication strategy. A successful strategy will be useful publicity when moving to the next site of land contamination.

Step 2 WHO to communicate with?

It is vitally important to identify those people with whom you will need to communicate. Collectively, this group of people can be regarded as the "stakeholders" who have an interest in the contaminated land in question. This group of people should initially be considered in the broadest possible context and include those with professional expertise and financial interests, along side those with local community knowledge or status. Participatory procedures generate fuller and better information, for example residents often know more about the history of their neighbourhood than official records may provide.

Stakeholders' views may be expressed by individuals or by groups of people, each representing a cross-section of interests, experiences and values. Individuals may belong to more than one group; they may be both doctors and mothers, teachers and members of an environmental group. Their experience, background and values will be reflected in how they interpret and respond to information about land contamination.

The affected communities will not necessarily be limited to the people who live in the proximity of a site. For example:

- If rivers are affected or the contaminated material is taken off site, the interested parties may be further afield.
- If the site reflects wider concerns, national interest groups may become active locally.
- If findings are controversial, academics and scientists may feel some ownership of the debate. Politicians, non-governmental organisations (NGOs) and trade associations may also become involved.

To anticipate and respond to the potential concerns of different interest groups, you will need to identify appropriate stakeholders for each site of contaminated land, remembering that those involved and their views may well change over time.

Table 1: Different interest groups may include

- Residents
- Families
- School children
- Teachers
- Colleges
- Religious groups
- Religious leaders
- Local councillors
- Caring professionals
- Hospitals & clinics
- Scientists / academics
- Journalists
- Local groups and organisations
- Landowners
- Lawyers
- Business people
- Local industry
- Trade associations
- Trade union organisations
- Community action groups
- Conservation groups
- Wildlife trusts
- National NGOs
- Members of Parliament
- Political organisations
- Financial institutions
- Developers

The Process of Identifying Stakeholders

A number of factors will play a role in determining the size and cost of any communication strategy. It may not be possible to communicate with all groups and individuals with an interest in a site. Technical factors such as the scale, degree, and nature of the land contamination; socio-economic factors, for example issues of local blight, and historical interest/use of a site by stakeholders, will assist your decision.

In order for your communication strategy to remain focussed and balanced, it may be necessary to build communication links with representative, but randomly selected, stakeholders. It is important to remain open and inclusive. Some individuals or groups volunteer their time or information and will be easy to identify; they may be active in a local area or have special expertise that is relevant to your site e.g. a local history group. Communication with these groups can be undertaken according to the needs presented and resources available (see Step 4).

However, some stakeholders may not put themselves forward and may be difficult to identify. Curiously, it has been found that denial of risks is most frequently expressed by those at greatest risk from the hazard (Baird, 1986). Denial of risk implies that individuals are unlikely to be concerned or have the time to consider contaminated land issues. Therefore, practitioners need to be aware that in some instances, the very individuals that are most at risk from the hazards posed by the site, (hence the ones that need to be made aware of the contaminated land issues), may in fact be the people with which it is

hardest to establish any formal communication. Within your communication strategy, careful consideration needs to be given to the needs of such groups or individuals.

Costs and resources must be carefully considered to ensure communication is both effective and efficient. Staff resources must be high on the list of considerations and a thorough planning stage should aim to consider who the stakeholders are. However, when implementing your risk communication strategy a flexible approach is required to deal with the unexpected.

Always use professional public relations expertise and guidance.

Transparent processes, timely communications and accessible information will be key to meeting the likely expectations of the various groups involved and achieving effective communication of the risks.

Step 3 WHAT to communicate?

What KEY MESSAGES do you want to communicate?

The overarching communication objective should be to establish yourself as OPEN, ACCESSIBLE, LISTENING & RESPONSIVE.

Within this context, a key objective will be to share understanding of the risk assessment process with interested parties, to allow them to raise concerns, and, hopefully, buy into the process.

Where a specific site is being discussed, a key objective will be to establish support amongst interested parties of the scientific evaluations underlying that assessment. This may require ensuring the interested parties support the organisation conducting the scientific investigation, or getting the results of the investigation independently reviewed by a body acceptable to all involved.

Explaining RISK

WARNING!
Risk comparisons can seriously damage your credibility

People will generally be more concerned with the consequences of an incident than the likelihood of its occurrence. Their perceptions of the issues involved will be based upon their values, life experience, culture and background.

You need to be very careful when you are trying to explain and quantify risks posed by contaminated land. It may be tempting to contextualise a risk by comparing it to an everyday risk - like smoking or driving - that expert evaluation may find more hazardous than a risk posed by contaminated land. However, where smoking or driving are voluntarily undertaken with some sort of value to the risk-taker, contaminated land risks are IMPOSED, INVOLUNTARY and have NO UTILITY OR VALUE to those affected.

Comparing voluntary risks with involuntary risks is like comparing apples with pears in the eyes of most stakeholders, and is very likely to provoke hostility and criticism. DON'T DO IT!

Inherent to risk assessment is the need to address uncertainty. Some uncertainties can be addressed by further data gathering, research or a more refined level of analysis. However, some uncertainties, such as the inherent heterogeneity of soil contamination, will be more challenging to explain. Uncertainties should be grouped according to those that can be realistically addressed and explained, and those that cannot be resolved within the confines of the risk assessment. Careful consideration must be given to the presention of each group. Uncertainties should be clearly described by the risk communicator and it is suggested widely that the best method is to provide a range of estimations based on 'best case' and 'worst case' scenarios. Communication should be based on good robust scientific data and whole numbers or simple fractions used, where possible with visual aids.

In summary, careful risk communication should ensure that interested parties understand and support the process and results of risk assessment and how they affect decisions on remediation. As emphasised throughout, risk communication is not a one-way process, and it is essential that the views of interested parties be carefully assessed.

Working tips

- Never assume information is "too difficult" or "too specialist" for the person in the street. With careful explanation, interested parties can understand the data and assessment.
- Don't generalise or hypothesise - talk about the specific issues in their local 'context.
- Always take care to be transparent.
- Use graphs, charts and visual aids, but take care not to distort information, and always be prepared to make the raw data available.
- Clearly explain any assumptions and uncertainties in the evaluation.
- If you need to put risk information in a broad context, use a "before and after" scenario rather than making 'apples and pears' risk comparisons. e.g. Current guidelines for the presence of this substance is 'a'. Before the contamination took place, the concentration was 'a'. Since the contamination, the concentration has risen to 'b'. When remediation is complete, it will be reduced back to 'a'.

- Carefully explain risk terminology like 'conservatism' and 'significance'. The general public may find such terms meaningless or interpret them differently to the expert.
- Similarly, take care to explain terms like 'ground water', 'gas in soil' and other contaminated land terminology with which the general public may be unfamiliar.
- Build trust and credibility by identifying alternative independent sources of information that stakeholders can pursue for more information should they wish.
- Take care to distinguish between environmental concentration and dose.
- Identify the sources of information used.

WORKING TIP: Your evaluation will be more robust if you consider the issues with colleagues from different professional backgrounds.

There are a number of questions and issues that can be considered systematically to get an indication of likely concerns for the different stakeholders. The following tables should act as a prompt and are not intended to be exclusive.

Scoping the issue: Checklist of issues, questions and considerations

Questions to consider...	How the questions relate to likely concerns	Management considerations/ possible solutions
Is there a recent history of contamination?	If people are familiar with a similar problem, that has been well managed, they are less likely to feel anxious. And vice versa, if they are aware of a similar problem that has been poorly managed, they are likely to feel more worried.	Communications will be enhanced if you can give examples of SIMILAR INSTANCES of contamination that were well managed and were supported by local community involvement.
Where a particular party is responsible for the contamination is it traditionally regarded as a liability or an asset? Does it have a good or bad track record of responsible community relations and environmental management?	If an organisation is involved, which has a poor reputation - even amongst a minority of interested parties - it is likely to increase public anger and concern.	Where the organisation involved has a poor reputation, INDEPENDENT FACILITATION by a trusted third party of the interface with the community will be extremely valuable, as will an independent review of the science. The Agencies must ensure they are seen as independent of any other representatives to ensure credibility is maintained and public confidence is assured.
Is the assessment process governing 'how clean is clean' seen as fair? Are the impacts focused on one particular part of the community? Will the 'science' establishing the nature and extent of contamination be seen as biased towards industry?	If effort has been made to build understanding of the risk assessment early in the process, interested parties are more likely to have faith in the results. If explanations are made after the event, parties are more likely to challenge the whole process as a way of undermining the results.	It will be extremely valuable to work with potentially interested parties - especially key local opinion-formers - to help them understand and comment upon the risk assessment process BEFORE it is applied.

Questions to consider...	How the questions relate to likely concerns	Management considerations/ possible solutions
Are 'high profile' pollutants involved (like benzene or radioactivity)	People are likely to be more alarmed by pollutants which are known as carcinogenic - regardless of the likelihood of that effect being realised.	People are more likely to trust assessments if they have been INDEPENDENTLY REVIEWED by a trusted third party - especially if chemicals are 'high profile' or the organisation conducting the scientific research is not 'trusted'.
Are the potential impacts known and reversible or unknown and permanent?	Naturally, impacts which are understood and can be reversed will cause less concern than those where the impacts are poorly understood and lasting.	TRANSPARENCY of process and scientific evaluation, INCLUSIVE DIALOGUE and CAREFUL COMMUNICATION will help mitigate concerns and their potential for escalation.
Is there long-term health and environmental damage that could have been avoided or not?	People are likely to be more angry if the consequences of the pollution could have been easily avoidable at the time it occurred.	TRANSPARENCY of process and scientific evaluation, INCLUSIVE DIALOGUE and CAREFUL COMMUNICATION will help mitigate concerns and their potential for escalation.
Are children or other vulnerable populations likely to be perceived as exposed?	People tend to be especially protective towards children, the elderly and unwell, and will be more alarmed if they are exposed.	Make LINKS WITH TRUSTED THIRD PARTIES - like doctors or local health organisations - to support your communications.
Is the surrounding environment perceived as 'precious' , utilitarian or particularly vulnerable?	People are likely to be more concerned if adjacent or affected land is parkland than if it is used for industrial purposes.	ANTICIPATE TENSIONS - remember that different groups will use local facilities at different times of the day and for different purposes. Also remember that an environment that one party may perceive as functional another may perceive as very precious.

Questions to consider...	How the questions relate to likely concerns	Management considerations/ possible solutions
Could the issue be represented as symbolic of wider social concerns: industrial exploitation v. environmental protection; rich v. poor?	Outrage is more likely if the contaminated site is seen as one incident in a portfolio of broader social issues / abuses.	Make sure you UNDERSTAND ONGOING WIDER ISSUES amongst local and national media and opinion-formers, so that you can anticipate connections and seek advice on their management.
Is the contamination visually powerful?	Visual images are always powerful. They are more likely to offend and upset, and may attract a higher profile of media attention.	Plan and programme activities in a way that AVOIDS SPECTACULAR EVENTS where this will not benefit your case.
Are there local, regional, national or international political or NGO actors / events that have an interest or mission to draw attention to the issue?	Activist interest groups are more likely to use an incident to highlight a broader mission, if it suits their own profile raising (e.g. local elections) or if they feel it has not been handled transparently, or if it is seen as representative of wider 'abuses'.	TIMING your actions and communications will be crucial. Keep a calendar of activities and events that may impact on your plans.

Note: You will be able to see that depending on the answers to each of the questions posed above, there is implied potential for elevated third party perceptions of the contaminated land issue. The greater the number of such influencing features for a particular issue, the greater the chance of heightened public concern.

Step 4 HOW to Communicate

The communication of risks, is itself a skill that may be acquired through formal training. Useful sources of information for the non-expert include ILGRA (1998) and Bennet (1998). In particular, sensitive land contamination issues require skills in listening and knowing how to listen. To be seen to listen and to respond appropriately, and to know the best forums in which to listen all provide credibility to the communicator.

> Remember that the most effective communication is a two way process, that respects the views of all participants.

Your audience will be most receptive if you:

- focus on a few clear and consistent messages;
- make sure the information is presented in a simple, visual way and is not overly technical;
- have an understanding, patient manner - don't patronise;
- do not assume you know all the issues and already have all the answers;
- always invite feedback - whether it's a meeting or a freephone line;
- always be responsive, even if it involves demonstrating why you can't meet everybody's expectations;
- acknowledge - visually and verbally - that people's worries are legitimate;
- allow equal access to relevant information;
- say you will get back to someone with information, then do so as quickly as possible;
- open-minded about outcomes and wider decision-making power.

Check-list of communications approaches

The following checklist summarises some different communications approaches, their advantages and disadvantages. You should always seek professional public relations guidance and support. You will probably need to use a range of different approaches depending upon whether you are:

- gathering information and views from interested parties;
- considering informal ways of sharing information, or
- looking for a more formal means of generating public participation.

Any communications activity takes time and will have resource and budget implications. Public relations experts can advise on in-house capabilities (where relevant) and the likely cost of external support to ensure appropriate financial planning.

Learning About Different Views	Advantages	Limitations	Helpful hints
Focus Groups: Forum to help understand views and test messages prior to actioning them.	Opportunity to learn about concerns and test messages. Works best for select target audience.	Interested parties need to be selected carefully to ensure they are representative. Responses can be shaped by questions asked.	You will need to conduct at least 2 focus groups to have confidence in the output. Use a skilled facilitator.
Mailed surveys and questionnaires: Enquiries mailed randomly to sample population to gain specific information for statistical validation.	Provides input from individuals who may not be able to attend meetings.	Can seem cold and impersonal. Response rate is generally low, and responses can be shaped by questions asked.	Survey/ questionnaire should be professionally developed. Most suitable for general attitudinal surveys.

Learning About Different Views	Advantages	Limitations	Helpful hints
Telephone surveys: Random sampling to gain specific information for statistical validation.	Higher response rate than mailed surveys.	More expensive and labour intensive than mail surveys.	Same as mailed surveys and questionnaires
Media monitoring: Watch both local and national media - radio, TV, newspapers, newsletters - to keep track of different agendas and changing views.	Should help you to identify key commentators and opinion-formers.	If you learn about stakeholder concerns and issues in the media first, your communications have not been good enough! Views and articles may not always be representative.	Keep a cuttings file. Make sure to keep a list of key commentators and their perspectives.
Proactive Media Management: Media briefing. Telephone responses. Press releases.	Gets your message across to key journalists, and enables you to take control of the issue and establish yourself as a key information source.	Proactive media management gives no guarantee of balanced coverage. Non-media stakeholders should not learn about an issue first in the media.	Always take professional public affairs advice. Never rely just on media-briefing. Always engage with key stakeholders directly.
Open Day: Allows interested parties to find out about issues and at their own pace.	Fosters small group and one-on-one discussions. Allows vivid presentation of issues and information. Builds credibility.	Potentially difficult to document public input. Staff intensive.	Be prepared for a crowd. Encourage people to comment. Provide feedback mechanisms.

Learning About Different Views	Advantages	Limitations	Helpful hints
'Coffee morning' meetings: Similar to the above, but less formal or structured - allows interested parties to find out about issues at their own pace.	Informal and non-threatening. Encourages discussion around issues. Builds trust. Gives impression of accessibility. Opportunity for vivid presentation of issues and information.	The loose structure may be difficult to record. May attract limited audience due to time constraints.	Imposing too much structure will defeat the relationship-building aspect. Make sure you are well briefed and participating colleagues are giving consistent messages. Provide information for participants to take away.
Briefings: Regular meetings to inform and learn reactions.	Control of information. Similar briefings can be re-used for different groups.	Some people may be hostile. Audience may feel unable to express views / concerns.	Simple, accessible information - not overly technical. Provide time/ mechanisms for feedback and discussions.
Public information material: Factsheets Newsletters Brochures Briefing notes Displays	Can reach target audience. Encourages written response if comment form is enclosed.	Only as effective as the mailing list. No guarantee materials will be read.	Keep it simple, brief and accessible. Use visual material. Include a pre-paid response envelope. Q&As work well. Could be left in libraries, schools or other public facilities for wider access.

Learning About Different Views	Advantages	Limitations	Helpful hints
Website:	Has a broad reach. Interactive. Can hold a lot of information / visuals.	Potentially limited target audience.	You can use materials you have already prepared for other publications. Make sure it is kept up-to-date. Make sure somebody responds to e-mail promptly.
Hotline: 0800 number	Controls information flow. Conveys impression of accessibility and openness.	Needs to be manned professionally and sensitively. Can be costly.	Make sure staff are well-briefed, kept up-to-date and with good telephone manner.
Workshops: Informal public meetings that may begin with a presentation, but end with interactive working groups.	Fosters discussion in small groups. Maximises feedback from participants. Fosters public ownership in solving difficult issues. Builds credibility and trust.	Some participants may be hostile. Several small group facilitators are necessary.	Know how you plan to use public input before you start the workshop. Plan for good presentation materials.

Public Participation Approaches	Advantages	Limitations	Helpful hints
Citizen's Jury or Panel: A 'jury' is a randomly selected pool of citizens to evaluate decision alternatives, typically be choosing between 3 or 4 options. A panel is more flexible and participants can ask own questions and invite 'witnesses'.	Peer debate in both the jury and panel. Panel has freer range of expression, rather than deliberating on given options.	Certain interested parties may not feel represented by the jury. Jury doesn't promote critical inquiry into factual issues. Costly and labour intensive. Local councillors and politicians may feel this is inappropriate.	Expert advice and facilitation needed. Obtain support from local politicians and councillors.
Advisory Committees: A representative group of interested parties to provide public input.	Provides for discussion around range of issues. Peer debate lends itself to sharing understanding rather than confrontation.	General public may not always support output. Time & labour intensive. Unlikely to achieve consensus.	Define clear roles & responsibilities. Be open. Ask Committee if any interest group has been over looked.
Facilitated dialogue: Particularly useful in contentious circumstances, where debate is being polarised.	Focuses on peer debate. Mitigates against single issue advocacy. Promotes accountability on all sides. Can be used to inform decision-making.	Time and labour intensive. Considerable preparatory work to define key parties and the views they represent. Do not expect consensus.	Establish firm ground rules. Manage participant's expectations of output. Ask participants who may have been overlooked. Experienced facilitator is essential. Don't try to squeeze it into one session!

Summary of key considerations

In summary, managing potential conflict around environmental risk issues requires attention not only to the content of risk information, but also to the appropriate procedures at the relevant stages in the decision-making process. At the same time, the choice of these procedures should be based on sound criteria, which address:

- the need for two-way communication
- transparency to create trust in the regulatory role;
- openness to enhance the legitimacy of the overall process to the stakeholder.

Risk communication needs to address strategic risk management issues in order to gain public and stakeholder confidence. Risk communication for a site needs to be flexible in terms of procedures and reflect the content and history around a particular contaminated site. Stakeholder access to a regulator's skills and information will improve risk communication and thereby environmental protection and public safety.

Further reading

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Dissemination Status
Internal: Released to Regions
External: Released to Public Domain for Consultation

Statement of Use
This publication describes a proposed approach to the preparation of health criteria values, Soil Guideline Values and other supporting guidance for assessing the risks to health of petroleum hydrocarbons in soil. The report has been written for technical professionals familiar with the risks posed by land contamination to human health but who are not necessarily experts in risk assessment. It is expected to be of use to all parties involved with or interested in contamination, but in particular to those concerned with the assessment of land contamination.

Keywords
petroleum hydrocarbons, total petroleum hydrocarbons, TPH, land contamination, risk assessment, human health

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During the consultation period (before 3rd October 2003) copies of this report can be obtained from: Petroleum Hydrocarbons Consultation, MRC Institute for Environment and Health, University of Leicester, 94 Regent Road, Leicester, LE1 7DD.

After the consultation period

Further copies of this report are available from: Environment Agency R&D Dissemination Centre, c/o WRc, Frankland Road, Swindon, Wilts SN5 8YF

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R&D Technical Report P5-080/TR1

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EXECUTIVE SUMMARY

This document is an Environment Agency consultation paper on the principles for assessing the health risks from petroleum hydrocarbons in contaminated soil. A significant change to current UK practice is needed, in order to take account of the risk-based approach of Part IIA of the Environmental Protection Act 1990 and the requirements of Town and Country Planning Acts, in which land contamination is a material planning consideration. The Agency is inviting your views on the principles, before preparing a detailed risk-based approach to assessing health risks from petroleum hydrocarbons in soil.

Petroleum hydrocarbon contamination is complex. The type of crude oil, its distillation, processing and blending, and the subsequent processes that act on the material once it is released into the environment all result in the development of petroleum residues of extreme chemical complexity. Yet sound, defensible and practical decisions are required on how to manage the risks to human health from exposure to petroleum hydrocarbons in soil.

Other industrialised countries have been faced with the same problem. The modern, risk-based approaches that have been developed, largely as a result of exhaustive reviews and consultations, offer some direction as to the approach that should be adopted in the UK. Decisions need to be made about the handling of compounds that exhibit threshold and non-threshold toxicological effects, about the degree of sophistication that should be adopted in a UK approach and about issues of implementation, including the practical aspects of analysis and the costs for site and risk assessments.

In this consultation we introduce the need for change, summarise the approaches used internationally and propose a way forward, outlining the key issues requiring input from consultees.

The outcome of this consultation will be a framework setting out the approach to be used and the representative substances or petroleum fractions to be considered in the health risk assessment of petroleum hydrocarbons in soils. Following this, detailed toxicological and fate and behaviour reviews will be prepared for those substances or fractions selected as representative of petroleum contamination. The framework and the review information will be combined to derive Soil Guideline Values (SGVs) for petroleum hydrocarbons in soils.

We look forward to receiving your input to this process and hearing of your practical experiences.

Professor Michael Depledge
HEAD OF SCIENCE

Toby Willison
HEAD OF LAND QUALITY

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1. INTRODUCTION

Petroleum hydrocarbons in soil

1.1 Past releases of petroleum hydrocarbons to the soil environment may pose potential risks to human health, water resources, ecosystems, property and other environmental receptors. Managing the potential risks requires an understanding of the impact of exposure to petroleum on each of these receptors, enabling the development of a structured risk assessment framework.

1.2 Unacceptable risks to human health and the environment from past land contamination are being addressed in the UK by Part IIA of the Environmental Protection Act 1990. Implementation of Part IIA provides the opportunity to develop a framework for the risk assessment of petroleum contamination in soils that addresses UK legislation and its supporting guidance and provides clarity in the process. This will also assist planning authorities to make decisions under the Town and Country Planning Acts, for which land contamination is a material consideration.

Purpose of consultation

1.3 This document deals only with risks to human health. It is an Environment Agency consultation paper on the principles for assessing the health risks from petroleum hydrocarbons in contaminated soil. A significant change to current practice is needed in order to take account of the risk-based approach in Part IIA. The Agency is inviting views on the principles, before preparing a detailed risk-based framework.

1.4 Understanding the toxicology of environmental contaminants in soil is essential if the risks to human health are to be managed responsibly. The toxicological evaluation of petroleum hydrocarbons is particularly difficult because these substances are present in the environment as complex mixtures, containing many hundreds of individual compounds, each with their own toxicological properties (IARC, 1989; ATSDR, 1999; CCME, 2000). Similarly, it is impractical to analyse for individual compounds when present in complex mixtures. Hence a scientifically sound and practical approach to managing risk is required that is protective of human health.

Who is being consulted?

1.5 Views are being sought from industry and its advisors, trade associations and trade bodies, Government departments and their agencies, non-government organisations, regulators, sector bodies, analytical laboratories, special interest groups, land remediation specialists, consultants and interested members of the public.

1.6 Views are welcomed on the specific issues and questions highlighted in section 4 of this document. Comments received will be considered and addressed in a separate publication. **Respondents should clearly state if they do not wish to be named, do not want their comments to be detailed in the publication and if they are commenting as individuals or on behalf of an organisation.**

What happens next?

1.7 The outcome of this consultation will be a framework setting out the approach to be used and the representative substances or petroleum fractions to be considered in the health risk assessment of petroleum hydrocarbons in soils. Following this, detailed toxicological and fate and behaviour reviews will be prepared for those substances or fractions selected as representative of petroleum contamination. The framework and the review information will be combined to derive Soil Guideline Values (SGVs) for petroleum hydrocarbons in soils.

Structure of this document

1.8 This consultation document is an extended summary of the issues and options rather than an exhaustive review. The remaining part of this document summarises the context and background to the need for a revised approach (section 2), briefly reviews other approaches adopted internationally (section 3), and presents a way forward, setting out the key technical issues on which the Environment Agency is inviting comment (section 4). Section 5 explains how comments can be submitted to the Agency. References are provided in section 6.

2. CONTEXT AND BACKGROUND

2.1 'Petroleum' is the term used for the naturally occurring liquid and gas produced when 'kerogen' is subject to high pressure and temperature, usually within the depths of the marine environment. Kerogen is the most abundant form of organic carbon in the earth's crust. It forms as organic matter from dead plants and animals decays and is deposited in marine sedimentary rocks. The organic matter is first broken down and then re-formed into complex chemical structures. As the temperature increases with increasing depth of burial below the sea, these complex chemical structures break down and some of the resulting hydrocarbons form oil (and gas), which then accumulate (Killops and Killops, 1993). The chemical structure of crude petroleum is complex and variable and alters according to both the nature of the parent material and conditions under which the crude petroleum has formed.

2.2 Petroleum refining is the process of distilling and processing various fractions of the crude oil for use as fuels (Table 2.1), petroleum products and feedstocks for many industrial products and synthetic chemicals.

Table 2.1 – Typical composition of some petroleum fuels

Composition / Product	Automotive gasoline [a]	Automotive diesel (DERV) [a]	No.6 Fuel oil
Alkane carbon number range	*n*-C_4–*n*-C_{12}	*n*-C_8–*n*-C_{21}	*n*-C_{12}–*n*-C_{34}
Boiling point range (°C)	40–200 (25–220) [b]	200–325 (160–390) [c]	350–700
Average composition (wt %)			
n-alkanes (straight chain)	>12.1	13.0	1.7
Total straight chain and iso-alkanes	47.0 (30–90 % vol) [b]	41.0	13.0
Total cycloalkanes	3.2 (1–35 % vol) [b]	37.0	15.2
Alkenes	10.0 (0–20 % vol) [b]	1.3	ND
Benzene	1.9	0.03	ND
Total xylenes	9.0	0.5	ND
Total monoaromatics	19.0 (BTXs) [d]	16	>4.0
Total polynuclear aromatics	ND	0.36	>0.37
Total aromatics	35.0 (5–55 % vol) [b]	22	34 (78.9) [e]

From TPHCWG, 1999a
ND, No data
[a]'Automotive gasoline' and 'Automotive diesel' are broadly synonymous with the UK terms 'Petrol' and 'Diesel', sold for use in motor vehicles, respectively
[b]Data from CONCAWE, 1992
[c]Data from CONCAWE, 1996, these values refer to fuels marketed in Europe
[d]BTXs, benzene, toluene and xylenes (commonly classified as BTEXs, which also includes ethylbenzene)
[e]Data from ATSDR, 1999, the large disparity between the percentage figures for total aromatics is probably due to the ATSDR data including heterocyclic (*O*, *N*, *S*-containing) aromatic compounds; the TPHCWG data on which the table is based detail No.6 fuel oil as containing 30% polar material

2.3 The refining, processing, transportation, blending, storage and use of petroleum products as fuels and feedstocks have resulted in the growth of numerous inland refinery, distribution, storage and auxiliary facilities. The petroleum

contamination of soils has often been an undesirable consequence of the operation of facilities, such as complex integrated refineries, manufacturing sites, power plants, distribution depots and retail service stations (Environment Agency, 1998). The nature and extent of contamination at these facilities can vary greatly from being insignificant to substantial, and the potential for human exposure to harmful components in the released oils can also vary widely. Site conditions, the local environmental setting, the extent and nature of contamination and the proximity to human populations all have a bearing on the nature of the risks to human health posed at these sites (Institute of Petroleum, 1993; CONCAWE, 1997).

2.4 The chemical complexity of petroleum releases to the soil arises, in part, from the chemical complexity of petroleum itself. Commercial fractions of petroleum (e.g. naphtha, gasoline, kerosene, gas oil, fuel oils, asphalt *etc.*), which are defined in terms of their boiling point range, each contain many hundreds of individual chemicals amassed together as a 'spectrum' of closely related compounds. The fractions produced from distillation, each of which is a characteristic subset of the crude oil from which it is distilled, overlap in their composition because there is never a perfect 'cut' or separation during distillation (API, 2001). Conventionally, the notation *n*-C_x–*n*-C_y for these fractions describes the carbon number range of straight chain *n*-alkanes in the fraction. The fraction C_6-C_9, for example, represents the fraction between *n*-hexane (6 carbon atoms) and *n*-nonane (9 carbon atoms).

2.5 The secondary processing of petroleum distillates adds further complexity. Thermal and catalytic 'cracking' is used to increase the yield and performance of petroleum products with high market demand, such as gasoline. Typically, the gaseous cracked products from kerosene or gas oil feedstocks are fed into a flash distillation chamber and further separated into gasoline and light gas oil, and the liquids are sent to a vacuum fractionator and separated into heavy gas oil and vacuum tar or residuum (Schobert, 1990).

2.6 Once released to the environment in a spill or leak, petroleum constituents partition, to differing extents, between the oil phase and the air, soil and water phases of the environment (Zemanek *et al*, 1997). Physical, chemical and biological processes 'weather' or age the spilled product, resulting in additional changes in composition and complexity (Westlake *et al*, 1974; Morgan and Watkinson, 1989; Pollard *et al,* 1999).

2.7 Decision-makers (e.g. site owners, developers, occupiers and regulators) charged with making informed and scientifically sound decisions about how to manage risks at petroleum-contaminated sites must take into account the complexity of the situation, within a practical decision framework. Among the factors they must take into account (section 4) are:

- the chemical and physical complexity of the source of contamination and the changes in composition of the contaminating material that have taken place since spillage;
- how to measure the extent and nature of contamination in a way that is meaningful and relevant to the risks it may pose;
- how to establish toxicological criteria for petroleum contamination in soil;

- how to account for the different toxicities of the thousands of individual compounds that may be present in the contaminating material and the range of potential adverse health effects that could result from short-, medium- or long-term exposure to these compounds; and

- how to make clear, consistent, pragmatic and sustainable decisions that protect human health but are not over-burdensome in terms of the societal costs of remediation.

2.8 These issues are not new. Many other countries have, in consultation with their stakeholders, developed decision frameworks that guide decision makers through a series of steps to determine how best to manage risks from petroleum contamination. Several reviews underpinning the development of these frameworks have been published (CCME, 2000; API, 2001; MaDEP, 2002a).

2.9 A formalised approach has yet to be established in the UK. Historically, *ad hoc* approaches have been applied to managing petroleum contamination, using simple analytical procedures to quantify the extent of contamination. Measurements such as 'total petroleum hydrocarbons (TPH)' have been used as surrogates for estimating the petroleum load of soils. This parameter, as with all analytical methods, is defined by the method used for analysis. Unless the spillage is well defined, reliance on a single parameter for petroleum hydrocarbons is unlikely to provide a sound basis for risk management. Surrogate measures, such as TPH analysis, indicate little about the risks posed by contamination (Gustafson, 2002). For example, TPH can be measured in material that is not derived from petroleum (API, 2001; Table 2.2).

Table 2.2 – Representative TPH measurements of naturally- and petroleum-derived materials

Sample	Grass	Dried oak leaves	No.6 Fuel oil	Household petroleum jelly
TPH (mg kg^{-1})	14,000	18,000	16,000	749,000

From API (2001)

2.10 Recognising this and other limitations, some of the international approaches to analysing and assessing the risks from petroleum-contaminated sites have been adopted in the UK over the last 10 years (*e.g.* ASTM, 1995, 2000; TPHCWG, 1997a,b; TNRCC, 2001). These approaches offer a more robust basis for assessing the risks from petroleum contamination as they focus on the components that pose most risk owing to their toxicological potency, presence in the environment and environmental fate and behaviour.

Legal framework

2.11 Two predominant pieces of legislation directly impact on contaminated land in the UK: The Town and Country Planning Acts, and Part IIA of the Environmental Protection Act 1990 (the contaminated land regime). Both Part IIA and the planning regime embrace the 'suitable for use' approach.

Under the Town and Country Planning Acts land contamination is a material planning consideration. This means that a planning authority has to consider the potential implications of contamination both when it is developing structure or local plans (or unitary development plans) and when it is considering individual applications for planning permission. Where contamination is suspected or known to exist at a site, a planning authority may require investigation before granting planning permission, or may include conditions on the permission requiring appropriate investigation and, if necessary, remediation.

2.13 Part IIA of the Environmental Protection Act 1990 (which was inserted by Section 57 of the Environment Act 1995) is a regime for the identification and remediation of contaminated land. This introduces a definition of contaminated land, for the purpose of the regime, and (as regards England) is described fully in DETR Circular 02/2000 (DETR, 2000). Part IIA has also been implemented in Wales and Scotland, with only minor differences from the regime implemented in England. The main functions under the regime are exercised by local authorities and, in certain circumstances, the Environment Agency or the Scottish Environment Protection Agency.

2.14 Part IIA is intended to complement the planning regime (which deals with risks to new development or land–uses arising from existing contamination). It also complements other regulatory regimes, including the Pollution Prevention and Control regime, Groundwater Regulations, Consents to Discharge and the system of waste management licensing, which control and limit future pollution.

2.15 Given the requirements of the contaminated land legislation (DETR, 2000) in England and Wales, the Environment Agency considers that a framework for the evaluation of human health risks from petroleum hydrocarbons in soils should:

- be scientifically authoritative and based on the principles of toxicology, exposure and risk;
- be based on a state-of-the-art understanding of petroleum in the environment;
- be able to be implemented by the full range of practitioners and disciplines involved in the contaminated site assessment and management processes;
- be proportionate to the risks posed; and
- enable decision-makers to arrive at practical, sound management decisions that are protective of human health.

2.16 The Environment Agency has concluded that a consistent approach is required and sets out its draft proposals in section 4 of this document. Prior to this, the international approaches that have been adopted elsewhere are briefly reviewed in the next section. More detailed descriptions of these approaches can be obtained from the references in section 6.

3. APPROACHES TO ASSESSING THE HEALTH RISKS FROM PETROLEUM HYDROCARBONS IN SOIL

3.1 A number of national organisations have proposed approaches for setting soil assessment criteria for petroleum hydrocarbon mixtures, using reviews of petroleum toxicology and existing regulatory approaches as a starting point. The approaches used fall broadly into two groups, as described below.

(1) *The use of generic assessment criteria for TPH or whole products* (diesel fuel, fuel oil etc.). These are usually developed following a review of international values for petroleum hydrocarbons in soil, and are levels above which action is required. Such criteria may or may not be risk based, and the toxicological basis for the criteria may be unclear. This approach was widely used for the development of soil assessment criteria in the late 1980s to mid 1990s. In practice, few sites have distinct, recent (i.e. unweathered), and well-characterised petroleum contamination, and the Environment Agency considers it necessary to progress to the adoption of authoritative risk-based approaches. Approaches based on TPH or whole products are, therefore, not reviewed in detail in this document.

(2) *The use of generic assessment criteria for indicator compounds and/or petroleum fractions together with the use of exposure models*. These criteria are *toxicologically driven* and developed from *risk-based approaches*. Here the emphasis is on identifying the key indicator compounds and/or petroleum fractions presenting risks at a site, by reference to their toxicology and/or environmental behaviour. These approaches usually start with simple initial assessments and build in complexity, as required, into a 'tiered' approach, similar to that adopted for environmental risk assessment in England and Wales (DETR *et al*, 2000). Screening criteria act as an initial check for site assessors; more detailed assessments are undertaken in later tiers if screening criteria are exceeded.

3.2 For evaluations of petroleum fractions rather than individual compounds, some working groups have adopted the 'Equivalent Carbon' (EC) number convention (Twerdok, 1999). The Total Petroleum Hydrocarbon Criteria Working Group (TPHCWG) chose the concept of EC numbers because these values are logically related to compound mobility in the environment (TPHCWG, 1999b). The EC index is used to normalise petroleum constituents by reference to boiling point and to the carbon number of their *n*-alkane equivalents. For compounds with fewer than about 10 carbon atoms EC numbers are generally similar to the number of carbon atoms. However, above 10 carbon atoms EC values for aromatic compounds are smaller than those for aliphatic compounds with the same number of carbon atoms (MaDEP 2002a).

3.3 Most approaches in the second group, described in (2) above, distinguish between the risks posed by exposure to contaminants that exhibit threshold toxicological behaviour and those that exhibit non-threshold effects. For threshold effects many of the approaches adopt the US Environmental Protection Agency (USEPA) 'reference dose' (RfD) and 'reference concentration' (RfC) as the basis for the toxicological criteria that underpin soil assessment criteria (USEPA, 1986). The RfD is 'an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population that is

likely to be *without* an appreciable risk of deleterious effects during a lifetime'. The RfC is the inhalation equivalent and is expressed as an air concentration (USEPA, 1986).

3.4 Although reducing the number of petroleum hydrocarbon constituents to a smaller number of representative fractions simplifies the risk assessment process, it can still be complex. Some authorities have adopted *streamlined approaches* in an attempt to develop risk assessment processes that are easier to use. These approaches are toxicologically based and recognise the costs of assessment. They attempt to reconcile thoroughness with efficient decision-making by reducing the number of petroleum fractions considered when assessing the risk from threshold substances.

3.5 The following paragraphs summarise the approaches adopted by various jurisdictions to evaluate the human health risks of petroleum hydrocarbons in soils. Most are risk-based approaches for indicator compounds or petroleum fractions (2, above).

The ASTM guides to risk-based corrective action

3.6 An example of a risk-based indicator compound approach is that developed by the American Society for Testing and Materials (ASTM). ASTM standards E1739-95 and E2081-00 represent three-tier approaches to risk-based corrective action (RBCA) at petroleum- and chemically-contaminated sites (ASTM, 1995, 2000) and are in wide use in North America and Europe. They rely on reviews of toxicology and environmental fate and exposure, which are used as the basis for the development of risk-based soil screening levels (RBSLs) and site-specific target levels (SSTLs) for assessing risks from contaminated soil. As site assessors move down the three tiers of the assessment, the tiers become less generic and less conservative, although each tier has the objective of compliance with an acceptable level of risk.

3.7 The RBCA approach assumes a significant proportion of the total impact on human health from all chemicals in soil is due to specific compounds, termed 'chemicals of concern', of significant toxicological potency. Other compounds or petroleum fractions are not considered. The most commonly selected chemicals of concern for sites contaminated by gasolines, kerosene and jet fuels are benzene, toluene, ethylbenzene and xylene (BTEX). Depending on the nature of the spill, it may also be necessary to test for lead and other fuel additives. For kerosene and fuel oils, polycyclic (or polynuclear) aromatic hydrocarbons (PAHs) are important, and twelve PAHs, including benzo[*a*]pyrene, are evaluated.

3.8 Under RBCA, a Tier 1 evaluation is a risk-based analysis that compares the environmental concentrations of chemicals of concern from an initial site assessment with conservative (health-protective) RBSLs. Where the RBSLs are exceeded, the site assessor proceeds to Tier 2. Tiers 2 (simple fate and transport analyses) and 3 (complex fate and transport analyses) require the derivation of SSTLs. Each tier involves increasingly sophisticated levels of data collection and analysis with the conservative assumptions of earlier tiers being replaced with site-specific data and information. A RBCA site remediation is governed by the most conservative RBSL or SSTL (depending on the tier of assessment). The use of whole mixture toxicity data and the assumption of additivity for chemicals in a

mixture are mentioned as options for Tiers 2 and 3, but neither approach is recommended by the ASTM (ATSDR, 1999).

The US State of Massachusetts Department of Environmental Protection approach

3.9 For assessing the threshold risk[1] at petroleum-contaminated sites, rather than evaluating individual compounds, another approach is the use of representative petroleum fractions. The Massachusetts Department of Environmental Protection (MaDEP, 1994, 1997, 2002a,b), which has been instrumental in implementing revised approaches to petroleum risk assessment since the early 1990s, proposes that focussing on a select few compounds is insufficient for characterising the risks posed by all hydrocarbons present (MaDEP, 2002a). MaDEP work from 1994 onwards (MaDEP, 1994; Hutcheson *et al,* 1996) on the petroleum fraction approach has influenced the work of the *ad hoc* TPHCWG and, in turn, that of the ATSDR (1999), described later in this section.

3.10 The MaDEP approach assesses key contaminants, 'target analytes', on an individual basis. Target analytes include non-threshold compounds (e.g. benzene, benzo[*a*]pyrene and some PAHs) and substances that have been conventionally used to characterise petroleum contamination (e.g. toluene, ethylbenzene, xylene and threshold PAHs). Toxicological criteria are derived for threshold risks by treating groups of petroleum compounds present in environmental samples as if all compounds in the group were all equally toxic. For each compound group or fraction, a 'reference compound' is identified. Oral and, more recently (MaDEP 2002 a,b), inhalation health criteria values for the reference compounds are then applied to the whole fraction. The underlying assumption is that the toxicity of each of the other compounds within the fraction is equal to that of the reference compound.

3.11 The original basis for the grouping of compounds was the segregation of petroleum constituents into four broad chemical classes, namely alkanes, cycloalkanes, alkenes and aromatics. The alkanes and cycloalkanes were treated together, owing to their toxicological similarities (MaDEP, 1994), as were the alkenes and aromatics, as they were separated together in the recommended analytical procedures (MaDEP, 1994). Toxicological justification for the consideration of aromatics and alkenes together was based on their similar metabolic pathways and the low proportion of alkenes in petroleum products (typically less than 5%) (MaDEP, 1994). Following a review of the toxicology of these groups of compounds, it was apparent that the toxicity of the alkanes/cycloalkanes decreased with an increase in the number of carbon atoms. For the aromatics/alkenes there was comparatively little variation in toxicity values. On this basis, rather than considering the four chemical classes originally proposed, four petroleum fractions were selected, three for alkanes/cycloalkanes and one for the aromatics/alkenes.

3.12 The 1994 MaDEP approach has since been updated (MaDEP, 2002a,b) to ensure that the most recent toxicological and analytical advances are incorporated into the guidance. Terminology was altered in accordance with that of the TPHCWG (see paragraphs 3.19 to 3.30) which divided petroleum hydrocarbons into

[1] MaDEP documents refer to carcinogenic and non-carcinogenic risks. MaDEP 1994 uses these terms synonymously with non-threshold and threshold risks (MaDEP, 1994).

aromatic and aliphatic fractions. Given the toxicological dominance of the alkanes and the aromatics MaDEP (2002 a,b) simply refers to aromatics/alkenes as aromatics and alkanes/cycloalkanes as aliphatics. Toxicological criteria for individual fractions have been revised in accordance with the recommended Volatile Petroleum Hydrocarbon (VPH) and Extractable Petroleum Hydrocarbon (EPH) methods of analysis. Although the four fractions identified in the 1994 guidance are retained, MaDEP (2002b) chose to designate six sub-fractions to minimise the use of both VPH and EPH methods on all samples. These fractions and sub-fractions are summarised in Table 3.1.

Table 3.1 – MaDEP hydrocarbon fractions

Toxicologically defined hydrocarbon fraction	Analytical/program defined hydrocarbon fraction	Analytical method	Reference dose (mg kg^{-1} bw d^{-1})	Reference concentration (mg m^{-3})
C_5-C_8 Aliphatics	C_5-C_8 Aliphatics	VPH	0.04	0.2
C_9-C_{18} Aliphatics	C_9-C_{12} Aliphatics	VPH	0.1	0.2
	C_9-C_{18} Aliphatics	EPH	0.1	0.2
C_{19}-C_{36} Aliphatics	C_{19}-C_{36} Aliphatics	EPH	2.0	N/A
C_9-C_{22} Aromatics	C_9-C_{10} Aromatics	VPH	0.03	0.05
	C_{11}-C_{22} Aromatics	EPH	0.03	0.05

From MaDEP 2002b
N/A, Not applicable

3.13 The MaDEP VPH Method (MaDEP 1998a) is a purge and trap, gas chromatography, with photoionisation detection or flame ionisation detection (GC/PID/FID), procedure. As well as measuring the petroleum fractions identified in Table 3.1, the VPH method may also be used to measure concentrations of the target VPH analytes, namely BTEX, methyl-tertiary-butylether and naphthalene.

3.14 The MaDEP EPH Method (MaDEP 1998b) is a solvent extraction/fractionation GC/FID procedure. As with the VPH method, the EPH method may also be used to measure concentrations of the PAH target EPH analytes.

3.15 The MaDEP approach for undertaking a risk assessment is implemented through the Massachusetts Contingency Plan (MCP). The MCP details the State regulations that govern the remediation of sites contaminated by oil or hazardous materials and now includes provisions for the VPH/EPH approach and standards (MaDEP, 2002b). The MCP offers three methods for assessing the risks associated with contamination, each of which requires an increasing level of site-specific knowledge and assessment:

- Method 1 - generic cleanup standards in soil and groundwater;
- Method 2 - site-specific modification of generic cleanup standards; and
- Method 3 - completely site-specific risk assessment.

Method 1 uses generic 'soil standards', which were designed to be protective at most sites. The standards were developed using a series of conservative site scenarios to evaluate risks to human health, public welfare, and the environment via a number of exposure routes and pathways, including direct contact, ingestion, leaching (soil), and volatilisation (groundwater). Method 2 involves the modification of the standards used in Method 1 to include consideration of site-specific fate and transport factors, such as depth to groundwater, soil permeability, soil organic carbon content, etc. Method 3 is entirely site-specific and involves the determination of quantitative risk levels for all contaminants present at a site, for comparison with specified risk management standards for threshold and non-threshold health effects.

3.16 Whichever method is chosen, analyses for appropriate target analytes and fractions are undertaken concurrently, helping assessors to identify the key risk drivers prior to any remedial activity. It is not a requirement to test for all target analytes and fractions - only those considered to be of interest, given knowledge of contamination at a site. To avoid the double counting of substances, the mass of target analytes present is subtracted from the corresponding mass fraction. For example, the mass of benzo[*a*]pyrene in a sample would not be included when determining the overall mass of the aromatic fraction.

3.17 In producing cleanup standards for each fraction based on toxicology alone, MaDEP recognised that the low toxicity of some of the components of petroleum hydrocarbons (e.g. heavy aliphatics) could result in significant levels of residual material being left behind in soils. At these levels other issues of 'public welfare' could be affected, such as staining, odour and other aesthetic concerns. To address the issue of public welfare, MaDEP introduced 'ceiling levels' of contaminants in soils, thereby limiting the potential for significant amounts of residual material to be left in the soil. Ceiling levels were derived for use in Method 1 and 2 assessments. For Method 3 assessments, the parties involved are required to demonstrate that 'public welfare' has been appropriately addressed.

3.18 A precautionary approach is used for the assessment of the additive effects of substances. For substances exhibiting non-threshold toxicological effects (e.g. benzene, benzo[*a*]pyrene), the overall risk is estimated using oral slope factors and unit risk estimates. If the resulting excess lifetime cancer risk exceeds 1 in 100,000, further investigation or remedial work is required. For the substances and fractions exhibiting threshold effects, a hazard index is calculated, based on the ratio of the expected dose or concentration to the toxicological criteria value. All of the ratios are added together to produce an overall hazard index. If this value exceeds 1, further assessment or site remediation is required.

The Total Petroleum Hydrocarbons Criteria Working Group approach

3.19 The TPHCWG (the Working Group) was established in 1993 as a US national *ad hoc* consortium with wide representation from the oil and gas industry, the environmental consulting community, the US military, academia and the US regulatory agencies to 'develop scientifically defensible information for establishing soil cleanup levels that are protective of human health at hydrocarbon contaminated sites' (TPHCWG, 1997a, Twerdok, 1999). Much of the work builds on the MaDEP (1994) proposals. Reports published to date (TPHCWG 1997a,b, 1998a,b, 1999a,b) are available on the internet at www.aehs.com.

3.20 The Working Group first considered whether human health toxicity associated with petroleum contamination should be evaluated using toxicity data on the whole product, on a fraction, or on indicator compounds (TPHCWG, 1999b). The whole product method is considered to be appropriate for fresh spills not subject to weathering. However, for the more common problem of weathered product, a hybrid method has been selected that employs fractions and carcinogenic (non-threshold) indicator compounds. The Working Group supports the use of appropriate indicator compounds, based on the type of petroleum used at the site (e.g., benzene and MtBE for gasoline sites, PAHs for heavy oil sites).

3.21 Understanding the potential exposures resulting from petroleum contamination is essential for reasonable estimates of human health risk (TPHCWG, 1999b). The Working Group has established petroleum hydrocarbon fractions based on transport properties of the compounds (TPHCWG, 1997a). The fractions selected are based on EC numbers (paragraph 3.2), as they are considered to be closely related to compound mobility in the environment (TPHCWG, 1999b).

3.22 In considering the transport properties of petroleum constituents, the Working Group calculated leaching factors and volatilisation factors for 250 individual petroleum compounds. Plotting these factors against EC numbers for each compound (TPHCWG, 1999b) indicated differing behaviours for aromatic and aliphatic compounds in the environment. Aromatic compounds tend to be more soluble in water and slightly less volatile than aliphatic compounds with similar EC numbers. On this basis, the Working Group has divided petroleum constituents into aromatic and aliphatic hydrocarbon fractions.

3.23 The data review undertaken by the Working Group shows that leaching and volatilisation factors for aromatic and aliphatic compounds cover several orders of magnitude. Thus in the TPHCWG approach the aromatic and aliphatic fractions are further divided into 13 transport fractions, with leaching and volatilisation factors that differ by approximately one order of magnitude. The Working Group considers a 'one order of magnitude' criterion for defining fractions is appropriate in view of the levels of uncertainty associated with toxicity assessments and exposure assessments (TPHCWG, 1999b).

3.24 The Working Group reviewed a number of methods for analysing petroleum contamination in soils (TPHCWG, 1998a). The recommended method for analysing petroleum hydrocarbon fractions is the 'direct method' (AEHS, 2000), which is a GC method developed by the Working Group to analyse for the 13 fractions. The first step of the direct method includes TPH quantification and identification of contamination type and EC number distribution. If more detailed data are needed, subsequent steps in the direct method can be followed to quantify the 13 transport fractions.

3.25 Having identified appropriate fractions and a suitable analytical technique, the Working Group has characterised the threshold toxicity of each fraction using RfDs and RfCs for 'surrogate' compounds or mixtures. A surrogate is an individual compound or mixture within each fraction that is representative of the toxicity of the fraction. The Working Group has preferred the use of mixtures as surrogates, as they include some of the interactions between compounds within the fraction. For fractions exhibiting similar toxicity, the same toxicity criterion is applied to each fraction. Thus, the toxicity of TPH can be estimated by

quantifying seven broader fractions. However, the Working Group has recommended (TPHCWG, 1999b) quantification of all 13 fractions, thus enabling the detailed modelling of the potential for human exposure owing to different transport properties.

3.26 In using fraction specific RfDs and RfCs, the Working Group (TPHCWG, 1999b) has assumed that the toxicity of all compounds present in a fraction does not vary significantly from the toxicity of the surrogate compound. To ensure that the risk is not underestimated, the toxicity criteria are designed to account for uncertainty in the underlying toxicity database; hence they are more likely to overestimate than underestimate the toxicity of any fraction.

3.27 Although surrogates are used as the basis for the toxicology of each fraction, the transport data used to evaluate exposure in risk assessments are based on correlations with EC numbers; hence transport data are representative of an entire fraction, rather than just a single material within it. A summary of the 13 fractions identified by the Working Group and the associated toxicity values is presented in Table 3.2.

Table 3.2 – TPHCWG petroleum fractions

Equivalent carbon number	Reference dose ($mg\ kg^{-1}\ bw\ d^{-1}$)	Reference concentration ($mg\ m^{-3}$)
Aliphatic fractions		
>5-6	5.0	18.4
>6-8	5.0	18.4
>8-10	0.1	1
>10-12	0.1	1
>12-16	0.1	1
>16-21	2.0	NA[a]
Aromatic fractions		
>5-7	0.004[b]	0.03[b]
>7-8	0.2	0.4
>8-10	0.04	0.2
>10-12	0.04	0.2
>12-16	0.04	0.2
>16-21	0.03	NA[a]
>21-35	0.03	NA[a]

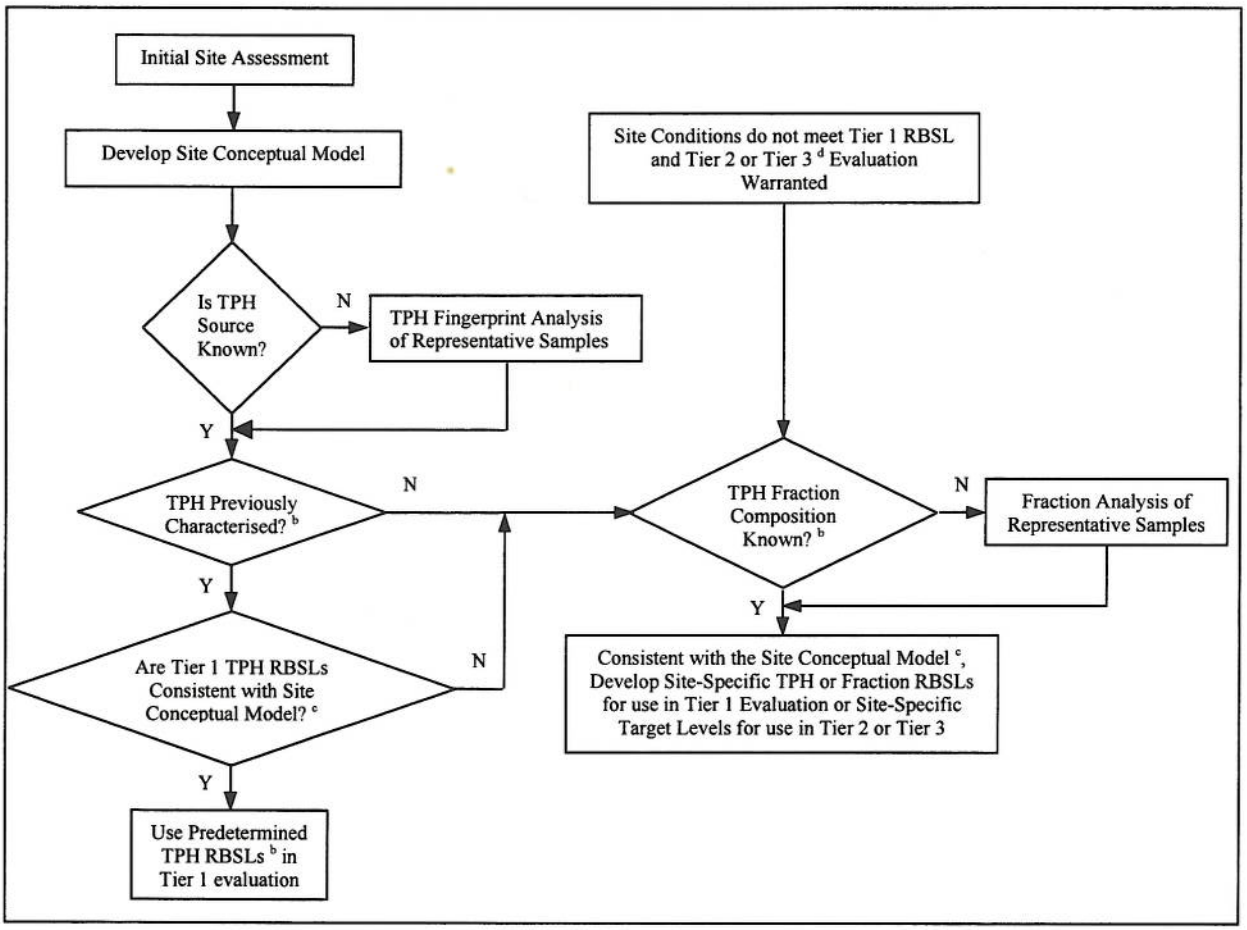
After TPHCWG (1999b)
[a]NA, Not available
[b]Based on USEPA benzene value (USEPA, 2003)

3.28 Application of the TPHCWG approach gives priority to the assessment of non-threshold compounds that are likely to be present at sites. These indicator compounds include benzene, lead, 1,3-butadiene, and carcinogenic PAHs. They are regulated individually in the USA, either federally or at state level. After

evaluation of indicator compounds, petroleum fractions are considered. The fractions are defined as mixtures of threshold toxicity compounds 'which represent the mass of petroleum remaining *after evaluation of the carcinogenic indicators*'. Thus, as with the MaDEP approach, when determining the mass of a fraction within a sample, indicator substances are subtracted to avoid double counting.

3.29 The approach developed by the Working Group can be incorporated into an ASTM RBCA programme (see paragraphs 3.6 to 3.8). The key difference between the two approaches is that the ASTM uses RBSLs and SSTLs for individual substances, whereas the Working Group uses petroleum fractions. In applying its approach, the Working Group has advocated the initial assessment and remediation of indicator substances, followed by a second phase of assessment and remediation for the petroleum hydrocarbon fractions (TPHCWG, 1997b). In practice however, it is recognised that, when applying the approach within a RBCA programme, it is more appropriate to consider indicator substances concurrently (TPHCWG, 1999b). The overall application of the Working Group approach in this context is presented in Figure 3.1.

Figure 3.1 – Implementation of risk-based TPH analysis within a 3-tiered RBCA framework [a]



From TPHCWHG, 1999b

[a] Assumes parallel assessment of potential indicator compounds (e.g. benzene, carcinogenic PAHs, lead, MtBE, etc., as appropriate)

[b] Assumes TPH RBSLs based on TPH fingerprints and associated fraction composition have been developed and approved by the appropriate regulatory agency

[c] RBSLs and SSTLs must be consistent with the site conceptual model

[d] Tier 3 evaluation similar to Tier 2 except based on more complex fate and transport models and site-specific exposure information

3.30 As with MaDEP, the Working Group approach assumes additivity of non-carcinogenic toxicity across the fractions. The assumption of additivity is claimed to ensure that TPH risk-based screening levels would be protective to human health, as not all fractions exert toxicity on the same target organ (TPHCWG, 1999b).

The US Agency for Toxic Substances and Disease Registry review

3.31 The toxicology of petroleum hydrocarbons has been reviewed by the US Agency for Toxic Substances and Disease Registry (ATSDR, 1999) as part of their national (US) 'toxicological profile' series. The philosophy of the MaDEP and the TPHCWG was identified as the preferred approach, with the initial step being an examination of the carcinogenic effects, using indicator compounds for which there are existing USEPA carcinogenic potency factors. At the time of the ATSDR report only benzene and benzo[*a*]pyrene had been evaluated in this way by USEPA. ATSDR (1999) concluded that the USEPA potency factors (relative to benzo[*a*]pyrene) 'can be applied' to the PAHs benz[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, chrysene, dibenz[*a,h*]anthracene and indeno[1,2,3-*c,d*]pyrene.

3.32 The petroleum fractions selected by the ATSDR for the threshold effects of petroleum hydrocarbons are similar to those favoured by the TPHCWG. One amendment made by ATSDR is the broadening of the aromatic EC_5–EC_8 fraction, used by TPHCWG, to EC_5–EC_9, to include all of the BTEX compounds. The ATSDR noted that 'these fraction-specific values are provisional values, reflecting the uncertainty inherent in this approach'. Also, the ATSDR adopted a precautionary approach and tended to use the most toxic representative compound or mixture to indicate the toxicity of the entire fraction.

3.33 The ATSDR (1999) report identifies the difficulties and uncertainties in analysing and modelling complex petroleum hydrocarbon mixtures in the environment. Although no specific analytical method or model for exposure assessment is recommended, physicochemical data determined for fractions (rather than individual compounds) are presented and the application of risk assessment methods within the ASTM RBCA framework are discussed.

3.34 The ATSDR addressed additivity across different petroleum indicators and fractions using an 'index of concern'. An assumption is made that the health effects are additive for all compounds or fractions that affect the same system or target organ. The index of concern is the sum of the ratios of the monitored level of exposure to the accepted level of exposure for each of the constituents of a mixture. Where this index is greater than 1, appropriate action must be taken. This approach to additivity is a refinement of the approaches of the MaDEP and TPHCWG, which assume additivity across fractions, irrespective of the nature of the toxic effect.

The Canada-Wide Standard for Petroleum Hydrocarbons in Soil

3.35 The Canada-Wide Standard for Petroleum Hydrocarbons in Soil (CCME, 2000, 2001a,b) was endorsed by the Canadian Council of Ministers of the Environment (CCME) in 2001. The Petroleum Hydrocarbons Canada-Wide Standard (PHC CWS) is a three-tiered, risk-based, remedial standard developed for four generic

land uses, namely agriculture, residential/parkland, commercial and industrial. It adopts many of the benefits of the US approaches, including, separate evaluation of indicator substances and petroleum hydrocarbon fractions, and provision of generic soil assessment levels for Tier 1 and 2 evaluations.

3.36 The approach is simplified through the use of only four fractions for the assessment of threshold effects and specifically removes the need for an aliphatic/aromatic split of the samples. The approach uses the 13 TPHCWG sub-fractions as the basis of four PHC CWS fractions:

- Fraction 1: nC$_6$-C$_{10}$;
- Fraction 2: >nC$_{10}$-C$_{16}$;
- Fraction 3: >nC$_{16}$-C$_{34}$;
- Fraction 4: >nC$_{34}$.

3.37 Based on an analysis of representative hydrocarbon products, the CCME (2001a) made the assumption that, within a TPHCWG sub-fraction, the balance between aromatic and aliphatic constituents was 20/80 (CCME, 2001a). The analyses were also used to determine appropriate proportions of different carbon ranges within a fraction. Toxicological information for each TPHCWG sub-fraction was combined with the information on the expected mass of each sub-fraction to produce a toxicological benchmark for each PHC CWS fraction. Using the toxicological criteria for each of the four fractions, Tier 1 soil assessment criteria were developed through the application of generic exposure assessment tools. Transport properties for the various fractions were also derived from the TPHCWG sub-fractions. The algorithms used for these calculations are described in the scientific rationale behind the PHC CWS approach (CCME, 2000).

3.38 A benchmark analytical method for determining petroleum hydrocarbons in soil has been developed to address major sources of variability and uncertainty in the extraction, purification and quantification of petroleum hydrocarbons and the data reported (CCME, 2001c). Fraction 1 is isolated through purge and trap procedures followed by GC/FID. Fractions 2–4, up to C$_{50}$, are extracted and 'cleaned up' on silica gel and determined by GC/FID. Petroleum hydrocarbons greater than C$_{50}$, if present, may be determined gravimetrically or through extended chromatography. The analytical method has been tested in laboratories across Canada and found to reduce variability in results significantly over previous tests where analytical procedures were not controlled (CCME, 2000).

3.39 Application of the PHC CWS involves separate assessments of the indicator compounds and the four fractions. Indicator compounds include the most toxic compounds (termed 'target compounds', including benzene and benzo[a]pyrene) and other hydrocarbons frequently tested for (toluene, ethylbenzene and xylenes). The mass of each fraction in a sample is determined by subtracting the mass of the indicator compounds from the overall value, thereby avoiding double counting (CCME, 2000).

3.40 The assessment process is based on the ASTM RBCA (1995, 2000) and CCME (1996) approaches. There are three successive tiers of evaluation, which can be described as follows:

- Tier 1 – the application of generic (national) assessment criteria that are protective of human health and the environment;
- Tier 2 – site-specific adjustments to the Tier 1 criteria to determine criteria that accommodate site-specific characteristics; and
- Tier 3 – levels that are developed from a site-specific ecological or human health risk assessment, when assumptions inherent in the Tier 1 values are not appropriate for a site.

3.41 The tiered approach essentially represents increasing levels of precision in a site assessment, through consideration of more specific site characteristics. Details on the phased acquisition of site information to support sound petroleum hydrocarbon management decisions are presented in separate guidance documents being developed by each Province (e.g. Saskatchewan Environment, 2002).

3.42 The approach to additivity of effects across the fractions, recommended by several US groups (MaDEP, TPHCWG, ATSDR), is not adopted by the PHC CWS[2].

3.43 In its evaluation of the overall impact of the PHC CWS, the Development Committee and Technical Advisory Groups identified a number of areas requiring additional research (CCME, 2000). There was concern about basing management decisions on aesthetic considerations, specifically odour, owing to the general adoption of qualitative, site-specific criteria. The need for a systematic and objective approach to the evaluation of aesthetic issues was identified, to ensure that site management decisions have a sound basis. The scope for including such guidance in a risk-based approach was also highlighted as an area for further consideration.

The Dutch National Institute for Public Health and the Environment approach

3.44 The Dutch National Institute for Public Health and the Environment (RIVM) recently undertook a critical review of the toxicology of petroleum hydrocarbons (RIVM, 2001). The review considered the advantages and limitations of a number of approaches and frameworks for evaluating the human health risks of exposure to petroleum hydrocarbons in soils. RIVM favoured the TPHCWG approach, with minor modifications. Taking account of the available toxicological data, RIVM assigned revised maximum permissible risk (MPR) levels to seven petroleum fractions and updated their 1991–1996 MPRs (Vermeire, 1993; Janssen *et al*, 1995) accordingly. These values are presented in Table 3.3.

[2] While the TPHCWG recognises that the additivity of health effects across fractions that might affect different organs is a precautionary approach, the CCME has confirmed that the PHC CWS Development Committee recommends a different approach. The Committee considers that, as different toxicological endpoints and/or routes of exposure are involved for each of the four PHC CWS fractions, it is not appropriate to add effects across the different fractions.

3.45 The revised (2001) MPRs can be used to develop 'so-called' serious risk concentrations (SRCs) by using the Dutch C-Soil generic exposure assessment model[3].

3.46 Influenced by both the ATSDR (1999) work on hazard indices and the TPHCWG approach, the RIVM decision framework (RIVM, 2001) can be described as follows:

(1) assess for indicator compounds (i.e. those with individual SRCs) – if the SRC for one or more of the compounds is exceeded, appropriate remedial measures should be considered or undertaken;

(2) assess fractions based on toxicity of surrogate compound or product – if the SRC for one or more of the compounds is exceeded, appropriate remedial measures should be considered or undertaken;

(3) if the petroleum fraction-specific SRCs are not exceeded, calculate an overall site specific contamination index by summing together the ratios of measured concentrations to the SRCs – where this exceeds 1, appropriate remedial measures should be considered or undertaken.

Table 3.3 – Human toxicological maximum permissible risk (MPR) levels for petroleum fractions

TPH fraction	TDI[a] (mg kg^{-1} bw d^{-1})	TCA[b] (mg m^{-3})
Aliphatic >EC_5-EC_8	2[c]	18.4
Aliphatic >EC_8-EC_{16}	0.1	1
Aliphatic >EC_{16}-EC_{35}	2	NA[d]
Aliphatic >EC_{35}	20	NA
Aromatic >EC_5-EC_9	0.2	0.4
Aromatic >EC_9-EC_{16}	0.04	0.2
Aromatic >EC_{16}-EC_{35}	0.03	NA

After RIVM (2001).
EC, equivalent carbon number – based on retention times on a non-polar gas chromatography column so as to normalise to *n*-alkane equivalents
[a]TDI, tolerable daily oral intake equivalent to TPHCWG RfDs except for aliphatics >EC5-EC8
[b]TCA, tolerable concentration in air, equivalent to TPHCWG RfC
[c]The value proposed by the TPHCWG was 5000 μg kg^{-1} bw d^{-1}; the basis of this was not considered to be robust, hence RIVM chose to adopt the more conservative value of 2000 μg kg^{-1} bw d^{-1}
[d]NA, not available (and not applicable due to extremely low volatilisation

3.47 The analytical procedure for petroleum hydrocarbons (NEN 5773) was developed for the initial 1991–1996 MPRs. The current recommended test method, modified to take account of the revised MPRs, is based on a GC/FID analysis and is designed to test for substances with carbon numbers from 6 to 40.

[3] In evaluating exposure potential, RIVM recommends the use of the fraction-based transport properties developed by the TPHCWG. However, where appropriate, site-specific information may be used to determine exposure.

Approaches in New Zealand / Australia

3.48 New Zealand has adopted the TPHCWG approach in its guidance for managing petroleum hydrocarbons from contaminated sites (Ministry for the Environment, 1999). However, the distinction between aromatic and aliphatic compounds in the TPH fractions has been dropped because the aromatic component is addressed separately by direct measurement of BTEX and PAH concentrations, and the analytical technique proposed for New Zealand does not distinguish between aromatic and aliphatic compounds. The criteria developed for New Zealand using this simplified approach apply principally to the aliphatic components of petroleum hydrocarbons. In combining the approach adopted by the TPHCWG with the standard analytical method technique being developed for use in New Zealand, Tier 1 soil and groundwater acceptance criteria have been developed on the basis of the following fractions:

- C_7 to C_9;
- C_{10} to C_{14}; and
- C_{15} to C_{36}.

3.49 Due to minor differences between the fractions selected for use in New Zealand and those proposed by the TPHCWG, some minor changes have been made to the toxicological (Table 3.4) and fate and transport properties adopted, based on a weighted averaging approach.

Table 3.4 – Toxicological reference doses for aliphatic petroleum fractions adopted in New Zealand

Fraction	C_7–C_9	C_{10}–C_{14}	C_{15}–C_{36}
Oral reference dose (mg kg^{-1} bw d^{-1})	5.0	0.1	1.5
Inhalation reference dose (mg kg^{-1} bw d^{-1})	5.0	0.3	1.5

After Ministry for the Environment (1999)

3.50 The assessment of petroleum contamination in Australia comes under the jurisdiction of individual states (Buddhadasa *et al,* 2002). Current approaches appear to be based on the use of generalised threshold concentration levels for hydrocarbons in soils. For example, in a recent draft guideline for the assessment of former gas-works sites (New South Wales Environment Protection Authority, 2002), 'threshold concentrations for sensitive land uses' were provided for two ranges of petroleum hydrocarbons (C_6–C_9 and C_{10}–C_{40}), BTEX, phenol, benzo[*a*]pyrene and total PAHs. Threshold concentrations are intended to protect both human and ecological health and are based on soil concentrations recommended by other expert groups (e.g. ANZECC/NHMRC, 1992). Although the expert groups initially proposing the values may have developed them using a risk-based approach, the guidance document issued by the New South Wales Environment Protection Authority does not demonstrate a risk basis in its adoption of these values as threshold concentrations.

Summary

3.51 A number of approaches to the evaluation of petroleum hydrocarbons in soil for the protection of human health have been described above. The key issues are addressed differently by the various approaches and an overall summary is presented in Table 3.5.

Table 3.5 – Summary of approaches to key issues

	ASTM	MaDEP	TPHCWG	ATSDR	PHC CWS	RIVM	New Zealand	New South Wales
Reference paragraphs	3.6 to 3.8	3.9 to 3.18	3.19 to 3.30	3.31 to 3.34	3.35 to 3.43	3.44 to 3.47	3.48 to 3.49	3.50
Indicator substances	Use of 'chemicals of concern' only.	Target analytes include most toxic compounds and others frequently tested for.	Indicator compounds include most toxic compounds only.	Indicator compounds include most toxic compounds only.	Indicator compounds include most toxic compounds (target compounds) and others frequently tested for.	Indicator compounds include most toxic compounds and others frequently tested for.	Use of 'contaminants of concern' to address most toxic substances and aromatics	Individual compounds identified
Fractions								
Number and basis	None	6 analytical fractions (3 aromatic and 3 aliphatic) using 4 toxicity values (3 aliphatic and 1 aromatic).	13 analytical fractions (6 aliphatic and 7 aromatic) using 7 toxicity values (3 aliphatic and 4 aromatic).	Similar to TPHCWG. Minor modification to aromatic groups to include all BTEX compounds in same fraction.	4 fractions based on 13 developed by TPHCWG. Separate evaluation of aromatic/aliphatic compounds not required.	7 fractions based on toxicity values (3 aliphatic and 4 aromatic).	3 aliphatic fractions only.	2 petroleum hydrocarbon fractions
		Fractions based on carbon number and driven by analytical methods and toxicology.	Fractions based on EC number, driven by fraction transport properties.	EC numbers, as per TPHCWG	EC numbers, as per TPHCWG	EC numbers, as per TPHCWG	EC numbers, as per TPHCWG	Various
Basis of toxicity and transport properties		Toxicity values based on surrogate compounds, transport properties based on TPHCWG approach (i.e. entire fraction).	Toxicity values based on surrogates, transport properties based on entire fraction.	Most toxic compound/mixture in fraction generally used as surrogate for toxicity values	Use of TPHCWG toxicity and transport data.	Toxicity values based on surrogates, transport properties based on entire fraction (as per TPHCWG).	Use of TPHCWG toxicity and transport data.	Basis unclear, as soil threshold concentrations taken directly from other expert groups

	ASTM	MaDEP	TPHCWG	ATSDR	PHC CWS	RIVM	New Zealand	New South Wales
Additivity of effects	Not recommended	Precautionary approach, based on addition of hazard quotients across fractions.	Precautionary approach, based on addition of hazard quotients across fractions.	Precautionary approach, developing 'index of concern', based on addition of hazard quotients across fractions for compounds affecting same target organs or systems.	Not advised due to different toxicological endpoints and exposure pathways of different fractions.	Precautionary approach, based on addition of hazard quotients across fractions.	Additivity of excess lifetime cancer risk for non-threshold substances Precautionary approach, as for ATSDR.	Not discussed in guidance document
Application of approach	Use of RBCA 3-tiered approach. Look up tables for Tier 1 and increasing use of site-specific information in Tiers 2 and 3.	Three Methods can be used, with generic standards for Method 1 and increasing use of site-specific information for Methods 2 and 3. Approach is not tiered, as appropriate Method is selected prior to assessment.	Use of RBCA 3-tiered approach. Look up tables for Tier 1 and increasing use of site-specific information in Tiers 2 and 3.	As for TPHCWG	Use of RBCA 3 -tiered approach. Look up tables for Tier 1 and increasing use of site-specific information in Tiers 2 and 3.	Use of a tiered approach, moving from generic guidelines to less conservative values using site-specific I	Use of a 3-tiered approach, moving from generic guidelines to less conservative values using site-specific I	Unclear
Recommended analysis	No specific method of analysis	Use Vapour Petroleum Hydrocarbon (VPH) and Extractable Petroleum Hydrocarbon (EPH) methods developed by MaDEP. Target analytes reported in these analyses.	Direct Method Indicator compounds not reported.	As for TPHCWG	2-step analytical method developed and benchmarked across laboratories in Canada. Indicator compounds not reported.	Single analytical method (NEN 5733) recommended. Indicator compounds not reported.	Based on American Petroleum Institute 'Method for Characterisation of Petroleum Hydrocarbons in Soil' Chemicals of concern not reported	Various, depending on source of threshold concentration
Other comments	Consideration given to aesthetic characteristics (e.g. odour) when identifying chemicals of concern	Address issues of 'public welfare', such as odour and staining, through the use of ceiling limits for soil concentrations			Aesthetic issues, such as odour, identified as a need for further research.		Aesthetic issues, such as odour, identified as consideration on a site-by-site basis	Basis of approach unclear and appears to be a mixture of ideas from various expert groups

4. PROPOSED APPROACH AND KEY ISSUES AND QUESTIONS FOR CONSULTATION

4.1 The review in section 3 raises a number of issues for consideration in developing an approach for assessing human health risks from petroleum hydrocarbons in the UK. Many of these issues are addressed by national conventions and accepted protocols already in place (Table 3.5). Thus it is not desirable to undertake an *a priori* review without considering them first, as they may influence the final way forward. Key issues to be addressed include:

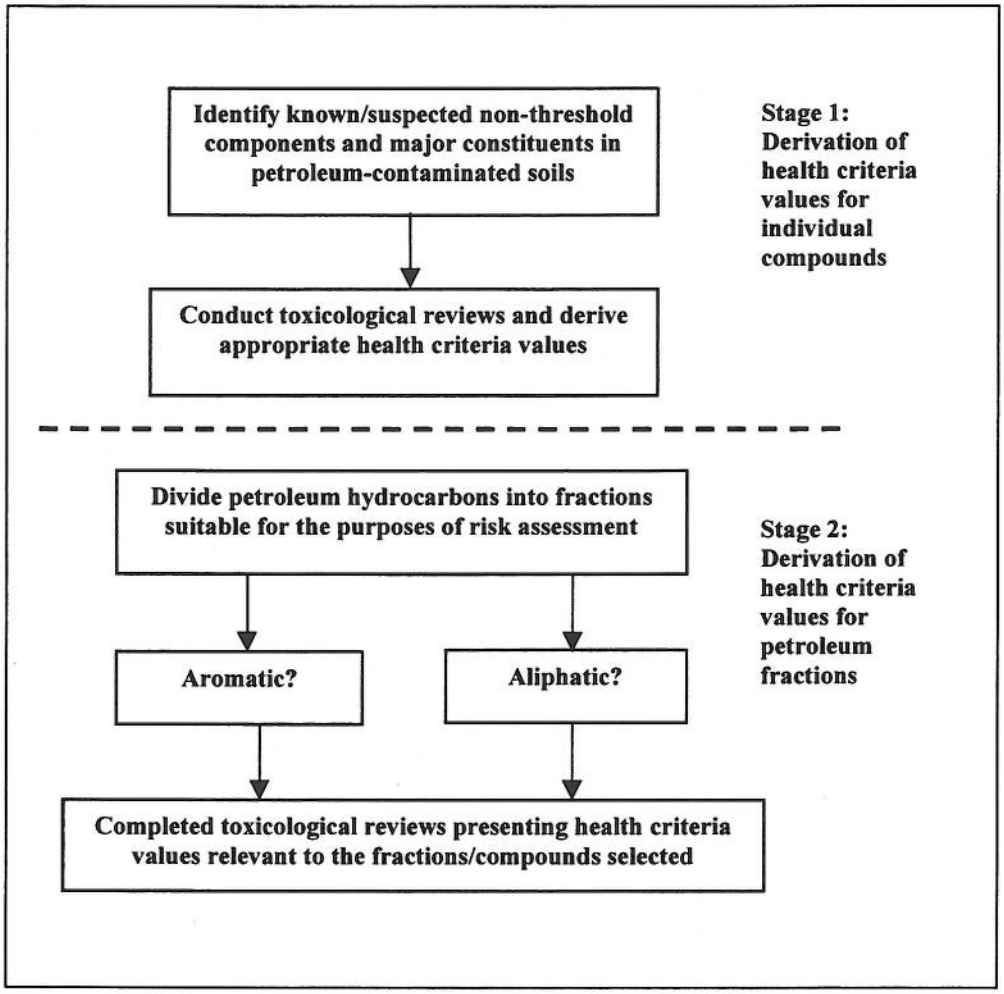
- the approach to assessing threshold and non-threshold risk;
- accepted approaches and philosophies of risk assessment and management;
- the availability and design of exposure assessment models for generating SGVs from toxicological criteria;
- the availability of standard analytical methods for the analysis of toxicologically relevant compounds and fractions in petroleum; and
- the cost of implementation and relative benefits in terms of improved decision-making.

4.2 The Environment Agency seeks to provide, for practitioners, clear guidance on the evaluation of human health risks from petroleum hydrocarbons in soils. The Agency recognises that some of the individual constituents of petroleum (e.g. benzene, PAH) may be assessed independently in establishing whether land is statutorily contaminated under Part IIA of the Environmental Protection Act 1990.

4.3 The Environment Agency proposes, for comment, a staged risk-based programme of research and development for the derivation of health criteria values for petroleum hydrocarbons in soil (Figure 4.1). Stage 1 will involve the development of Index Doses and Tolerable Daily Soil Intakes (health criteria values[4]) for individual compounds. Stage 2 will involve the development of health criteria values for petroleum fractions. The health criteria values from the two stages will then be used to derive SGVs for petroleum hydrocarbons. Key issues influencing the development of such an approach, on which the Agency seeks your views, are discussed below.

[4] see Defra and Environment Agency (2002c) for definitions of Index Dose and Tolerable Daily Soil Intake

Figure 4.1 – Environment Agency proposed programme of research and development to determine health criteria values for individual substances and fractions



Complexity of approach

4.4 The approaches summarised in section 3 vary in sophistication from those involving a full review of the available toxicology (ATSDR, TPHCWG, MaDEP), through the setting of generalised threshold concentrations (New South Wales Environment Protection Authority to approaches that are, to varying degrees, hybrids of both (CCME, RIVM, New Zealand Ministry for Environment). The Environment Agency seeks to ensure scientific integrity in its approach, alongside practicality in implementation.

Issue 1 ***The Environment Agency welcomes views on whether the UK should adopt a combined indicator and petroleum fraction approach to the evaluation of petroleum hydrocarbons in soil.***

Issue 2 ***What are consultees' experiences of applying these approaches in practice?***

Issue 3 ***The MaDEP has selected petroleum fractions on the basis of the available analytical techniques and the toxicology of petroleum compounds. The TPHCWG has selected fractions based on transport properties.***

If a petroleum fraction approach is favoured, what should be the basis for the selection of fractions?

Issue 4 ***Do consultees consider that a simplification of the TPHCWG approach is appropriate?***

4.5 One option, though not a necessary requirement, is the fractionation of the sample into aromatic and aliphatic sub-components (Figure 4.1).

Issue 5 ***The Environment Agency invites the views of consultees on the merits and practicalities of separating the aliphatic and aromatic class components (e.g. MaDEP, TPHCWG), compared with an approach based on carbon number alone (e.g. CCME).***

4.6 The major health risks associated with historic petroleum contamination in the environment are widely considered to be non-threshold effects posed by genotoxic carcinogens present in the complex mixture. Other threshold compounds are frequently present in petroleum contaminated soils. Some of these substances (Table 4.1) are listed in CLR8 (Department for Environment, Food and Rural Affairs (Defra) and Environment Agency, 2002a) and are currently being or have already been subject to review (Defra and Environment Agency, 2002b). The Agency proposes the separate toxicological review of each of these substances, to be termed 'indicator compounds', as part of Stage 1 (Figure 4.1) of the assessment.

Issue 6 ***The Environment Agency welcomes views on the proportions of sites where remediation is driven by the risks from non-threshold substances or threshold substances or both (and/or other assessment criteria).***

Table 4.1 – Some individual compounds to be considered during Stage 1 toxicological reviews

Non-threshold indicator compounds	Threshold indicator compounds
Benzene	Toluene
Benzo[*a*]pyrene	Ethylbenzene
Benz[*a*]anthracene	Xylene
Benzo[*b*]fluoranthene	Naphthalene
Benzo[*k*]fluoranthene	Fluoranthene
Chrysene	Phenanthrene
Dibenz[*a,h*]anthracene	Pyrene
Indeno[1,2,3-*c,d*]pyrene	

4.7 The Environment Agency proposes that Stage 2 of the assessment (Figure 4.1) will be the toxicological review and derivation of health criteria values for petroleum hydrocarbon fractions, based on vales for surrogate compounds or mixtures representative of each fraction. The basis for the selection of surrogates for each fraction can have considerable influence on the derivation of SGVs. For example, MaDEP (2002a) adopts *n*-hexane, with a RfD of 0.04 mg kg^{-1} bw d^{-1} and an RfC of 0.2 mg m^{-3}, as a surrogate compound for the aliphatic C_5–C_8 fraction because it is the most toxic constituent of this fraction. However, RIVM (2001) considers *n*-hexane to be a minor constituent and hence adopts less stringent criteria, based on *n*-heptane; that is, a tolerable daily oral intake of 2 mg kg^{-1} bw d^{-1} and a tolerable concentration in air of 18.4 mg m^{-3}, unless there is clear evidence for high amounts of *n*-hexane in contaminated soil.

Issue 7 ***If petroleum fractions are to be adopted, what should be the toxicological basis for the selection of surrogate compounds or mixtures?***

Issue 8 ***How many petroleum fractions do consultees consider to be toxicologically relevant?***

Issue 9 ***How, if at all, should additivity of health effects across the fractions be taken into account?***

Practicality – staged frameworks

4.8 Having established an approach for the derivation of health criteria values and SGVs for petroleum hydrocarbons, consideration needs to be given as to how these values will be applied in a site assessment. There are some differences in the practical application of the various approaches described in section 3. The approaches of the TPHCWG and ATSDR give precedence to non-threshold risks from individual compounds *within the framework* (i.e. initial evaluation of non-threshold risk, then subsequent evaluation of threshold risk). In contrast, the MaDEP approach explicitly assesses the risks from both individual compounds and fractions concurrently. The Environment Agency proposes use of the latter approach, in which all risks (and pollutant linkages) are determined prior to remedial activity.

Issue 10 ***The Environment Agency welcomes views on the concurrent assessment of all risks from both indicator compounds and petroleum fractions.***

Issue 11 ***However if an approach were adopted that gave precedence to the non-threshold risks (e.g. TPHCWG) over threshold risks, what are consultees' views on the practical application of such a staged approach in the context of identifying Part IIA pollutant linkages?***

4.9 A further consideration in the development of a decision-framework is the use of different *tiers* of approach – reflecting increased levels of sophistication as the assessment proceeds from the application of Tier 1 screening values through to site-specific risk-based endpoints. This feature is consistent with the Defra and Environment Agency guidelines on Environmental Risk Assessment and Management (DETR *et al,* 2000) and the forthcoming Model Procedures (Defra and Environment Agency, in preparation) and is a familiar concept of RBCA assessments (e.g. ASTM, 2000).

Issue 12 ***The Environment Agency seeks comments on the application of a tiered approach in the context of identifying the significance of Part IIA pollutant linkages.***

Analytical feasibility and approach

4.10 The limitations of TPH methods as a basis for the analysis of risks from petroleum hydrocarbons in soil are widely reported (Nyer and Skladany, 1989; Gustafson, 2002). No universal method exists for petroleum contamination owing to the complexity and specificity of the source, which can range from light distillates to heavy, residual fuels. In devising a risk-based framework for petroleum in soil, it is important to develop analytical strategies, methods and reporting conventions that are capable of reliably and reproducibly estimating the concentrations of risk-critical compounds and fractions. In the USA, the Texas Natural Resource Conservation Commission (TNRCC) direct method (AEHS, 2000) is gaining acceptance for the evaluation of the TPHCWG fractions. In Canada, the CCME reference method (CCME, 2001c) for the Canada wide standard (Tier 1 method) has been adopted. UK laboratories, using accredited methods for the analysis of petroleum hydrocarbons, apply a range of GC and mass spectrometric methods, including those for the analysis of:

- petrol- (C_5–C_{10}), diesel- (C_{10}–C_{30}) and 'total' petroleum (C_{10}–C_{40}) organics (using USEPA Modified method 8015M);
- TPH (using USEPA or modified USEPA Method 1664, the replacement for 418.1); and
- petroleum hydrocarbons in environmental samples (using TNRCC methods 1005 and 1006).

4.11 The analytical strategy and the methods developed for the UK will need to reflect the risk assessment approach chosen and the selection of toxicologically relevant compounds or fractions.

Issue 13 ***In devising its approach, the Environment Agency wishes to ensure that analytical methods can be suitably matched to the needs of the risk assessment.***

Consultees are invited to express their views on experiences in using the above (paragraph 4.10) and related analytical methods for characterising petroleum in environmental samples.

What are costs and requirements of these methods?

What are the implications for site investigation, soil sampling, analysis and analytical reporting?

What levels of uncertainty in analytical measurement are typically experienced in applying these methods?

Weathered petroleum contamination in the soil

4.12 Heavy and highly weathered oils present a particular challenge in terms of their chemical analysis, toxicological evaluation and risk assessment. The analysis of petroleum hydrocarbons using methods designed for lower boiling point compounds is inappropriate for highly weathered oils and residual fuel products (Pollard *et al*, 1994; Douglas *et al,* 2001; API, 2001). Their high boiling points, weathered composition and extreme chemical complexity mean that specialised analysis is often required. A common feature of the GC analysis of these oils is the presence of an unresolved complex mixture (UCM) of components in the mid-distillate range of the chromatogram (Hrudey and Pollard, 1993).

4.13 Acknowledging these constraints, recent revisions to the TPHCWG methodology have allowed the fractionation and detection of oils with a carbon number of up to C_{44}, that is with a carbon equivalent boiling point of > 548 °C (API, 2001). An oral RfD of 0.03 mg kg^{-1} bw day^{-1} and a dermal RfD of 0.8 mg kg^{-1} bw day^{-1} have been recently assigned to the C_{44+} fraction (API, 2001). Given that many petroleum-contaminated sites have oils present that are highly weathered, the Environment Agency wishes to incorporate within its risk-based framework clear guidance to practitioners on how these oils should be assessed.

Issue 14 ***The Environment Agency seeks views on appropriate methods for the chemical analysis of heavy, weathered and residual oils and on the approach to their toxicological evaluation.***

Aesthetics, costs and socioeconomic considerations

4.14 Petroleum, or more broadly hydrocarbon contamination, is found at most historically contaminated sites. Consequently the development and application of risk-based SGVs could have a considerable influence on the extent and cost of risk management measures.

Issue 15 ***The Environment Agency welcomes views on the implementation costs and implications of the various approaches described in section 3, specifically with respect to site and risk assessment.***

4.15 Petroleum oils present at historically contaminated sites often produce a residual odour, cause staining of materials and are unsightly at the surface. The MaDEP addressed this issue of 'public welfare' by introducing ceiling limits, based on aesthetic considerations, for Method 1 assessments, thereby limiting the amount of residual material remaining in the soil after remediation. Similar issues were raised during consultation with stakeholders in development of the CCME Canada Wide Standard (CCME, 2000), which recommended that risk management should include consideration of aesthetics and physico-chemical effects on soil.

Issue 16 ***Aesthetic impacts are not covered by Part IIA of the Environmental Protection Act 1990. However, the Environment Agency wishes to take this opportunity to consider separately views relating to aesthetic impacts of oil at contaminated sites.***

The Environment Agency invites practitioners to summarise their experiences of the influence that aesthetics currently play in risk management at petroleum-contaminated sites and their considered opinions on the influence they might play in the future.

What typical concentrations of petroleum hydrocarbons remain in the soil after remediation? Please relate concentration data to remedial techniques.

5. SUBMITTING YOUR COMMENTS

The Agency welcomes comments on this document and your responses to the issues and questions posed in section 4. In accordance with the Cabinet Office Code of Practice, the Agency has determined that a three-month review period for our proposals is appropriate. Please provide your response by 3rd October 2003 and send your response to:

- by e-mail to: ea_tph_consultation@leicester.ac.uk
- or by post to :

Petroleum Hydrocarbons Consultation,
MRC Institute for Environment and Health
University of Leicester
94 Regent Road
Leicester LE1 7DD
United Kingdom

In your response please:

- explain who you are and, where relevant, who you represent;
- state if you want your comments treated as confidential; and
- provide your comments against the issue numbering in the consultation document.

Please note that responses may be made public unless consultees specifically request confidentiality. All responses will be included in any statistical or other summary of results.

Code of Practice on written consultation

This consultation document has been produced in accordance with the Cabinet Office Code of Practice on written consultation.

The consultation criteria are:

1. Timing of consultation should be built into the planning process for a policy (including legislation) or service from the start, so that it has the best prospect of improving the proposals concerned, and so that sufficient time is left for it at each stage.

2. It should be clear who is being consulted, about what questions, in what timescale and for what purpose.

3. A consultation document should be as simple and concise as possible. It should include a summary, in two pages at most, of the main questions it seeks views on. It should make it as easy as possible for readers to respond, make contact or complain.

4. Documents should be made widely available, with the fullest use of electronic means (though not to the exclusion of others), and effectively drawn to the attention of all interested groups and individuals.

5. Sufficient time should be allowed for considered responses from all groups with an interest. Twelve weeks should be the standard minimum period for a consultation.

6. Responses should be carefully and open-mindedly analysed, and the results made widely available, with an account of the views expressed, and reasons for decisions finally taken.

7. Departments should monitor and evaluate consultations, designating a consultation co-ordinator who will ensure the lessons are disseminated.

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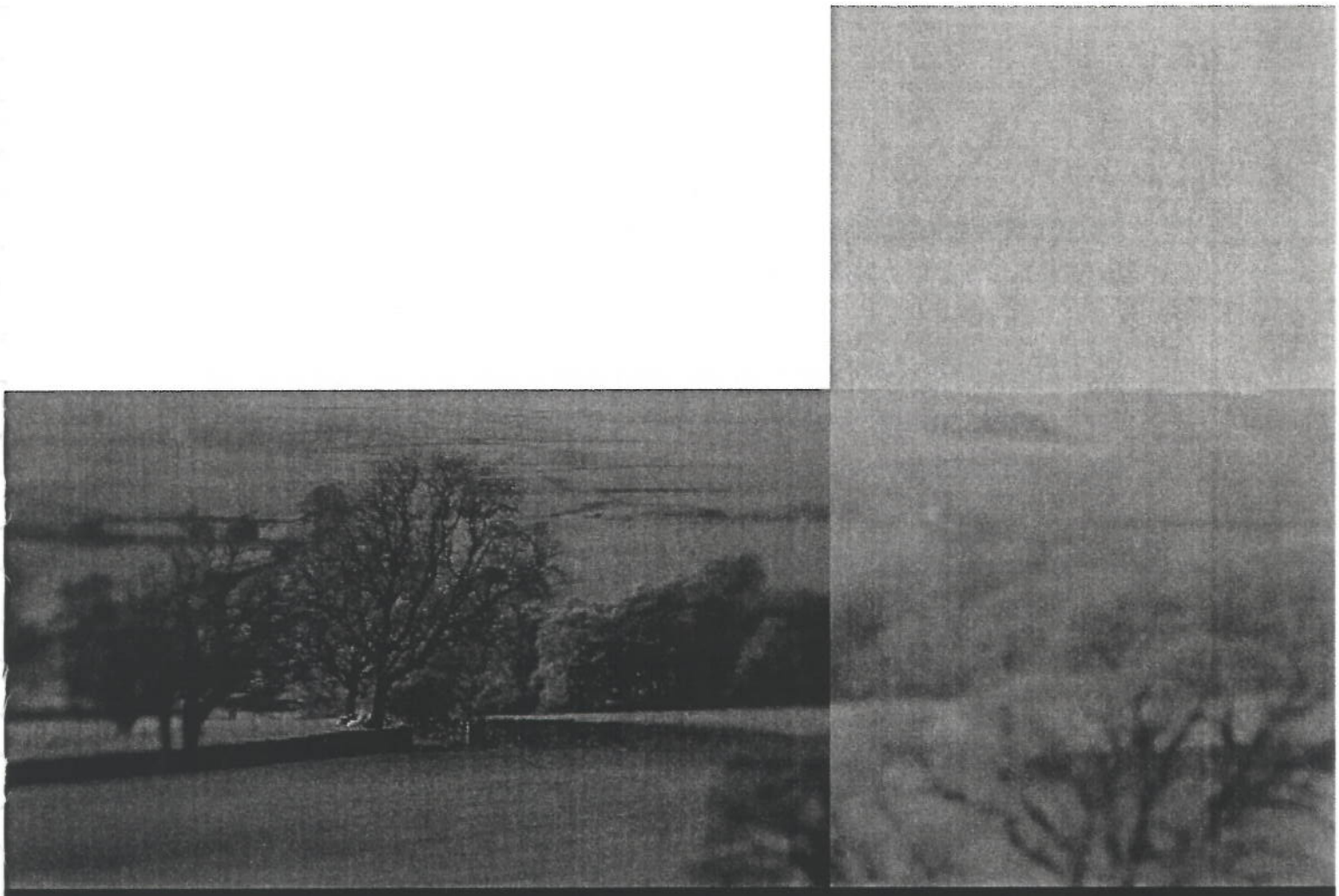

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The UK Approach for Evaluating Human Health Risks from Petroleum Hydrocarbons in Soils

Science Report P5-080/TR3

ENVIRONMENT AGENCY

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Professor Mike Depledge Head of Science

EXECUTIVE SUMMARY

This document presents the Environment Agency's framework for evaluating the health risks from petroleum hydrocarbons in soil. The framework has been developed through public consultation and subsequent discussions with relevant stakeholders. The document sets out the future research required to produce a comprehensive set of baseline toxicological reports and Soil Guideline Values (SGVs) for contaminants of concern present on land affected by petroleum hydrocarbons.

The basis of the framework is the United States Total Petroleum Hydrocarbon Criteria Working Group (TPHCWG) approach, which is already used extensively within the UK. The TPHCWG approach will be modified for the UK and extended to consider the work of the American Petroleum Institute (API) on heavier hydrocarbon fractions. The approach in this document has been developed as part of the Environment Agency's Contaminated Land Exposure Assessment (CLEA) science programme. The framework and forthcoming reviews of contaminant toxicology and fate and behaviour will be used in the derivation of SGVs for petroleum hydrocarbons.

The TPHCWG method uses a combination of indicator compounds and 13 petroleum hydrocarbon fractions. Incorporation of the API method would add another three fractions. Indicator compounds represent the most toxic contaminants and those found most frequently at petroleum-hydrocarbon contaminated sites. Assessment of fractions addresses threshold toxicity only. The toxicological basis of each fraction, the associated fate and transport data and application of the CLEA model will be reviewed as part of a UK adaptation of the TPHCWG method.

The responses to the Environment Agency's consultation on this issue indicated a high degree of variability in the data associated with the more complex analytical methods for characterising and quantifying petroleum hydrocarbons. However, methods that can achieve required standards and performance criteria for the analysis of petroleum hydrocarbons in soil are available and the Standing Committee of Analysts (SCA) is developing guidance. This will help to improve consistency in the reporting of analytical results and the overall performance of analytical test methods.

Aesthetic issues, such as odour and visual impact, which might require consideration at sites affected by petroleum contamination, are not covered by this framework. Whilst these issues are important, aesthetics are excluded from Part IIA of the Environmental Protection Act 1990, with respect to human health, and are beyond the scope of the CLEA programme, which is concerned with the toxic health effects of long-term exposure to soil contaminants.

We trust you will find this document useful in your work and that it sets out a clear way forward for the Environment Agency's work in this important area.

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ABBREVIATIONS

DRO	Diesel range organics
GRO	Gasoline range organics
HI	Hazard index
HQ	Hazard quotient
HCV	Heath criteria value
ID	Index Dose
MADEP	Massachusetts Department of Environmental Protection
MCERTS	Monitoring Certification Scheme
MDI	Mean daily intake
SCA	Standing Committee of Analysts
SGV	Soil Guideline Value
TDI	Tolerable daily intake
TDSI	Tolerable daily soil intake
TPH	Total petroleum hydrocarbons
TPHCWG	Total Petroleum Hydrocarbon Criteria Working Group

1 INTRODUCTION

Purpose of this document

1.1 This document sets out the Environment Agency's (the Agency's) approach for evaluating potential risks to human health from petroleum contaminated soils. It is intended for practitioners dealing with land contamination and is to be considered alongside the risk assessment guidance already published as part of the Contaminated Land Exposure Assessment (CLEA) science programme.

1.2 This document has been developed following a wide consultation with industry, Government, academia and other independent experts on the guiding principles for evaluating the human health risks from petroleum hydrocarbons in soils (Environment Agency, 2003). Development of the approach has been informed by the consultation comments received (Environment Agency, 2004a), a subsequent expert workshop that discussed the issues raised in the consultation (Environment Agency, 2004b) and through technical discussions with key stakeholders.

1.3 This document presents the framework that the Environment Agency will use for the preparation of detailed toxicological and fate and behaviour reviews for substances and petroleum fractions that are representative of petroleum contamination. The Environment Agency will use these various components to derive Soil Guideline Values (SGVs) for petroleum hydrocarbons.

1.4 Health criteria values or SGVs for petroleum in soils are not presented in this document. However the approach that will be adopted for deriving values for use in health risk assessment from petroleum contamination in soil is described, along with the future programme of work.

The need and opportunity for change

1.5 Unacceptable risks to human health and the environment from historic land contamination are being addressed in the UK through Part IIA of the Environmental Protection Act 1990 (DETR, 2000). Further context and background to the technical issues of petroleum hydrocarbons in soil, and the need for the development of a new approach to risk assessment, were set out in the initial consultation document (Environment Agency, 2003).

Structure of this document

1.6 This document briefly summarises the responses made to the Agency's consultation document (section 2) and the conclusions from a workshop held to discuss key issues (section 3). The resulting framework to derive SGVs for petroleum hydrocarbons is presented in section 4 and supporting references are provided in section 5. In the interests of brevity, readers are referred to the 2003 consultation (Environment Agency, 2003) and other supporting documents for background information.

2 RESPONSE TO THE 2003 CONSULTATION

2.1 Comments on the 2003 consultation paper and the specific issues raised within it were received from a wide range of respondents, including local authority contaminated land officers, environmental professionals/consultancies, analytical laboratories, UK regulators, representatives of the petroleum industry and interested parties from overseas. A full list of the respondents is detailed in the consultation responses summary document (Environment Agency, 2004a).

2.2 The key technical issues that were considered in the consultation included:

- the approach to assessing threshold and non-threshold risk from petroleum hydrocarbons;
- accepted approaches and philosophies of risk assessment and management;
- the availability of analytical methods for the analysis of toxicologically relevant compounds and fractions in petroleum; and
- the costs of implementation and relative benefits in terms of improved decision-making.

2.3 A detailed summary of responses was published in August 2004 (Environment Agency, 2004a) and a brief overview of these responses is provided in paragraphs 2.4 to 2.13.

2.4 Twenty-six consultation responses were received. Consultees welcomed the development of guidance on the human health risk assessment of petroleum hydrocarbon-contaminated soils and the opportunity to input into the Agency's decision making process. Practitioners currently use a variety of approaches in an *ad hoc* manner, highlighting the need for a clear UK position that can be consistently applied to generate comparable assessments.

2.5 Most respondents favoured adoption of a combined indicator and fraction approach within a tiered risk-based framework. The majority view was that specific indicator compounds should be assessed because these are often the key risk drivers at petroleum contaminated sites. Some examples of indicator compounds are presented in Table 2.1. Views were expressed that for threshold toxicity, the assessment of fractions would facilitate a more representative picture of risk at those sites where the origin of the petroleum contamination may be unclear.

Table 2.1 – Some petroleum hydrocarbon indicator compounds

Non-threshold indicator compounds	Threshold indicator compounds
benzene*	toluene*
benzo[*a*]pyrene*	ethylbenzene*
benz[*a*]anthracene	xylene*
benzo[*b*]fluoranthene	naphthalene*
benzo[*k*]fluoranthene	fluoranthene
chrysene	phenanthrene
dibenz[*a,h*]anthracene	pyrene
indeno[1,2,3-*c,d*]pyrene	

* = already published

2.6 The majority of respondents favoured a concurrent (rather than sequential) assessment of indicator compounds and fractions, in line with the requirement of Part IIA to identify all pollutant linkages. However, some involved in the preparation of risk assessments for contaminated sites would prefer a degree of flexibility in how the approach is applied. One suggestion was that an assessment should only require consideration of those compounds/fractions that would be expected to be present based on initial observations, a screening analysis or detailed prior knowledge of the composition of the contamination. A limited number of consultees preferred precedence to be given to the indicator compounds, with the option to consider fractions only at higher tiers of the assessment framework.

2.7 A number of consultees cautioned that although the approach adopted should have scientific integrity, it must be practical in application and not entail excessive costs that would deter the redevelopment of brownfield land. The potential increased costs for analysis and assessment were highlighted by a number of consultees. However, it was also noted that this would be offset by increased confidence in the risk assessments, and that analytical and risk assessment costs were generally less than site investigation and sampling costs. It was suggested that this should be emphasised to developers and that re-emphasis on the tiered approach to risk assessment be made.

2.8 Overall, most respondents thought that fractions should be selected on the basis of their fate and transport properties and the practicality of analysis, providing the approach was protective of human health. With regard to the choice of surrogates[1] for the toxicity of fractions, a number of respondents explicitly expressed the desire for compounds that were frequently encountered at contaminated sites. There was some support from Local Authorities for a precautionary approach that used the most toxic representative surrogate or mixture. It was suggested that the fractions should only consider threshold health effects, as non-threshold effects would be addressed by the indicator compounds.

2.9 There was a mixed response on the issue of additivity across the fractions. Some consultees from environmental consultancy are already using methods that adopt this approach. Others believed that it was too conservative and that additivity should only be assumed when there was evidence that compounds or fractions have the same target or mechanism of toxicity.

2.10 Differing opinions were offered on the need for an aliphatic/aromatic split of petroleum hydrocarbons. Some consultees suggested this was not justified by the additional costs, whereas others pointed out that it avoided adoption of overly-conservative toxicity values for fractions containing both aliphatic and aromatic compounds. Respondents from commercial analytical laboratories indicated that the split was relatively easy to achieve. However, practical experience from risk managers suggested that data are often highly variable and not easily replicated.

2.11 There was general agreement that the analytical requirements of the approaches discussed in the consultation were within current capabilities. The key issue was the need for clear guidance on the outputs and performance criteria that are required. Some laboratories and other consultees requested a prescriptive analytical methodology. However, the SCA (Standing Committee of Analysts) was of the general opinion that 'performance criteria' should be recommended, with freedom given for individual laboratories to apply or adapt existing methodologies to meet the standards. Analytical

[1] A "surrogate" in this context is an individual compound or mixture within each fraction representing the toxicity of the fraction.

costs are expected to increase significantly following adoption of the final framework, but may be anticipated to decrease once the techniques become common practice.

2.12 Aesthetic issues were highlighted as a major concern for those involved in the assessment and redevelopment of petroleum contaminated land. Issues such as staining and odour are drivers for a large proportion of remediation. Guidance on how to assess aesthetics was encouraged, but it was questioned whether this was appropriate within a risk-based framework.

2.13 A large number of consultees requested that methods for human health risk assessment of petroleum hydrocarbons should be integrated with those for environmental risk assessment (including the risks to controlled waters).

3 DEVELOPMENT OF GUIDING PRINCIPLES: SUMMARY OF AN EXPERT WORKSHOP

3.1 The consultation responses were considered at an Environment Agency Workshop held in February 2004 (Environment Agency, 2004b) designed to explore the technical issues in detail, develop consensus on key issues and agree a way forward on a risk assessment framework. Workshop attendees with a variety of regulatory responsibilities, technical expertise and stakeholder interests used breakout groups to address the consultation responses in technical and procedural detail. The workshop conclusions are summarised below by reference to the key consultations issues.

Combined indicator and fraction approach

3.2 The workshop agreed that a combined indicator and fraction approach was appropriate and that:

- indicator compounds should be the most toxic compounds and most prevalent in the petroleum hydrocarbon-contaminated environment;
- health criteria values for fractions will reflect threshold toxicity, the basis of which will be toxicologically relevant surrogate compounds or mixtures;
- SGVs will be developed for indicator compounds and fractions;
- the TPHCWG approach to identifying fractions, based on fate and transport considerations, is most appropriate because indicators will have accounted for the most toxic compounds;
- many practitioners are familiar with the TPHCWG approach, and a framework based on this approach would develop existing knowledge, rather than require a wholesale change.

3.3 Workshop participants discussed the advantages and limitations of simplifying the number of fractions in the TPHCWG framework. It was suggested that reducing the number of fractions would reduce the accuracy and robustness of risk assessments, potentially leading to over-conservatism. From an analytical perspective, simplification makes little difference. For modern GC/MS peak integration techniques, this simply represents a change in data presentation. In view of this, it was concluded that the starting point should be the 13 TPHCWG fractions, which could be developed and refined as data become available.

3.4 Adopting the TPHCWG approach might result in additional data analysis costs, but this, it was argued, would lead to greater confidence in the risk assessments. Potentially it would also lead to less conservative risk assessments, with subsequent reductions in remediation costs.

3.5 The workshop concluded that the aromatic and aliphatic fractions should be considered separately owing to differences in their toxicity and fate and transport characteristics. Assuming a standard split between aromatics and aliphatics would oversimplify the analysis, as the division will vary on a site-specific basis. Again, this might result in additional cost but it would lead to greater confidence in the risk assessments.

Specific toxicological considerations

3.6 The surrogate compound for assessing the toxicological properties of a fraction should be the most toxicologically relevant; that is, it should be 'representative' in terms of toxicological properties and be detected relatively frequently at petroleum hydrocarbon contaminated sites. Compounds present within a fraction that exhibit a distinct toxicology (*e.g. n*-hexane, a potent neurotoxin but rarely found in the C_6 fraction unless there has been a specific source) should be identified and considered separately (as an indicator).

3.7 It was suggested that consideration should be given to adding 'hazard quotients' (HQs) across fractions. The HQ for a fraction would be calculated by dividing the measured concentration of the fraction in the environment by the SGV for that fraction. HQs for all fractions could be added together to give an overall Hazard Index. If the Hazard Index were greater than unity there would be a requirement to proceed to the next tier of assessment. This was suggested as a pragmatic approach for petroleum hydrocarbons on grounds of practicality, despite reservations about the scientific robustness of assumed additivity of toxic effects for contaminants with different toxicological endpoints. It was recognised that this is a conservative risk management approach and that assumptions of the validity of such an approach will need testing. The workshop did not discuss whether additivity across fractions would be considered in higher tiers of assessment or whether it would be applied during tier 2 Generic Quantitative Risk Assessment only.

3.8 Even where SGVs for indicators and fractions were not exceeded, the possibility remains of an unacceptable risk from petroleum hydrocarbon contamination because its composition may be poorly understood. For example there may be concerns about the toxicity of compounds present within heavier fractions (*e.g.* the substituted benzacridines, benzocarbazoles and benzothiophenes). Depending on the choice of surrogates for each fraction, the toxicity of these compounds may remain unaddressed. Thus there may be a need to review, assess and refine the framework once implemented.

Sampling and analysis

3.9 There is considerable variation in the results from the laboratory analysis of petroleum hydrocarbons. This is considered to be a function of laboratory quality, variability in the analytical methods used, the extreme complexity of the matrices analysed and current absence of guidance for laboratories on what is required. For example, upon request, many laboratories will provide data for total petroleum hydrocarbons (TPH), gasoline range organics (GRO) and diesel range organics (DRO). However, the exact description of these terms is often vague and individual laboratories apply their own interpretations by reference to the specific methods adopted.

3.10 The introduction of quality requirements for analytical performance criteria should address this situation. The workshop consensus was that the analytical methods and associated skills are available to provide data needed for more complex risk assessment methods. It was also noted that the variability in analysis, large as it is, is far exceeded by the variability introduced during sampling.

3.11 Costs of £50–100 per analysis should not prove prohibitive to site investigation. In many instances these costs should not greatly exceed the cost of an existing analysis for TPH, GRO and DRO. Quality requirements are outlined in the Environment Agency's

Monitoring Certification Scheme (MCERTS) performance standard for laboratories undertaking chemical testing of soil.

3.12 It was considered that for competent laboratories, there are few analytical restrictions on generating data on concentrations of heavily weathered materials. As previously mentioned, the main requirement is to give clear instructions to analytical laboratories about what is required, including for the heavy-end fractions.

Costs and implementation

3.13 A concurrent approach to indicators and fractions is practical and not prohibitively expensive. This approach has already been used in risk assessments, demonstrating consistency with the regulatory requirements of Part IIA.

3.14 It was recognised that there will be an initial increase in costs associated with the new approach. This will arise through increased analytical costs, adoption of quality assured performance based criteria (MCERTS, where appropriate) and more data analysis for use in the risk assessment. The initial rise in costs is not considered to be prohibitive and would be expected to fall as an increasing number of laboratories adopt these methods. The benefits include greater confidence in the risk assessment output and, potentially, a less conservative risk management plan. This, in turn, may result in less material requiring remediation, thereby reducing the costs of site clean-up.

3.15 Increased costs should help to focus site investigations, optimising time and effort. It was acknowledged that, in some instances, this might lead to a reduction in the quality of some risk assessments. For example, a less comprehensive sampling programme might be adopted to offset the increased costs of chemical analysis and risk assessment. Regulators need to be aware of this issue as they will be using risk assessments to inform their decisions.

3.16 Adoption of the new approach will increase consistency in both the risk assessment process and the evaluation undertaken by the regulators. In the absence of guidance, many risk assessors have attempted to provide what they think the regulators require. Standardising the approach will help risk assessors to produce what is required and reduce the regulatory time and costs. In summary, therefore, it is considered that the benefits of introducing a standardised, more comprehensive approach far outweigh the increase in costs.

3.17 Aesthetic issues will vary from site to site, making it particularly difficult to develop generic guidance. While several consultation responses noted that remediation is often governed by aesthetic issues, it was unclear whether these aspects should be covered by this framework document. Given that the CLEA programme covers the toxicological risks of chemical contaminants to human health only, aesthetic issues are excluded from this framework. The workshop noted:

- aesthetics are not within the scope of Part IIA. Table A of the English statutory guidance (DETR, 2000) sets out descriptions of harm which are to be regarded as "significant harm", and for human beings this means effects such as death, disease, impairment of reproductive function, and serious injury, rather than discomfort, or odour;
- aesthetic factors can contribute to overall health impact;

- odour thresholds may be incorporated into some quantification of aesthetic impact; and
- a wider approach to dealing with aesthetic impacts at contaminated sites (not just for petroleum hydrocarbon contaminated land) is required.

However, aesthetics are not matters for this technical guidance framework.

3.18 There is a need to address uncertainties in petroleum hydrocarbon risk assessments. The Environment Agency has already published guidance on soil sampling for the assessment of contaminated land (Environment Agency, 2001a and b). Concurrently with this framework, the guidance being developed by the Standing Committee of Analysts (SCA) will improve the repeatability and performance of analytical methods. Addressing these areas will help to improve the reliability of data, increasing confidence in the subsequent risk assessment.

Recommendations

3.19 Following the workshop and clarification over these issues, the Environment Agency committed to:

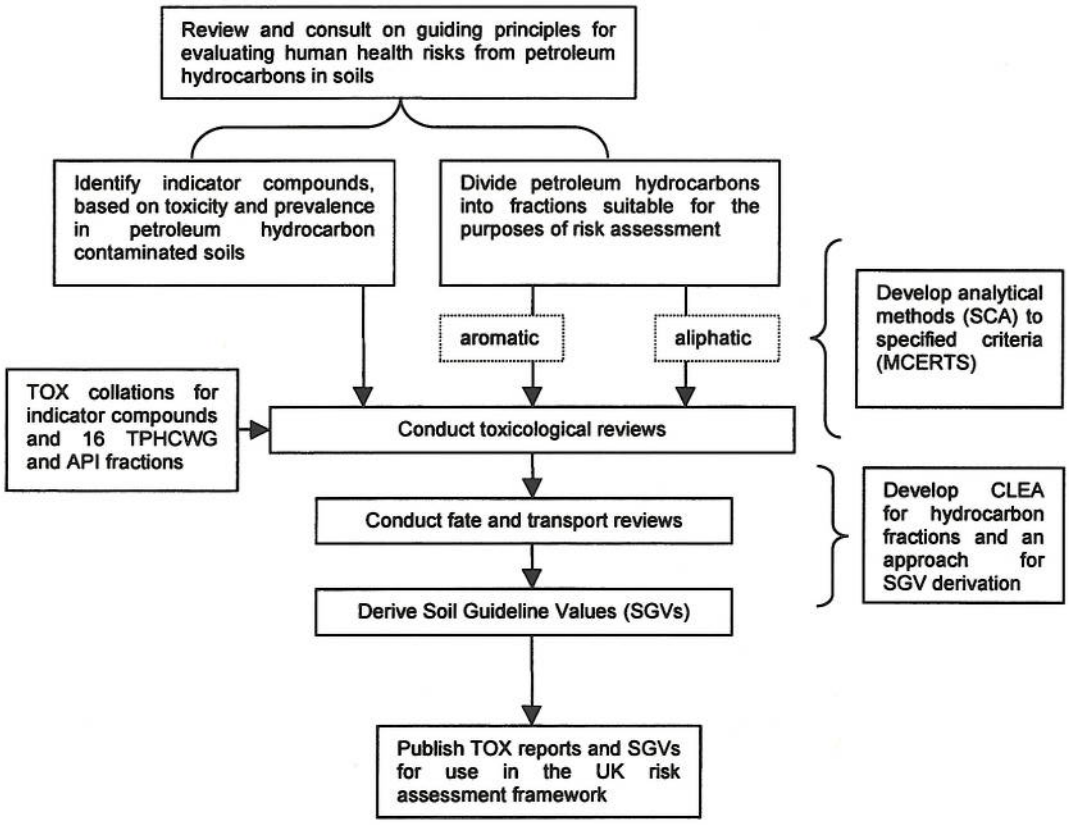
- developing the framework in light of the consultation responses, workshop discussions and through liaison with key stakeholders;
- undertaking evaluations of the toxicology of petroleum hydrocarbons;
- reviewing petroleum hydrocarbons fate and transport data;
- developing Soil Guideline Values for petroleum hydrocarbons; and
- providing practical guidance on petroleum hydrocarbons risk assessment.

4 THE FRAMEWORK

Introduction

4.1 The conclusions of the consultation and workshop indicate that adoption of the TPHCWG approach in the UK would improve risk assessments without prohibiting development. Many practitioners indicated that similar approaches have already been successfully used. In view of this, the Environment Agency will apply the basis of the TPHCWG approach, as modified by the American Petroleum Institute (API) to include heavier fractions, in line with UK policies on analytical conventions, land contamination and derivation of health criteria values and SGVs (Figure 4.1). This chapter sets out the framework and the follow-on programme of work.

Figure 4.1 – Developing the UK Approach



4.2 In adopting the modified TPHCWG approach, it is useful to provide an overview of the key issues that need to be taken into account. The work of the TPHCWG is discussed in the initial consultation document (Environment Agency, 2003) and a brief overview is presented in paragraphs 4.3 and 4.4. The work of the API, in developing a methodology for risk assessing the heavier fractions, is discussed in paragraphs 4.5 and 4.6.

The TPHCWG Framework

4.3 The TPHCWG was established in 1993 as a US national *ad hoc* consortium with representation from the oil and gas industry, the consulting community, the military, academia and the US regulatory agencies to 'develop scientifically defensible

information for establishing soil cleanup levels protective of human health at hydrocarbon-contaminated sites' (TPHCWG, 1997a; Twerdok, 1999).

4.4 The TPHCWG approach gives priority to the assessment of non-threshold compounds likely to be present at sites. These 'indicator compounds' include benzene, 1,3-butadiene, and individual carcinogenic polynuclear aromatic hydrocarbons (PAHs). In summary:

- TPHCWG considered whether human health toxicity associated with petroleum contamination should be evaluated using toxicity data on the whole product, on a fraction, or on indicator compounds (TPHCWG, 1999). The whole product method was considered appropriate for fresh spills not subject to weathering.

- For the more common problem of weathered hydrocarbon products, a hybrid method was developed that uses fractions and carcinogenic (non-threshold) indicator compounds. TPHCWG supports the use of appropriate indicator compounds, based on the type of petroleum identified at the site (*e.g.* benzene for gasoline sites, PAHs for heavy oil sites).

- TPHCWG established its petroleum hydrocarbon fractions on the basis of the fate and transport properties of the compounds (TPHCWG, 1997a). The fractions selected are based on equivalent carbon (EC)[2] numbers and are considered to be closely related to compound mobility in the environment (TPHCWG, 1999).

- In considering the properties of petroleum constituents, the aromatic compounds tend to be more soluble in water and slightly less volatile than aliphatic compounds with similar EC numbers. On this basis, TPHCWG divided petroleum constituents into aromatic and aliphatic hydrocarbon fractions.

- In the TPHCWG approach, the aromatic and aliphatic fractions are further divided into 13 transport fractions, with leaching and volatilisation factors that differ by approximately one order of magnitude (TPHCWG, 1999).

- The recommended analytical method for petroleum hydrocarbon fractions is the 'direct method' (AEHS, 2000), a GC method developed by TPHCWG for the 13 fractions. The first step of the direct method includes TPH quantification and identification of contamination type and EC number distribution. If more detailed data are needed, subsequent steps can be followed to quantify the 13 fractions.

- The threshold toxicity of each of the 13 fractions is represented by reference doses (RfDs)[3] and reference concentrations (RfCs)[4] for 'surrogate' compounds or

[2] The equivalent carbon (EC) number of an hydrocarbon is related to its boiling point (b.p.) normalised to the boiling point of an *n*-alkane series, or its retention time on a non-polar b.p. gas chromatographic (GC) column. For hydrocarbons where the boiling points are known, an EC can be calculated. Hexane contains six carbon atoms and has a boiling point of 69°C and an EC number of 6. Benzene also contains 6 carbon atoms and has a boiling point of 80°C. Based on benzene's b.p. and its retention time on a b.p. GC column, benzene's EC number is 6.5. This approach offers a more appropriate differentiation between hydrocarbons. For hydrocarbons with higher relative carbon number indices, the disparity (in terms of EC) between aliphatic and aromatic hydrocarbons is substantial (after Komor, 1998).

[3] An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime.

mixtures. A surrogate is an individual compound or mixture within each fraction deemed to represent the toxicity of the fraction. TPHCWG preferred the use of mixtures as surrogates, as they allow for the interactions between compounds within the fraction. For fractions exhibiting similar toxicity, the same toxicity criterion is applied to each fraction. In this way, the toxicity of petroleum hydrocarbon in soil can be estimated by quantifying seven broader fractions. However, TPHCWG recommended (TPHCWG, 1999) quantification of all 13 fractions, thus enabling the detailed modelling of the potential for human exposure owing to different transport properties.

- In using fraction-specific, threshold reference doses (RfDs) and reference concentrations (RfCs), TPHCWG assumed that the toxicity of all compounds present in a fraction does not vary significantly from the toxicity of the surrogate compound. The TPHCWG approach assumes additivity of non-carcinogenic toxicity across the fractions as this would be protective of human health, even though not all fractions exert toxicity on the same target organ, (TPHCWG, 1999).

American Petroleum Institute

4.5 Following the publication of the TPHCWG methodology, the API reviewed the suitability of this methodology for evaluating human health risks from petroleum contamination at oil exploration and production (E&P) facilities (API, 2001). The API found that the TPHCWG approach was suitable for refined products, such as petrol and diesel, but was not suitable for the heavier petroleum fractions associated with mineral oils, petroleum jelly and crude oil. The API resolved this by modifying the TPHCWG fractions on the following basis:

(1) The >EC_{21} to EC_{35} aromatic carbon number fraction was replaced by a >EC_{21} to EC_{44} carbon number fraction.

(2) The >EC_{16} to EC_{35} aliphatic carbon number fraction was replaced by a >EC_{16} to EC_{44} carbon number fraction.

(3) A EC_{44+} carbon number fraction was added that included both aliphatic and aromatic hydrocarbons since it was not physically possible to separate hydrocarbons of this size into separate fractions and the toxicity data were only available for the vacuum residuum[5] as a whole. Most of the resins and asphaltenes reside in the EC_{44+} carbon number fraction.

4.6 The API found that there was a general paucity of data on the fate and transport and toxicology of these heavier fractions. For the EC_{35} to EC_{44} fractions this was addressed through assigning the characteristics of the next closest aliphatic (>EC_{16} to EC_{35}) or aromatic (>EC_{21} to EC_{35}) carbon number fractions. This was recognized as a conservative approach, as the extended fractions (up to EC_{44}) are heavier and less mobile. In the absence of toxicity data for the EC_{44+} fraction, a conservative oral RfD of 0.03 mg kg^{-1} bw day^{-1} and a dermal RfD of 0.8 mg kg^{-1} bw day^{-1} was proposed, based on

[4] An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime.

[5] The hydrocarbon fraction with carbon numbers greater than C44 (i.e., C44+) is sometimes called the vacuum residuum, since it contains the compounds remaining after the vacuum distillation of crude oil (API, 2001).

the toxicity of pyrene (used as the basis of the TPHCWG aromatic EC_{16-21} and EC_{21-35} fractions). The API derived specific fate and transport data for the EC_{44+} fraction.

Health criteria values for contaminated soils in the UK

Overview

4.7 In the UK authoritative health criteria values (HCVs) for each soil contaminant are established through a review of the scientific literature and published in the TOX reports '*Contaminants in soil: Collation of Toxicological Data and Intake Values for Humans*'. HCVs are protective of human health, are used in the derivation of Soil Guideline Values (SGVs), and can be used for site-specific risk assessment. Report CLR9 (Defra and Environment Agency, 2002b) provides the framework for the derivation of HCVs.

4.8 The following health criteria value is derived for non-threshold contaminants:

- an Index Dose (ID).

The index dose represents a dose that poses a minimal risk level from possible exposure to contaminants in soil.

4.9 The following health criteria value is derived for threshold contaminants:

- a tolerable daily soil intake (TDSI).

The TDSI is defined as the difference between the tolerable daily intake (TDI) and the background mean daily intake (MDI). The only exception to this is when the MDI is greater than or equal to 80% of the TDI, in which case the TDSI is set at 20% of the TDI.

4.10 For petroleum contaminated soils, it is therefore necessary to review the toxicological basis of the modified TPHCWG fractions to ensure that health criteria values are derived in line with UK policy, taking into account those points raised in the consultation and the expert workshop.

UK health criteria values for petroleum-contaminated soils

4.11 Health criteria values are required for indicator compounds and the hydrocarbon fractions. Indicator compounds include threshold and non-threshold contaminants. HCVs have already been published for some of the indicator compounds identified in Table 2.1. Values based on non-threshold toxicity have been published for benzo[*a*]pyrene and benzene (Defra and Environment Agency, 2002c, 2003a). Values based on threshold toxicity have been published for naphthalene, toluene, ethylbenzene and xylene (Defra and Environment Agency, 2003b, 2004a,b and c). The list of indicator compounds in Table 2.1 is not exhaustive and additional indicator compounds may be identified for consideration in the future.

4.12 Based on the assumption of threshold toxicity, the intention is to derive tolerable daily intake (TDI) and mean daily intake (MDI) values for the fractions. The surrogate compounds used by the TPHCWG and the threshold toxicity values for each fraction are summarised in Table 4.1.

Table 4.1 - Oral and inhalation threshold toxicity values for petroleum hydrocarbon fractions for the TPHCWG (1997b), after MADEP (2002a; STSC, 2002)[a]

Exposure route	Carbon range[b]	Toxicity value	Surrogate and basis for TPHCWG derivation
Oral	**aliphatic**	**(mg kg^{-1} bw d^{-1})**	
	EC_5 - EC_8	5	*n*-Heptane / commercial hexane(s)
	$EC_{>8}$ - EC_{16}	0.1	Dearomatised petroleum stream
	$EC_{>16}$ - EC_{35}	2	Basis of 7 highly refined mineral oil studies
	aromatic		
	$EC_{>5}$ - EC_8	0.2	Toluene (C_6 benzene evaluated separately as a carcinogen)
	$EC_{>8}$-EC_{16}	0.04	Considered USEPA derived RfDs for isopropylbenzene, acenaphthene, biphenyl, fluorene, anthracene, fluoranthene, naphthalene and pyrene. 4 of these compounds had RfDs of 0.04 mg kg^{-1} bw d^{-1}
	$EC_{>16}$- C_{35}	0.03	Pyrene
Inhalation	**aliphatic**	**(mg m^{-3})**	
	EC_5 - EC_8	18.4	Commercial hexane
	$EC_{>8}$-EC_{16}	1	Isoparaffin mixture
	$EC_{>16}$ - EC_{35}	NA[c]	Inhalation exposure may depend on inhaled particulate matter
	aromatic		
	$EC_{>5}$ - EC_8	0.4	Fraction-specific RfC (C_6 benzene separately)
	$EC_{>8}$ - EC_{16}	0.2	C_9- C_{16} aromatic mixture surrogate
	$EC_{>16}$-C_{35}	NA[c]	Inhalation exposure may depend on inhaled particulate matter

[a] this table is for information only and does not represent the UK position
[b] equivalent carbon ranges
[c] not applicable to inhalation exposures of free compounds since compounds not volatile

4.13 The work of the API highlights the need to consider the risks from the heavier petroleum hydrocarbon fractions. The Environment Agency proposes to take these considerations into account in its framework, by adding three further fractions onto that of the original TPHCWG methodology. Rather than adopt the API's approach of simply extending the heaviest aromatic and aliphatic TPHCWG fractions up to EC_{44}, the Agency proposes aromatic and aliphatic fractions, covering $>EC_{35}$ to EC_{44}, and a new combined aliphatic and aromatic fraction $>EC_{44}$ to EC_{70}. Thus in total there would be 16 fractions, as detailed in Table 4.2 below.

Table 4.2 – Petroleum hydrocarbon fractions for use in UK human health risk assessment, based on Equivalent Carbon (EC) number

Aliphatic fractions	Aromatic fractions
>5-6	>5-7
>6-8	>7-8
>8-10	>8-10
>10-12	>10-12
>12-16	>12-16
>16-35	>16-21
>35-44	>21-35
	>35-44
>44-70	

4.14 Through the CLEA programme the Environment Agency will review the baseline toxicological studies for the 16 fractions in order to develop HCVs in line with UK policy. The purpose and benefit of the EC_{44} to EC_{70} fraction may be reconsidered following these toxicological reviews. A number of the surrogates used by the TPHCWG in their evaluation of petroleum fractions are already included in the current CLEA programme of work (Defra and Environment Agency, 2002a). Others may need to be added contingent on the toxicological review of baseline studies supporting the separation into 16 fractions.

4.15 Given the availability of the TPHCWG toxicity values, the need for a UK re-evaluation might seem excessive. However, since the publication of these values in 1997 there has been a substantial amount of additional work on the toxicology of petroleum hydrocarbons. This is demonstrated in the review of the TPHCWG approach by the Massachusetts Department of Environmental Protection (MADEP, 2002a and b) and the USEPA Superfund Health Risk Technical Support Center (STSC, 2002), and the Dutch National Institute for Public Heath and the Environment (RIVM, 2001) which recommended changes to the toxicity values adopted by the TPHCWG. Thus it is necessary to review the toxicological basis of each fraction to ensure that surrogate compounds are appropriate in a UK context and that health criteria values reflect the most recent evaluations.

Soil Guideline Values for petroleum hydrocarbon contamination

4.16 SGVs are developed through application of the CLEA model (Defra and Environment Agency, 2002d) and the supporting Briefing Notes[6]. The model uses information on the toxicity of soil contaminants (published in TOX collations as HCVs) with estimates of potential exposure by adults and children over long periods of time. Exposure scenarios have been developed for three standard land-uses: residential, allotments and commercial/industrial. By comparing predicted exposure with HCVs, the model is used to generate Soil Guideline Values that establish a contaminant concentration in soil for each land use. Contaminant fate and transport data are required to predict movement in the subsurface and through the ambient air, allowing for estimation of daily exposure.

[6] Available from:
http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/?version=1&lang=_e

4.17 The fate and transport data will be selected through a review of the literature. For individual indicator compounds this is a relatively straightforward process. It is more complex for petroleum hydrocarbon fractions as they are not pure substances and the associated fate and transport data are less clearly defined. The TPHCWG derived physico-chemical data for the 13 fractions (TPHCWG, 1997a). As a minimum these data need to be reviewed, to ensure suitability within a UK context, and data need to be identified for the additional heavier fractions. This work will be addressed through the Agency's ongoing CLEA programme.

4.18 If used correctly, an exceedance of a Soil Guideline Value can indicate a potentially significant risk to human health. However, this does not necessarily imply that there is an actual risk to health, and a risk assessor should take into account site-specific circumstances. Furthermore, if incorrectly applied to a site where the critical pathway or chemical form of the contaminant has not been evaluated, a potentially significant risk might be present even though a Soil Guideline Value is not exceeded. So it is important that a risk assessor uses SGVs as a component of an overall risk assessment and management strategy for a site in accordance with good practice.

Sampling and analysing petroleum contaminated soils

4.19 Sampling and analytical uncertainties can be addressed in part through the adoption of quality assurance and quality control techniques and programmes. The Agency has published guidance on soil sampling (Environment Agency 2001a and b) that should be referred to for guidance.

4.20 A key issue for the analysis of complex environmental samples is the development of a tiered analytical strategy (Pollard *et al.*, 1994). Analyses should be structured and targeted on the analytes of interest. The analytical work is driven by the needs of the risk assessment. For petroleum hydrocarbons, it is not envisaged that complete fractionation will be needed for all samples in all cases. It is the responsibility of the risk assessor to ensure that the analytical strategy adopted is informed and appropriate, taking into account factors such as site history, geology and end use.

4.21 No single universal method of analysis exists for determining petroleum contamination due to the complexity and specificity of the source, which can range from light distillates to heavy, residual fuels. In the US, the Texas Natural Resource Conservation Committee (TNRCC, 2001) direct method (AEHS, 2000) is gaining acceptance for the evaluation of the TPHCWG fractions. When undertaking a site investigation, it might be necessary to assess the suitability of this technique for the heavier fractions. The practicality and relevance of analysing the EC_{44} to EC_{70} fraction will be considered further following the toxicological review, assessments of likely exposure and discussions with the SCA.

4.22 The consultation responses (paragraph 2.11) and expert workshop (paragraph 3.12) highlighted that there are few analytical restrictions for petroleum hydrocarbon in soils. However, it was pointed out that clear guidance on exactly what laboratories should analyse for was required. Analytical techniques for petroleum hydrocarbons are required for the indicator compounds (Table 2.1) and the fractions (Table 4.3). It should be noted that the list of indicator compounds may be expanded to include additional substances frequently found at petroleum-hydrocarbon contaminated sites and those with specific toxicological properties.

4.23 Rather than prescribe analytical methods, the UK preference is to adopt performance criteria for analysis. In England and Wales, under the Agency's Monitoring Certification Scheme (MCERTS), performance standards are designed to improve the quality and reliability of data that are presented to the Environment Agency. Various performance standards have been developed and are managed by the Agency's Monitoring and Assessment Process. Some specific performance standards are operated on behalf of the Agency by SIRA Certification Service (SCS) and UK Accreditation Service (UKAS). The performance standards are based on a number of international and European standards including:

- ISO 17025 for monitoring and equipment testing;
- EN 45004 for inspection;
- EN 45011 for product certification and
- EN45013 for personnel competency;

Further information on MCERTS can be obtained from the Agency's website at www.environment-agency.gov.uk/mcerts.

4.24 The Environment Agency has launched its MCERTS scheme for the chemical testing of soils with publication of Version 2 of the MCERTS performance standard. MCERTS (www.mcerts.net) provides assurance to all stakeholders (*e.g.* laboratories, Local Authorities, consultants, members of the public) of the reliability of data from such tests. Chemical test data on soils are used by the Agency to support its regulatory activities under a number of regimes, such as Part IIA of EPA 1990, Pollution, Prevention and Control (England and Wales Regulations) 2000 and Waste Management Licensing Regulations 1994.

4.25 Analytical methods for environmental analysis are being developed by the Standing Committee of Analysts (SCA). The SCA (www.environment-agency.gov.uk/nls) has recently published methods for the analysis of selected PAHs and of mineral oils following spills to the aquatic environment. A working group has been established to identify methods for the analysis of petroleum hydrocarbons in soils and this will lead to the publication of a 'blue book' of methods for determining the specified indicators and fractions as required.

Practical application

4.26 Professional advisors and consultants undertaking risk assessments at petroleum hydrocarbon-contaminated sites are expected to follow existing guidance on risk assessment (Defra and Environment Agency, 2004d). Throughout, emphasis is placed on the adoption of a tiered approach to risk assessment and analysis and the development of a well-planned and intelligent analytical strategy during site investigation. The SGVs developed for indicator compounds and petroleum fractions will be values that can be used in connection with the formal requirements of Part IIA of the Environmental Protection Act 1990 ("the contaminated land regime"). However, they will also be relevant to many situations where the effect of land contamination on human health is an issue, such as in planning applications when judging the need for action to ensure that land after development does not pose unacceptable risks to health.

4.27 In applying the existing guidance for petroleum hydrocarbon contamination, consideration needs to be given to data interpretation. The following paragraphs describe how risk assessors will be expected to calculate concentrations of indicators and fractions from analytical data and the intended approach to dealing with the issue of additivity across the fractions.

4.28 In a hypothetical case where a site is believed to be contaminated with an unknown mixture of petroleum hydrocarbons, analysis of soil for both indicator compounds and petroleum fractions would be undertaken. Where the site conditions meet the requirements of the assumptions used in the generation of the SGVs, the upper 95% confidence limit of the measured mean concentrations (see Appendix A of Defra and Environment Agency, 2002e) can be compared with the SGVs. When calculating soil contaminant concentrations, indicator compounds should not be subtracted from the corresponding fractions. This is because indicator substances would be expected to contribute to the threshold toxicity of the fraction. In summary:

- measure concentrations of indicators and compare with SGVs for indicators;
- measure concentrations of fractions and compare with SGVs for those fractions (without subtracting concentrations of indicators included in those fractions and without adding the concentrations of indicators to the concentrations of the fractions).

4.29 Depending on circumstances, where a SGV is exceeded the site assessment can proceed to a site-specific risk assessment and/or directly to remediation. However, even where SGVs for individual fractions are not exceeded, potential additivity of toxicological effects between the fractions means that a significant possibility of significant harm could exist. To address this issue the hazard quotient (HQ) for each fraction should be calculated by dividing the measured concentration of the fraction by the SGV. The HQs are then added to form a hazard index (HI). Where the HI exceeds unity, this can indicate a potentially significant risk to human health and the investigation proceeds to the next stage (remediation or further assessment). Calculation of the HQ and HI is shown in Figure 4.2

Figure 4.2 – Calculation of the Hazard Quotient and Hazard Index

$$HI = \sum_{F_i=1}^{16} HQ\ F_i = \frac{Measured\ concentration\ F_i\ (mg\,kg^{-1})}{SGV\ F_i\ (mg\,kg^{-1})}$$

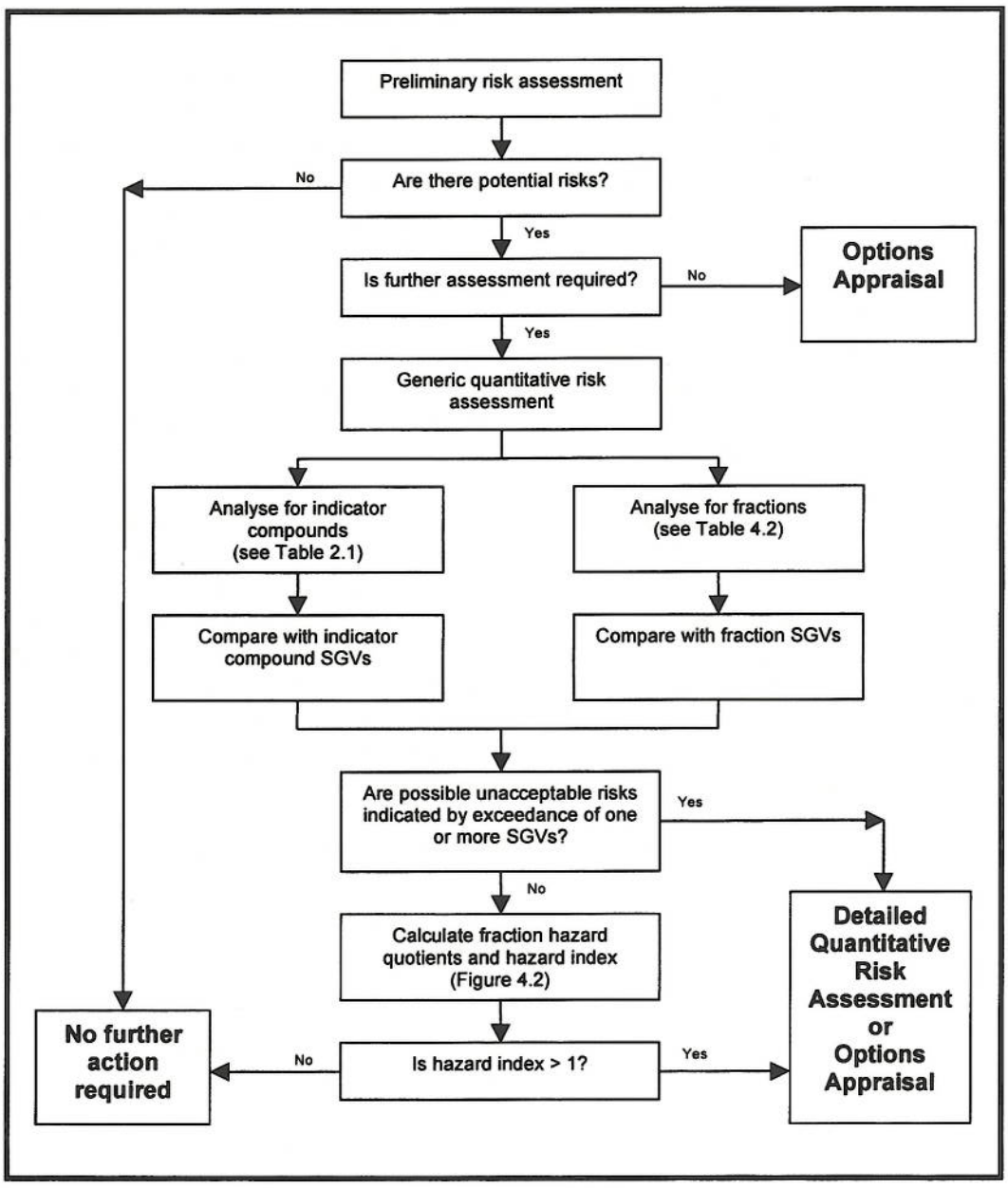
where HI = Hazard Index
HQ = Hazard Quotient
F_i = Fraction $_i$
SGV = Soil Guideline Value

4.30 Fractions exhibiting different toxicological properties might be excluded from the hazard index. Guidance on this issue will be published with the petroleum hydrocarbon fraction health criteria values.

4.31 It is expected that the approach to additivity will be typically applied to all tiers of assessment. This will minimise confusion and inconsistency arising from individual judgements on fraction toxicology.

4.32 An outline of the risk assessment procedure is presented in Figure 4.3.

Figure 4.3 – Petroleum hydrocarbons risk assessment[7]



[7] This framework is based on the principles outlined in Defra and Environment Agency, 2004d.

5 CONCLUSIONS

5.1 The Environment Agency has consulted widely on the approach to assessing the risks to human health from petroleum hydrocarbons in soils. The issues are wide ranging and significant because these are among the most common contaminants at sites affected by land contamination. Through consultation, an expert workshop and this document, the Agency will adopt an approach that:

- applies the modified TPHCWG approach within a UK context;
- uses indicator compounds and petroleum fractions concurrently;
- splits the aromatic and aliphatic portion of hydrocarbons;
- considers 16 fractions for the assessment of threshold toxicity;
- assumes additivity of toxicological effects across all fractions, unless there are scientific data to the contrary;
- is aligned with the risk assessment policy and guidance issued by Defra and the Environment Agency;
- facilitates the development of analytical methods and performance criteria required for use in risk assessment;
- is practical and cost-effective given the step change required; and
- is reviewed on an ongoing basis to assess performance and in the light of scientific advances.

5.2 The points listed above form the basis of the Agency's programme of work on petroleum hydrocarbons in soil and human health. The next step is to review the toxicology of petroleum hydrocarbon mixtures to generate health criteria values for fractions and identify those with similar toxicology. This will be followed by identification of appropriate physicochemical data for use within the CLEA model and consideration of an approach for deriving SGVs for petroleum hydrocarbon fractions. Once complete these components will enable the Agency to derive Soil Guideline Values for petroleum hydrocarbons.

5.3 The Environment Agency will continue to liase with industry, regulators, laboratories and all other interested parties. Views on the development of the approach in this document and feedback on practical experiences are very welcome and will be used by the Agency to inform and monitor the implementation of the framework. All feedback should be emailed to clea@environment-agency.gov.uk.

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Transparency in Risk Assessments - Presenting the 'Expectation Value' of Post - Closure Risks from Radioactive Waste Repositories

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Introduction

The Environment Agency of England and Wales (the 'Agency') became operational on 1st April 1996 as one of Europe's largest and most powerful environmental protection agencies. It has an extremely broad regulatory remit covering aspects of flood defence, integrated pollution control, water quality, waste management, abstraction control, navigation, fisheries, conservation and recreation.

Risk assessment, as a regulatory and management tool plays an essential role in the targeting and prioritisation of this activity, as well as in aiding site-specific decisions on authorisations for abstraction, discharge and/or disposal. From a regulatory perspective, the majority of the Agency's risk assessment activity is focused on critically reviewing risk assessments submitted to the Agency in support of requests for authorisation. With increasing calls for openness in all areas of regulatory decision-making, new demands are being placed on risk assessments with a view to allowing far more transparency and traceability of 'process' and 'content' than has historically been the case.

The Agency is responsible for the licensing of radioactive waste disposal facilities in England and Wales. It has issued guidance on what is expected of an application for an authorisation to dispose of low and intermediate level radioactive waste to land - the 'Guidance on Requirements for Authorisation' (the 'GRA') [1]. The 'GRA' includes a risk target and places a strong emphasis on confidence-building during the preparation and assessment of post-closure safety cases for such facilities. In this paper we discuss a recent study commissioned by the Agency which has

examined the use of the expectation value of risk in assessments and considered ways of improving transparency. We present some specific issues relating to the use of a numerical 'expectation value of risk' and suggest how the transparency of risk assessments aimed at meeting a risk target may be improved, recognising the range of stakeholders involved.

The Role of Risk Assessment and of a Risk Target in Determining Applications for Disposal

The GRA covers all aspects of an application for authorisation and includes 'Principles' and 'Requirements' for different stages of the site characterisation, design and assessment cycle. The Agency recognises that, where appropriate and, in the context of a specific application, there is scope for additional information to be provided to developers on individual topics within the GRA, to aid better definition of the type of material that the Agency would find appropriate and acceptable in a safety case. It will remain the developer's responsibility to determine the final form of any application and to decide on what work to undertake and to report. Any additional information or guidance provided by the Agency must take account of the developer's responsibility and, therefore, must not be overly prescriptive.

A risk assessment is likely to form a central part of any post-closure safety case for a disposal facility. Although basically quantitative, the risk assessment will be dependent on qualitative assumptions which need to be explicitly stated. In some cases it will be necessary to explore the effects of varying these assumptions. It will provide risk estimates that can be used to *inform* a regulatory judgement about the safety of the facility alongside other considerations (qualitative judgements regarding sound science and engineering design, for example). Used in an iterative mode, the risk assessment can also be a valuable tool for prioritising effort on research and development for the disposal facility and structuring the content of the safety case as a whole.

A specific issue arises with adoption of a numerical risk target as a criterion, alongside others, for a disposal facility once the period of control is withdrawn. The GRA adopts an individual risk target of 10^{-6}; that is,

'*after control is withdrawn from the facility, the assessed radiological risk (of a serious radiation-induced health effect) to a representative member of the potentially exposed group at greatest risk should be consistent with a risk target of 1 in a million per year*'.

Where the Agency is satisfied that good engineering and science have been adopted by the operator and the estimated risk is below this target, no further reduction in risk may be sought. If above the target, however, the Agency will need to be satisfied not only that an appropriate level of safety is assured, but also that any further improvements in safety could be achieved *only* at disproportionate cost.

Although the GRA focuses primarily on the radiological risk to human beings, the Environment Agency is currently contributing to international research on potentially harmful effects on organisms other than humans [2].

The Presentation of Numerical Risk Estimates

Risk is a concept that is used in a variety of ways in different contexts and by different stakeholders in the debate concerning radioactive waste and in the decision process concerning specific proposals for a disposal facility. As the regulator, the Agency needs to communicate with all stakeholders, and this entails understanding the different perceptions of stakeholders as a basis for effective communication. Moves to improve the transparency of risk assessments that adopt numerical criteria require a number of approaches to building confidence in the regulatory decision, including an examination of how assessed risks are presented in relation to the risk target.

A vast public perception literature exists to guide risk assessors on how such information may be received by stakeholders and recent experience in the UK would suggest that we need to look afresh as to how environmental risks are best framed and articulated. The House of Lords Select Committee on Science and Technology in its recent review of radioactive waste management in the UK [3] has provided some useful insights on the use of a risk target, risk perception and risk aversion:

- Several participants suggested that the use of numerical estimates of risk should only form part of the risk evaluation and should be treated with caution because few people have sufficient understanding of what the numbers represent. Drawing performance parameters together in a single risk estimate might obscure the significance of a particular element of the overall system which could be critical to the long-term safety.

- There was debate over the long-term acceptability of the current risk target of 10^{-6}. Some participants believed that 10^{-6} would continue to be acceptable. Others expressed the view that as the hazards of life in an industrialised society have diminished, tolerance of risk, particularly risk associated with technology, has also diminished. There was also a concern that we do not know what future generations might regard as an acceptable level of risk.

- Significantly, the Select Committee considered it inadequate to have only a single numerical risk target for assessing the long-term safety of a repository. There were concerns that the meaning of the risk target was unclear and that it did not address aspects such as cumulative releases of radionuclides to the surface environment; the extent of environmental contamination; or potentially deleterious effects on organisms other than humans. The Select Committee recommended that, in any future repository programme in the UK, the current

UK standards for long-term safety of a deep repository should be revised and expanded in parallel with progress on repository research and development.

- Evidence relating to risk perception was also presented. Disposal of radioactive waste was considered to have almost all the negative characteristics as far as perceived risks are concerned. The risks are not voluntarily accepted at the level of the individual, the benefits and costs are not seen clearly alongside each other, the nature of some risks, such as cancer, have a particular dread factor and the degree of risk is subject to uncertainty to which the public seem to have a particular aversion. It was however noted in the report that there is considerable debate over public tolerance or acceptance of different types of risk.

Overall the Select Committee's report has raised some significant and interesting issues with regard to use of a risk target and the need for judging the long-term safety of a repository. The work reported in this paper will aid the Agency's input to any debate on risk and risk criteria in relation to deep disposal of radioactive waste.

Estimating and Presenting an Expectation Value of Risk

An important risk paradigm used as a tool for developing understanding of a disposal system is the mathematical definition of risk as the consequence multiplied by the probability of occurrence. More formally, the risk R arising from an exposure to radiation is given by:

$$R = P(H_E)\,(H_E \qquad [1]$$

H_E is the effective dose equivalent (representing a weighted sum of organ and tissue doses),

γ is the probability of a serious detrimental health effect per unit effective dose equivalent (the dose-risk conversion factor), and

$P(H_E)$ is the probability of receiving a dose H_E.

In a probabilistic assessment, risk estimation is undertaken many times, with each 'simulation' using a particular set of parameter values sampled from probability density functions (PDFs) that describe the uncertainties and variabilities in different parts of the disposal system.

The result of a probabilistic assessment is thus a set, or distribution, of individual estimates of $(H_E$. For a comparison with a single-value criterion, such as the individual risk target of 10^{-6} presented in the GRA, this distribution must itself be presented as a single value. One way of doing this is to present the arithmetic mean, or 'expectation value' of the risk. The arithmetic mean of the distribution is a

measure of risk often specified in regulations. Collapsing the distribution in this manner, or in any other manner so as to produce a single value, is however potentially problematical because of the loss of information about the shape of the distribution. This is especially the case for highly-skewed distributions.

Other measures of the distribution are possible and, in particular, the form of the tail of the distribution containing the low probability-high consequence events and processes is of interest to regulators and stakeholders. It is, however, difficult to specify criteria in generic regulations that would be applicable to the tail of the distribution in all assessments.

Any risk assessment can only be made transparent by the presentation of the information used to *derive* the distribution of $(H_E$, together with a discussion of the level of confidence that can be attached to the estimated risks. Below, we discuss aspects of the scope of risk assessments and consideration of group risk and risk aversion with improved transparency in mind.

Scope of Risk Assessments

A key element in any risk assessment is the definition of the scope of the assessment in terms of the features, events and processes (FEPs) to be incorporated within the conceptual models and scenarios used in assessment calculations. The term FEPs is broad-brush, but 'features' are essentially characteristics of the disposal system which exist from the outset, 'events' are occurrences which change the behaviour of the system at a particular time and 'processes' modify the system and/or its behaviour over a period of time. A variety of approaches have been developed to provide traceable and transparent documentation of the FEPs accounted for and the basis for excluding other FEPs. Because of the long time-scales involved and the spatial scale of the overall disposal system, there will always be uncertainties as to which FEPs should be included in an assessment. FEPs are potentially subject to both variability and uncertainty. Two broad types of uncertainty are recognised:

- those uncertainties which clearly apply to the magnitude, scale or extent of the feature, event or process; and
- those which may or may not apply to the feature, event or process and where, for events and processes, there may be uncertainty regarding timing as well as about magnitude.

The first of these has been termed *epistemic* (related to knowledge) and the second *aleatory* (related to chance).

The likelihood of future human actions such as intrusion into a radioactive waste repository are open to speculation, where PDFs of magnitude and timing are matters of arbitrary judgement, based on assumptions about future societal behaviour and loss of information about the site. Extreme natural events and processes (e.g. seismic events, vulcanism, or meteorite strikes) are likely to be more predictable in

terms of the relationship between frequency and severity than human actions. The consequences of human intrusion into a repository could be as great as, or greater than, those arising from natural events or processes. A single performance assessment that includes all types of FEP, together with their associated variability and uncertainty, is liable to produce a distribution where the high-consequence tail is dominated by FEPs all of which are low probability and stochastic and some of which may also be speculative. The shape of the high-consequence tail may have a major effect on the expectation value of risk.

Undue speculation is not an appropriate basis for regulation. This has been recognised in assessments undertaken for nuclear power stations and for transport and infrastructure developments. In the former, probabilistic risk assessments are undertaken for failure of one or more components of the system, including operator failures in responding to anomalous events. These types of failure are termed *design basis accidents*. Separate assessments are undertaken for *beyond design basis accidents* which consider a range of extreme events and the extent to which the design would accommodate them. Such assessments examine, as appropriate, the frequency and the consequences of the event. If the consequences appear incompatible with the frequency, steps may be taken to modify the design even though the event may still be regarded as beyond the design basis. A risk assessment for a nuclear plant will normally take into account the consequences of beyond design basis events.

Assessments for infrastructure developments, such as the construction of a new airport or development of a refinery, are also limited in scope by a *maximum credible accident*. Consequence calculations may be performed for other initiating events or sequences of events, but they are not normally included within an assessment of risk either to individuals or to society.

It may be beneficial to adopt an analogous approach in risk assessments for a radioactive waste disposal facility. In order to make progress with the design and safety case for the facility, including the risk assessment, it may be appropriate to limit the range of FEPs which are initially taken into account. Low probability or speculative events and processes for which no data can be derived from site characterisation or laboratory experiments might be more suitably assessed through 'what-if' calculations outside the risk assessment. Transparency might be enhanced by a wide-ranging debate, involving developer, regulator and other stakeholders, about the types of low probability or speculative events and processes to be examined in this way. If there was a consensus view that a particular event or process of this nature should be given greater emphasis, steps might be taken to modify the safety case, and possibly the design of the facility. The given event or process might still not be incorporated in the risk assessment. The developer would maintain a basis for proceeding, while stakeholders would have the assurance that a mechanism existed for addressing their concerns in the overall safety case presented to the regulator.

Group Risk

Risks to groups rather than individuals are relatively easy to assess for *current* populations around proposed development sites. However, over the long time-scales considered in the assessments of post-closure performance for radioactive waste disposal sites, the location and composition of population groups grow more and more uncertain. During the development of a repository, illustrative assessments of group risks may be useful for comparing alternative designs and explaining design decisions. By proposing that assessments of collective dose should be divided into blocks of limited ranges of dose and time, ICRP 77 [4] suggests an approach that might help make these assessments more transparent. However, such calculations may not be sufficiently robust for regulatory decision-making.

Risk Aversion

There is general acceptance that events with greater consequences are only acceptable at proportionately lower frequency. If strict proportion is maintained, this implies that the product of the consequences and the frequency should be constant. Risk aversion would imply that events with greater consequences are only acceptable at a frequency which is more than proportionately lower. This in turn would imply a greater than proportionate allocation of resources to reducing the frequency and/or the consequences of higher consequence events.

One way in which greater consequences can arise from an event is if more people are injured or killed. Other ways would be more property damage or more environmental damage. An assessment of a major hazard site may, for example, show that the risk to any one individual living or working near the site is acceptable, but that the development is unacceptable because large numbers of people would be exposed to the risk. This conclusion does not in itself imply risk aversion.

Regulatory regimes in certain other countries, e.g. the Netherlands, do invoke risk aversion, that is, a greater than proportionate allocation of resources towards higher consequence events. The extent to which risk aversion is applied, if at all, is a value judgement. The Agency has considered the merits of an approach involving risk aversion in the context of radioactive waste disposal, but has provisionally concluded that there is no basis for adopting such an approach, although it is continuing to consider the matter.

Conclusions

Recent work commissioned by the Environment Agency has examined the use of the expectation value of risk in safety assessments for a radioactive waste disposal facility and has considered ways of improving transparency. Any risk assessment can only be made transparent by the presentation of the information used to *derive*

the distribution of risk (H_E), together with a discussion of the level of confidence that can be attached to the estimated risks.

The study has concluded that the expectation value is an appropriate measure of risk for comparison with a single-value criterion, provided that the scope of the assessment does not involve undue speculation regarding the FEPs to be included. Low probability or speculative events and processes for which no data can be derived from site characterisation or laboratory experiments might be more suitably assessed through 'what-if' calculations outside the risk assessment.

Transparency might be enhanced by a wide-ranging debate, involving developer, regulator and other stakeholders, about the types of low probability or speculative events and processes to be examined in this way. If there was a consensus view that a particular event or process of this nature should be given greater emphasis, steps might be taken to modify the safety case, and possibly the design of the facility. The developer would maintain a basis for proceeding, while stakeholders would have the assurance that a mechanism existed for addressing their concerns in the overall safety case presented to the regulator.

The study also concluded that the uncertainties concerning future populations were likely to be too great for assessments of group risk to be useful in regulatory decision-making. Comparative analyses of group risk may however be beneficial in making and explaining design decisions.

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NATIONAL CENTRE FOR RISK ANALYSIS AND OPTIONS APPRAISAL

Position Paper Number 25

Assessment of the Post-Closure Safety Case Development Programme for the Drigg Low-Level Radioactive Waste Disposal Site: Phase II

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SUMMARY

British Nuclear Fuels plc (BNFL) is currently authorised by the Environment Agency to dispose of solid low-level radioactive waste (LLW) at the Drigg site, in Cumbria. A condition of the Authorisation requires BNFL to provide a new Post-Closure Safety Case (PCSC) in September 2002. The Authorisation also required BNFL to provide a Status Report on the Development of the PCSC (the Status Report) in March 2000.

This document details the outcome of the Agency's review of the Status Report. However, it should be noted that the review of the Status Report is part of a wider review by the Agency of BNFL's PCSC Development Programme. The wider review has been in progress since late 1996 and many issues have already been raised with BNFL in the context of an agreed Issue Resolution Process and have not therefore been reproduced in detail in this report. The Agency also acknowledges that since publication of the Status Report, BNFL has presented the Agency with further information and has revised its approach in several areas.

The Agency accepts that the Status Report is not a completed safety case and has considered the Status Report as a statement of intent by BNFL. The Status Report has been evaluated against published regulatory guidance, with the primary objective to determine whether the 2002 PCSC is likely to provide an adequate basis for continued authorisation. The general conclusion to the Agency's review of the Status Report is that subject to satisfactory resolution of all the issues identified during the Agency's ongoing review of the PCSC Development Programme, BNFL has the potential to assemble a PCSC in 2002 that will provide a sufficiently comprehensive examination of the relevant issues to inform regulatory decision-making. Key points arising from the Agency's evaluation of the Status Report may be summarised as follows:

Quality Assurance: BNFL has a quality assurance regime in place and is continuing to develop procedures controlling the development of the PCSC. However, the Status Report contains insufficient information for the Agency to assess the appropriateness of BNFL's quality assurance system to the PCSC.

Regulatory Interpretation: BNFL's interpretation of available regulatory guidance is incompatible with the regulatory position or incompletely defined in three areas:

- BNFL suggests that planned future vaults are not new developments but are part of an existing facility. The Agency considers that future vaults are new developments.
- BNFL suggests that different criteria should be applied to past and future disposals. The Agency regards the entire disposal facility as a single source in the context of dose calculations and as a single entity in the context of risk calculations. The Agency expects BNFL to present risks both for the whole facility, and for the vaults and trenches separately.
- The Agency considers that the approach described in the Status Report is not entirely consistent with Principle 1 (see section 3.2.1) of the Guidance on Requirements for Authorisation (GRA) regarding the use of passive institutional controls. The Agency expects BNFL to ensure that the PCSC is consistent with the Principles of the GRA.

Comprehensiveness, Integration and Risk Management: BNFL's assessment methodology incorporates a number of features that should help to ensure the PCSC is comprehensive, and the Status Report has for the first time described how BNFL intends to integrate the various components of its programme into the PCSC. However, the Agency is concerned that BNFL is yet to demonstrate an understanding of which processes are likely to dominate radiological risks from Drigg. The Agency expects BNFL to demonstrate that post-closure risk assessment has been used iteratively to refine understanding of system behaviour, identify any necessary risk management measures, and prioritise the PCSC Development Programme.

Optimisation: BNFL has not clearly defined the optimisation studies to be considered in the 2002 PCSC. The Agency encourages BNFL to take a broad view of optimisation and to use the PCSC

to consider a range of options. For example, if disposal of the entire UK LLW inventory is not feasible within the capacity of the site, a reduced inventory could be considered. If estimated risks are greater than the risk target, then the Agency expects BNFL to provide quantitative estimates of disposal system performance for alternative engineering measures, to demonstrate that risks are as low as reasonably achievable, economic and social factors being taken into account, and that disposal practices and repository design represent best practicable means. In the case of existing disposals, if risks are substantially above the risk target then intervention would need to be considered. In the case of future vault disposals, if risks are above the risk target then such disposals may not be authorised.

Models and Data Flow: The illustrative modelling results provided in the Status Report demonstrate that BNFL has a working methodology for the calculation of post-closure risks. While the Status Report does not present results from all of the assessment codes that BNFL intends to use in the 2002 PCSC, it has provided the Agency with an improved understanding of how data will be used in BNFL's risk assessment. The 2002 PCSC will need to include a more extensive presentation of the risk assessment models and results.

Traceable Record of Assumptions and Data: BNFL's assessment methodology incorporates a number of features that will help BNFL to document the 2002 PCSC in a traceable manner, including Parameter Input Forms and Conceptual Model Uncertainty forms. However, the Status Report does not provide sufficient information for the Agency to trace the logic behind the conceptual models and parameter values presented.

Treatment of Uncertainty: BNFL's use of form-based procedures to record unquantified uncertainties is appropriate. However, the Status Report has not adequately described BNFL's approach to the quantification of uncertainty. The Agency expects BNFL to define and implement in the 2002 PCSC an approach to classify, prioritise and manage uncertainties. In addition, there is a pressing need for BNFL to define its strategy for undertaking and presenting results of sensitivity studies.

Progress and Forward Programme for the PCSC: The Agency acknowledges that BNFL has been responsive to the Agency's concerns with the PCSC Development Programme and has made progress in terms of developing its methodology. However, the Status Report has not provided a means of assessing BNFL's progress toward the 2002 PCSC or a sufficiently detailed forward programme. The Agency considers that in the period leading up to the 2002 PCSC, BNFL will need to ensure that its methodology is implemented effectively.

Comments raised by the Agency on the Status Report relate to expectations of a PCSC to meet regulatory requirements and are provided to BNFL as further guidance in planning any future work programme. Whilst the Agency has detailed these expectations, it is for BNFL to use a risk framework to guide their prioritisation and determine an appropriate programme to address them. Unless specifically stated, issues do not necessarily have to be resolved for the 2002 PCSC; however, unresolved issues will be considered by the Agency in determining any future authorisation requirements.

The Agency will continue to review BNFL's PCSC Development Programme and to monitor progress towards the 2002 PCSC.

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Appendix 1 Additional Comments
Appendix 2 Issue Resolution Forms

LIST OF ACRONYMS

AEA	Atomic Energy Authority
ALARA	As Low As Reasonably Achievable
BPM	Best Practicable Means
CFA	Conditions For Acceptance of Waste
CMU	Conceptual Model Uncertainty
DETR	Department of the Environment, Transport and the Regions
DOE	Department of the Environment
DTP	Drigg Technical Programme
EFEPs	External FEPs
FEP	Feature, Event, Process
GRA	Guidance on Requirements for Authorisation
HER	Hydrologically Effective Rainfall
HLW	High-Level Radioactive Waste
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IPCC	Intergovernmental Panel on Climate Change
IRF	Issue Resolution Form
ISAM	IAEA collaborative research programme for Improving long-term Safety Assessment Methodologies for near-surface radioactive waste disposal facilities.
ISO	International Standards Organisation
LLW	Low-Level Radioactive Waste
MAFF	Ministry of Agriculture, Fisheries and Food
NCRAOA	National Centre for Risk Analysis and Options Appraisal

NEA	OECD Nuclear Energy Agency
NRPB	National Radiological Protection Board
OECD	Organisation for Economic Co-operation and Development
OESC	Operational Environmental Safety Case
PAAG	NEA Performance Assessment Advisory Group
PCRSA	Post-Closure Radiological Safety Assessment
PCSC	Post-Closure Safety Case
PIC	Passive Institutional Control
PIF	Parameter Input Form
QA	Quality Assurance
RSA 1960	Radioactive Substances Act 1960
RSA 1993	Radioactive Substances Act 1993
US EPA	United States Environmental Protection Agency

1 INTRODUCTION

1.1 The Agency's Regulatory Role

The Environment Agency (the Agency) is responsible for authorisation of radioactive waste disposal under the Radioactive Substances Act 1993 as amended (RSA 1993). British Nuclear Fuels plc (BNFL) is currently authorised to dispose of solid low-level radioactive waste (LLW) by shallow burial at the Drigg site, in Cumbria. The current Authorisation for the Drigg site sets radiological limits on disposals, and requires the use of best practicable means (BPM) to compact relevant waste[1] and to limit the migration of any radionuclides from relevant waste. In accordance with Government policy, the Agency conducts periodic reviews of authorisations for nuclear licensed sites in order to ensure that they are appropriate to the operating practice and that the Authorisation continues to reflect current regulatory standards.

During the operation of a radioactive waste disposal site, such as Drigg, operating practices may evolve, and more information may become available on the site, the design of the repository, the waste inventory, and the processes that govern radionuclide behaviour. The Agency expects BNFL to update the safety case at periodic intervals throughout the operational lifetime of the repository to take account of new information and any revisions to regulatory requirements.

In September 2002, BNFL will provide a new Post-Closure Safety Case (PCSC) for the Drigg site that will be the first PCSC developed with regard to current guidance (e.g., Environment Agency *et al.* 1997; DETR *et al.* 2000) and current disposal practices (see Section 1.2). Furthermore, this will be the first time the Agency has used the Guidance on Requirements for Authorisation (GRA, Environment Agency *et al.* 1997) to inform an Authorisation review.

The Agency is reviewing BNFL's PCSC Development Programme in preparation for its assessment of the 2002 PCSC. The Agency's work includes document review and dialogue with BNFL, and is progressing in three phases:

(1) Review of early documents from BNFL's PCSC Development Programme. This phase was initiated in December 1996 and was completed at the end of March 1999.

(2) Review of later documents from BNFL's PCSC Development Programme, and discussion of issues raised. This phase began at the start of 1999 and will continue until submission of the PCSC in September 2002.

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[1] Relevant waste means solid radioactive waste which has been treated or packaged in such a way as to render it so far as is reasonably practicable insoluble in water and not readily flammable. Radioactive waste is as defined in RSA 1993.

(3) Review of the 2002 PCSC.

This report presents the Agency's review of BNFL's March 2000 Status Report on the Development of the 2002 Drigg Post-Closure Safety Case (the Status Report), which forms part of the Phase 2 review. The Status Report review has been conducted in accordance with the review plan described in Environment Agency (2001).

Comments raised by the Agency on the Status Report relate to expectations of a PCSC to meet regulatory requirements and are provided to BNFL as further guidance in planning any future work programme. Whilst the Agency has detailed these expectations, it is for BNFL to use a risk framework to guide their prioritisation and determine an appropriate programme to address them. Unless specifically stated, issues do not necessarily have to be resolved for the 2002 PCSC; however, unresolved issues will be considered by the Agency in determining any future authorisation requirements.

1.2 Radioactive Waste Disposal at the Drigg Site

The Drigg site is located in West Cumbria in northwest England, approximately six miles southeast of the Sellafield complex. The Drigg site was established in 1939 when an area of farmland was developed as a Royal Ordnance Factory. The site was subsequently taken over by the Atomic Energy Authority (AEA) which, in 1957, obtained planning consent for waste disposal in the northern part of the site. In the following year, AEA obtained an Authorisation for the disposal of solid LLW under the terms of the Atomic Energy Act 1954. Radioactive waste disposal began in 1959. AEA continued to manage waste disposal at the site until the Authorisation was transferred to BNFL in 1971.

The current Authorisation for Drigg was granted in 1987 by the then authorising departments, the Department of the Environment (DOE) and the Ministry of Agriculture, Fisheries and Food (MAFF) in accordance with the Radioactive Substances Act 1960 (RSA 1960). The Authorisation was based partly on a radiological assessment of the Drigg site by the National Radiological Protection Board (NRPB 1988). The Authorisation was varied in 1991, by DOE and MAFF, in accordance with RSA 1960. The Authorisation was varied again in 2000 by the Agency, in accordance with RSA 1993.

Initially, waste was tipped into a series of shallow clay-lined trenches and covered with soil. This practice was similar to that used by the landfill industry. In the period to 1995, approximately 800,000 m^3 of waste was disposed in seven trenches. These trenches are now covered by an interim cap that incorporates a plastic membrane to minimise water ingress.

In response to recommendations made by the House of Commons Environment Committee (HMSO, 1986), BNFL progressively changed disposal practices to the emplacement of containerised, grouted waste in an engineered concrete vault. A few large items of waste that are unsuitable for containerisation are disposed directly and grouted *in situ*. Disposals to the vault commenced in 1988.

The existing vault has a capacity of approximately 200,000 m^3. BNFL plans to build additional vaults to accept a further 750,000 m^3 of waste, and estimates that this will provide sufficient capacity for the site to remain operational until around 2050. After waste emplacement is complete, the entire disposal area (trenches and vaults) will be covered by a final site cap.

1.3 Report Structure

This report is structured as follows:

Section 2 Objectives and scope of the Agency's review.

Section 3 Principal results of the Agency's review.

Section 4 Conclusions from the review.

Section 5 References.

Appendix 1 Minor comments on the Status Report (e.g., editorial, requests for clarification).

Appendix 2 Issue Resolution Forms (IRFs) that will be taken forward into subsequent phases of the Agency's review of BNFL's Drigg PCSC. The purpose and use of the IRFs are described in Environment Agency (1999).

2 REVIEW OBJECTIVES AND SCOPE

2.1 Objectives

The Agency's review of documents provided by BNFL from the PCSC Development Programme, including the Status Report, has two principal objectives:

- To assess the information supplied by BNFL against the GRA, and to provide further guidance to BNFL on the future direction of its programme.

- To identify the need for additional assessments by the Agency, such as the examination of further BNFL documents, or the conduct of independent calculations, in order that the Agency can efficiently assess the 2002 PCSC.

Based on review of the Drigg Authorisation (DOE and MAFF 1988) and documents from BNFL's PCSC Development Programme, the Agency established a requirement for the Status Report and developed a set of specific objectives for its review.

The primary objective of the Agency's review of the Status Report is to determine whether the 2002 PCSC is likely to provide an adequate basis for continued authorisation. Fulfilling the primary objective has included an assessment of the Status Report against a set of more specific objectives:

(i) That the Status Report provides assurance that BNFL is developing the PCSC under a suitable quality assurance (QA) regime.

(ii) That the Status Report provides assurance that BNFL is developing the PCSC based on an interpretation of available regulatory guidance that is acceptable to the Agency.

(iii) That the Status Report provides evidence that the PCSC is likely to be sufficiently comprehensive, adequately integrate all of its component parts, and be based on a methodology that identifies and prioritises the issues of most significance to assessment results.

(iv) That the Status Report documents an acceptable approach for demonstrating optimisation in the PCSC.

(v) That the Status Report presents example results from each of the assessment codes that BNFL intends to use in the 2002 Post-Closure Radiological Safety Assessment (PCRSA), that demonstrate how the various parts of BNFL's PCRSA will be assembled, and how data will be used in the PCRSA.

(vi) That the Status Report provides assurance that BNFL is developing a traceable record of assumptions and data on which to base the 2002 PCSC.

(vii) That the Status Report describes an acceptable methodology for the treatment of uncertainties in the PCSC, including a clearly defined and comprehensive approach to quantification of uncertainty in the 2002 PCRSA.

(viii) That the Status Report provides assurance that BNFL is making adequate progress towards the 2002 PCSC and indicates that BNFL has an appropriate forward programme for developing the 2002 PCSC and subsequent revisions to the safety case.

(ix) To identify where the Status Report contains information on post-closure safety that may have implications for practices during the repository operational phase.

A further objective of the Status Report review is to identify any need for further work by BNFL and the Agency. The Agency's specific objectives can be linked to both the GRA and to BNFL's own objectives for the Status Report (see Table 1).

Table 1. The relationship between the Agency's specific review objectives, the GRA and BNFL's stated purpose of the Status Report.

Agency Specific Review Objective (see text for full description)		Section of the GRA		Purpose of the Status Report as described by BNFL
		Principle / Requirement	Paragraph	
i)	Quality assurance	R11 Quality assurance		To set out the intended approach for the 2002 PCSC
ii)	Regulatory interpretation	All		
iii)	Comprehensiveness, integration and risk management	R2 Risk Target		
iv)	Optimisation	P3 Optimisation		
v)	PCRSA models and data		8.18 to 8.19 Modelling studies	
vi)	Traceable record of assumptions and data	R10 System of Records		
vii)	Treatment of uncertainty		8.15 to 8.17 Treatment of uncertainty	
viii)	Progress to date			To summarise progress to date
i)	Quality assurance	R11 Quality assurance		To demonstrate that adequate plans are in place to complete the Drigg PCSC by 2002
vi)	Traceable record of assumptions and data	R10 System of Records		
viii)	Forward programme for the PCSC		4.14, ch8	

2.2 Scope

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This review is concerned with the radiological impacts of Drigg, and is being conducted in accordance with the GRA and Environment Agency (2001). In addition, the Agency has a wider duty to protect and enhance the environment under the Environment Act 1995.

As discussed in Section 1.1, the review of the Status Report represents part of a wider review by the Agency of BNFL's PCSC Development Programme. The wider review has been in progress since late 1996 and many issues have already been raised with BNFL in the context of an agreed Issue Resolution Process. The intent of the Agency's review of the Status Report was to focus, at an overview level, on BNFL's plans for the integration of the various components of its programme in the 2002 PCSC, as well as examining in detail any new material submitted by BNFL. This review includes the Agency's main concerns with the Status Report. However, since some of these have already been raised with BNFL through the Issue Resolution Process, there are instances where the detail of the Agency's concerns are not reproduced in this report. These concerns are being addressed by BNFL on an agreed timetable. Areas in which the Agency is aware that BNFL has made significant developments or changes to its programme since publication of the Status Report are indicated in this review using footnotes.

The Status Report provides a summary of BNFL's programme for developing the 2002 PCSC. The Agency accepts that the Status Report is not a completed safety case and has considered the Status Report as a statement of intent by BNFL. The Agency considers that while it would not be appropriate to review the Status Report as though it were a completed safety case, it is appropriate to compare BNFL's programme for developing the 2002 PCSC against the Principles and Requirements of the GRA (see Section 3.2).

3 REVIEW RESULTS

This section presents the Agency's evaluation of the Status Report in terms of its overall presentation (Section 3.1), technical quality as assessed against the Principles and Requirements of the GRA (Section 3.2), and fulfilment of the Agency's specific review objectives (Section 3.3).

3.1 Overall Presentation

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When assessing the overall presentation of the Status Report, the Agency has considered the appropriateness of its structure, its breadth and depth of content, evidence of quality control over its production, and the sufficiency of referencing.

3.1.1 Structure, Breadth and Depth of Content

The Agency considers that the structure of the Status Report is appropriate, and acknowledges the breadth and depth of the Status Report, while noting that greater detail will be required for the 2002 PCSC. Specific comments are provided below.

The Agency considers that BNFL's description, in Chapter 1 of the Status Report, of the objectives of the PCSC is not clear. For example, in Figure 1 (Status Report Section 1.2), the PCRSA, PCSC and Forward Programme collectively lead to a "Case for continued disposal operations." The Agency considers that the PCRSA will have a range of uses, including optimisation of facility design and disposal inventory, and identification and prioritisation of the issues of most significance to assessment results. The Agency expects the objectives of the PCRSA and PCSC to be consistently defined in accordance with the GRA (Environment Agency *et al.* 1997).

The Agency is broadly satisfied with BNFL's statement of Safety Case Context in Chapter 2 of the Status Report (however, specific comments are presented in Section 3.3.2). The Agency considers that Chapter 3 and Appendix A provide a good summary of the Drigg biosphere, site geology, hydrogeology and geochemistry, inventory and facility design (however, specific comments are presented in Section 3.2.6 and Appendix 1). Chapter 4 and Appendix B present BNFL's methodology for documenting assumptions on which the 2002 PCRSA will be based. In general this methodology is soundly based and, if properly implemented, is capable of providing information that the Agency will be able to use in regulatory decision-making. The Agency notes the supporting arguments put forward by BNFL in Chapter 5 of the Status Report. However, until BNFL provides results from the PCRSA, the Agency cannot place BNFL's arguments in context.

Chapter 6 presents information about BNFL's forward programme. The Agency considers that BNFL has provided insufficient information on its forward programme. Details of the Agency's comments are presented in Section 3.3.8.

Chapter 7 of the Status Report is entitled "Presenting the case for continued disposal operations". The Agency will assess all aspects of the case for continued operations at Drigg in the next Authorisation review commencing in 2003, and notes that its considerations will necessarily extend beyond the range of issues considered in the Status Report. In particular, BNFL's emphasis on a methodology for deriving radiological capacity is too narrow. The Agency welcomes, however, the inclusion in Chapter 7 of the mapping between the Drigg PCSC and the GRA.

The Agency welcomes the inclusion in the Status Report of a glossary of terms. The Agency encourages BNFL to continue to develop the glossary by including definitions of further terms and to include the glossary in the 2002 PCSC. As far as possible, the glossary should be consistent with nationally (e.g., Environment Agency *et al.* 1997) and internationally (e.g., IAEA 2000) recognised terminology.

Appendix C contains a relatively brief presentation of BNFL's assessment codes. Detailed comments on BNFL's assessment code documentation and application of QA procedures have already been provided to BNFL through the Agency's on-going review of the PCSC Development Programme. From the limited information presented in Appendix C, the Agency cannot assess whether these comments have been addressed.

Appendix D contains illustrative PCRSA models, data and results. BNFL has included two examples of conceptual model and parameter uncertainty analyses in Appendix D and both have raised concerns (see Section 3.3.7). The Agency attaches great importance to the treatment of uncertainty in the PCRSA, and considers that there is a need for BNFL to further define its strategy for undertaking PCRSA calculations.

3.1.2 Document Quality Control

The Agency considers that the Status Report is generally well presented and well illustrated. In order to build confidence in the PCSC, the Agency encourages BNFL to continue to check the implementation of its QA procedures for report review and approval, and to make continued efforts to eliminate editorial errors, ensure consistency and improve clarity.

3.1.3 Referencing

The Status Report generally does not provide citations to support the arguments that BNFL puts forward. Examples are presented in Section 3.2 and Appendix 1. The Agency expects BNFL to document and make public the evidence for observations and statements made in the 2002 PCSC.

The Agency accepts that the Status Report, as a standalone document, does not refer to interim documents from BNFL's PCSC Development Programme that would support certain arguments. The Agency expects the 2002 PCSC to include comprehensive cross-references so that BNFL's arguments can be traced and their basis assessed. The Agency acknowledges BNFL's intention to provide the basis for its arguments, as stated in Section 1.2.2 of the Status Report.

The Agency welcomes the inclusion in the Status Report of Appendix E, which contains a list of Drigg-related publications in the public domain, and encourages BNFL to place information in support of the 2002 PCSC in the public domain as soon as possible. Furthermore, the Agency encourages BNFL to make wider use of publication via peer-reviewed journals, as the Agency considers this one means of building confidence in BNFL's work.

3.2 Assessment of the Status Report Against the Principles and Requirements of the GRA

When assessing the technical content of the Status Report, the Agency has considered the Principles and Requirements contained in the GRA. In making its assessment, the Agency has also considered the clarity of the material presented, the validity of the judgements, evidence of quality control within BNFL's programme, the fitness-for-purpose of BNFL's models, and the sufficiency of the data presented.

The Agency's comments on the technical content of the Status Report are presented in the following sub-sections relating to the Principles and Requirements of the GRA. Each sub-section starts with an italicised quote from the GRA stating the Principle or Requirement under consideration. Cross-references to related parts of the GRA are provided as appropriate. Within the sub-sections, the Agency's review comments are presented by topic. Cross-references to relevant material in the Status Report are provided as appropriate.

3.2.1 Principle No. 1 - Independence of Safety From Controls

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> *Following the disposal of radioactive waste, the closure of the disposal facility and the withdrawal of controls, the continued isolation of the waste from the accessible environment shall not depend on actions by future generations to maintain the integrity of the disposal system.*

The Agency is concerned that BNFL's approach to the PCSC may not be entirely consistent with the aims of GRA Principle No. 1. The Agency's concern relates to BNFL's assumptions about passive institutional controls.

Passive Institutional Controls

The Agency has identified several issues relating to passive institutional controls (PICs):

- **Duration of the Passive Institutional Control Period.** BNFL has made inconsistent statements about the duration of the passive institutional control period. On page 126 (Status Report Section 5.3.1.1), BNFL states that there will be "...a period of at least 300 years when... ...passive institutional controls will minimise the risk of human intrusion." This statement is inconsistent with the statements on pages 34 (Table 1) and 128 that the passive institutional control period will be 100 years. In addition, BNFL has used a figure of 1,000 years in the illustrative PCRSA calculations (Status Report Appendix D). The Agency expects BNFL to clarify the assumed duration of passive institutional control.

- **Financial Liability.** BNFL indicates that operator control over the site will be withdrawn from 2150 (subject to regulatory approval) and that thereafter "The operator has no financial liability for passive control and no provisions will be made" (Status Report Section 2.7.2, Table 1, page 34). The Agency expects BNFL to explain why it would be reasonable for the operator to relinquish control and any continuing financial responsibility for the site on the commencement of "passive control", and why control and financial responsibility for the site should pass to public "institutions" at that time.

- **Nature of PICs.** BNFL has provided little indication of what kinds of PICs are envisaged for the Drigg site. The Agency expects BNFL to provide in the PCSC a description of the PICs that are envisaged for the Drigg site.

- **Effectiveness of PICs.** BNFL has not explained why it believes that PICs will be effective in the future, although it has put forward a view on the contribution that planning controls may make. BNFL argues that planning controls are "highly effective" and "...are likely to persist beyond the assumed passive institutional control period..." (Status Report Section 5.3.2, page 128). Reliance on planning controls alone is unlikely to provide sufficient assurance that the Drigg facility will not be affected by future human actions. The Agency expects BNFL to explain why the range of PICs envisaged for the Drigg site would be effective.

- **Assumptions Regarding Human Intrusion Frequency.** BNFL has not justified its assumptions about how PICs will reduce the probability of human intrusion in the illustrative PCRSA calculations. For these calculations, BNFL assumed that:

  - PICs will be effective up to 1,000 years post-2050. The result of this assumption is that the frequency of intrusion is relatively low in the period up to 3050: intrusion frequencies are reduced by a factor of 10^6 - 10^7 in the period 2150-2350 and by a factor of 10^4 - 10^5 in the period 2350-3050 (Status Report Table D36, page D77). These reduced frequencies result in similarly reduced estimates of risk in these periods.

  - At 3050, the planning process fails with a probability of between 10^{-1} and 10^{-3} (Status Report Table D31, page D72).

  BNFL states that its assumptions were "...derived by expert judgement" but provides no reference to records of how these expert judgements were made. In the Agency's view, justification of assumptions involving value judgements would be strengthened by dialogue amongst a wider range of stakeholders in the Drigg PCSC.

Whatever the justification provided by BNFL concerning its assumptions about the effectiveness of PICs, and whatever calculations are conducted as a result of these assumptions, the Agency also expects BNFL to provide results from PCRSA calculations that assume no reduction in the frequency of human intrusion because of PICs. For these calculations, it should be assumed that the presence of the repository will not be recognised and that human intrusion could occur as early as the beginning of the passive institutional control period, as well as at later times.

In summary, the Agency considers that the safety case should not rely on the effectiveness of PICs, but that the implementation of PICs has the potential to increase confidence in the post-closure safety of the site (see GRA paragraph 8.25).

3.2.2 Principle No. 2 - Effects in the Future

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Radioactive wastes shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today.

The Agency considers that BNFL's approach to the PCSC is consistent with the aims of GRA Principle No. 2.

3.2.3 Principle No. 3 - Optimisation (As Low As Reasonably Achievable)

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The radiological detriment to members of the public that may result from the disposal of radioactive waste shall be as low as reasonably achievable, economic and social factors being taken into account.

The Agency considers that the Status Report does not provide a clear picture of BNFL's intentions for optimisation studies to be included in the 2002 PCSC. The Agency has comments on the following topics:

- Scope of optimisation studies.
- Available technologies.
- Derivation of the inventory and inventory screening.
- Relationship between inventory and risk.
- Proposed annual disposal limits.

Further related comments are also presented in Section 3.2.11 and Appendix 1.

Scope of Optimisation Studies

On page 144 (Status Report Section 7.1.2.2), BNFL indicates that the radiological capacity of the Drigg repository has been limited based on controlling individual risk of a fatal cancer or severe hereditary defect to a level of 10^{-6} per year. On page 157, BNFL indicates that a risk of 10^{-6} per year will also be used as a basis for controlling the inventory in the 2002 PCSC, and that a key role of the 2002 PCSC is to reassess the radiological capacity. The Agency notes that a risk of 10^{-6} per year is a risk *target*, and not an absolute limit. If risks exceed this level, then the Agency expects BNFL to demonstrate the use of BPM to ensure that risks are as low as reasonably achievable (ALARA), economic and social factors being taken into account. In the case of existing disposals, if risks are substantially above the risk target then intervention would need to be considered. In the case of future vault disposals, if risks are above the risk target then such disposals may not be authorised.

On page 31, BNFL indicates that it intends to evaluate the potential impact if all UK LLW is disposed of at Drigg within the volume constraints of the site. The Agency considers that this is appropriate, even if it leads to a calculated risk greater than 10^{-6} per year, and expects BNFL to present optimisation studies that may include, among other alternatives, a reduced inventory (see also Section 3.3.4).

Available Technologies

On page 22 (Status Report Section 2.2, see also page 69, Status Report Section 3.4.3), BNFL states that "For some aspects of the safety assessment (for example, design of the final site cap) it would be inappropriate to make final decisions now when technological developments in the coming decades could significantly alter what is regarded as best practice." While the Agency agrees with this statement, the Agency expects that a PCSC should be based on repository designs that could be built using current technology and available materials, consistent with the principle of sustainable development.

On page 74 (Status Report Section 4.2.1.2), BNFL identifies the presence of "system state uncertainties," which are said to arise from "...lack of knowledge concerning the components and configuration of the process system." While the Agency agrees that such uncertainty is inevitable, it does not agree with BNFL's subsequent statement that the existence of alternative possible designs for the engineered system at the time of closure represents a lack of knowledge. As noted above, the Agency expects BNFL to present a PCRSA and a demonstration of optimisation based on current technology and available materials.

Derivation of the Inventory and Inventory Screening

On page 63 (Status Report Section 3.3), BNFL notes that the inventory information in Tables 5 and 6, and the illustrative PCRSA results discussed in Status Report Section 4 and Appendix D, are based on the 1994 UK Radioactive Waste Inventory (UK Nirex Ltd. and DOE 1996). BNFL used the 1994 UK Radioactive Waste Inventory for both future waste arisings and to hindcast the inventory of past disposals. BNFL indicates that the 2002 PCRSA will be based on the more recent 1998 UK Radioactive Waste Inventory (UK Nirex Ltd. and DETR 1999). The Agency welcomes BNFL's intent to update the inventory for the Drigg PCSC. The Agency notes that previously BNFL has used information from the Drigg disposal records to include a number of waste streams and specific disposals that were not part of the 1994 UK Radioactive Waste Inventory. The Agency expects BNFL to account for potentially significant additional waste streams and specific disposals, quantify the uncertainties associated with the inventory, and evaluate their potential significance to dose and risk in the 2002 PCRSA.

On page 126 (Status Report Section 5.3.1.1), BNFL describes a process of "inventory screening" that may be applied in the 2002 PCSC to eliminate from the PCRSA inventory all radionuclides possessing half-lives less than 30 years. BNFL proposed the 30-year cut off figure on the basis that there will be "...a period of at least 300 years when the final engineering will function as designed and passive institutional controls will minimise the risk of human intrusion" and that during a 300-year period, those radionuclides with a half-life of less than 30 years will decay to insignificant levels.

In the Status Report, BNFL also states that "...it is likely that decision making on the long-term impact of LLW disposal at Drigg will focus on [radionuclides with longer half lives] and their decay products." The Agency considers that while BNFL's focus on radionuclides with half-lives greater than 30 years may be appropriate for assessment timescales greater than about 300 years, it is not appropriate when considering shorter timescales, for example in the Operational Environmental Safety Case (OESC)[2].

Relationship Between Inventory and Risk

BNFL's proposed methodology for calculation of radiological capacity has not been fully explained or justified. On page 157 (Status Report Section 7.3.1), BNFL states that "For a limited number of radionuclides it is reasonable to assume that there is a direct [linear] correlation between the disposed inventory and the risk resulting from [the inventory]" but has not provided the rationale for this assumption. BNFL

[2] The Agency notes that since publication of the Status Report, BNFL has revised its approach to inventory screening.

acknowledges that "for a limited number of radionuclides there may not be a direct correlation between inventory reduction and risk reduction." The Agency considers it essential to examine the relationship between inventory and risk, if radiological capacity is used as one approach to managing risk. The Agency notes that the Status Report does not describe how radionuclides that do not exhibit a linear correlation would be considered in BNFL's methodology, other than that "...more complex considerations ... will be applied." In summary, the Agency expects BNFL to justify and explain clearly its approach for calculating radiological capacity in the 2002 PCSC.

3.2.4 Principle No. 4 - Radiological Protection Standards

> *The assessed radiological impact of the disposal facility before withdrawal of control over the facility shall be consistent with the source-related and site-related dose constraints and, after withdrawal of control, with the risk target.*

The Agency considers the way in which BNFL has presented results from the illustrative PCRSA calculations in Appendix D of the Status Report is confusing and potentially misleading. BNFL has assumed that it will retain control over the Drigg site at least until 2150, during which period the radiological impact of the disposal facility should be consistent with the dose constraints. However, in Appendix D of the Status Report, BNFL compares calculated risks and dose rates with the risk target for dates before and after 2150 (see e.g., Status Report Figures D3 and D33). Calculated risks presented for the period during active institutional control could be interpreted as implying that human intrusion may occur during the period of control and, therefore, that the controls were ineffective. The Figures ought to compare calculated dose rates with the appropriate dose constraint for the period until 2150 and compare calculated risks with the risk target thereafter.

3.2.5 Requirement R1 - Period Before Control is Withdrawn (Dose Constraint)

> *In the period before control is withdrawn, the effective dose to a representative member of the critical group from a facility shall not exceed a source-related dose constraint. Also during this period, the effective dose to a representative member of the critical group resulting from current discharges from the facility aggregated with the effective dose resulting from current discharges from any other sources at the same location with contiguous boundaries shall not exceed an overall site-related dose constraint of 0.5 mSv/y.*

The Agency requires BNFL to update its assessment of the impact of radioactive discharges during the operational phase of the site, in 2002. The Agency expects the OESC to consider the full period before control is withdrawn.

3.2.6 Requirement R2 - Period After Control is Withdrawn (Risk Target)

> *After control is withdrawn, the assessed radiological risk from the facility to a representative member of the potentially exposed group at greatest risk should be consistent with a risk target of 10^{-6} per year (i.e. 1 in a million per year).*

The Agency has comments on BNFL's description of its approach to post-closure risk assessment under the following headings:

- PCRSA methodology.
- Potentially exposed groups.
- FEP (feature, event, process) identification and screening.
- Scenario development.
- Clearing houses.
- Representation of trenches and vaults in interaction matrices.
- Engineering performance assessment.
- Performance of engineering.
- Hydrogeological interpretation and modelling.
- Illustrative PCRSA models, data and results.

PCRSA Methodology

BNFL has referred on page 75 to the risk assessment framework produced by the Agency's National Centre for Risk Analysis and Options Appraisal (NCRAOA). This framework has since been incorporated in revised guidance (DETR *et al.* 2000).

The bullet points on page 77 (Status Report Section 4.2.3) omit what are possibly the most important purposes of screening and prioritisation as discussed in DETR *et al.* (2000). This is to identify which radionuclides, exposure pathways and receptor interactions are likely to dominate estimates of risk. This information should be used iteratively to refine BNFL's understanding of the system behaviour, identify any necessary risk management measures, and prioritise the PCSC Development

Programme. Whilst the Agency acknowledges the inclusion in the Status Report of Appendix D, which provides examples of how conceptual model and parameter uncertainty may be assessed quantitatively in the PCRSA, the Agency is concerned that BNFL has yet to apply the PCRSA iteratively to this effect. As a result, the Agency considers that BNFL has yet to demonstrate an understanding of the key processes likely to dominate radiological risks from Drigg.

Further comments on BNFL's PCRSA methodology are presented below and in Appendix 1.

Potentially Exposed Groups

On page 40 (Status Report Section 3.1.6 - see also Status Report Page D23 and GRA Paragraphs 6.5 to 6.8 and 6.18 to 6.20), BNFL discusses human habits and behaviour, and its assumptions about the identity and habits of potentially exposed groups. The Agency expects BNFL to justify the selection of potentially exposed groups for the 2002 PCSC.

BNFL notes (page 40) that "A constant present day level of technological development is assumed" and that "an agricultural... ...type of society has been assumed to persist..." The Agency considers the former assumption to be a reasonable basis for the PCSC. The Status Report is not clear, however, as to whether BNFL will consider a potentially exposed group that practices subsistence agriculture. The Agency expects BNFL to assess risks to a potentially exposed group that practices subsistence agriculture, i.e., obtains all of its food from local sources. International best practice is to ensure that the characteristics of the potentially exposed group are consistent with the capability of the biosphere to support such a group (ICRP 2000).

Status Report Table 2 on page 41 identifies several potentially exposed groups and exposure pathways. BNFL gives age ranges for infants (0.5 to 1 years), children (1 to 11 years) and adults (16 to 64 years). It is not clear why the age range for infants does not start at zero, nor how the age range from 12 to 15 is considered. The exposure pathways include the consumption of water, which will occur throughout infancy, childhood and adulthood, beginning at zero. It is also not clear why the age range for adults does not extend beyond 64. By the mid-1990s, average life expectancy in the UK had increased to 74 years for men and 79 years for women, and is likely to have increased a further 3 years by 2021 (e.g., DETR, 1999). Furthermore, the Agency notes that that it may not be necessary to calculate doses to groups of different ages, if it can be assumed that radioactive contamination of the biosphere owing to releases from the repository remains relatively constant over periods that are considerably longer than the human life span (ICRP 2000).

In Status Report Section 5.3.2 (pages 127-128), BNFL identifies a number of issues that "...could be addressed by reasoned arguments". One of these issues relates to

assumptions about whether a potentially exposed group would drink a particular source of groundwater that is contaminated with radionuclides. It appears that BNFL may wish to advance an argument that the calculated dose to a potentially exposed group from a particular source of contaminated groundwater might be reduced by assuming that the group also uses water from uncontaminated sources. The Agency considers that such arguments are likely to be rather speculative, and expects BNFL to assess the critical pathways for radionuclide transfer to man in the 2002 PCRSA. Further, the Agency expects BNFL to account for the use of water from a shallow aquifer, or provide a justification for eliminating this potential source for exposure. BNFL should consider a potentially exposed group that obtains drinking water from a well into a shallow aquifer, the use of water from a shallow aquifer for livestock and, if appropriate under different climate conditions, the use of such water for irrigation.

FEP Identification and Screening

On page 86 (Status Report Section 4.5.2), Figure 22 illustrates BNFL's process for scenario development. It shows that the initial Reference FEP list is divided into lists of process system FEPs and external FEPs (EFEPs). An "augmentation" step follows, in which the EFEP list is compared to FEP lists from other PCRSAs. However, the process system FEPs are not shown as being subject to such comparison with other FEP lists. The Agency is concerned that not only should the EFEP list be shown to be comprehensive, but also that the process system FEP list should be shown to be comprehensive. The Agency expects BNFL to demonstrate comprehensiveness in its consideration of the assessment as a whole.

BNFL's discussion in Status Report Section B2 of FEP identification and analysis is not clear because:

- It refers to FEPs and FEP lists that are not included in the Status Report and which are not available or referenced.

- BNFL's FEP list for the Drigg PCSC is not presented.

- BNFL appears to have several methods for identifying FEPs. For example, in Status Report Section B4 (page B41) and Figure B7 (page B32), BNFL indicates that the Drigg FEP list will be "...derived from investigation of the process system and associated documentation." While on page B59, BNFL indicates that biosphere FEPs are identified in large part during system conceptualisation. The Status Report also refers to the independent derivation of FEP lists.

BNFL indicates (page B6) that the FEP list for Drigg is derived starting from the list developed within the ISAM programme, the International Atomic Energy Agency's (IAEA) collaborative research programme for improving long-term safety assessment

methodologies for near-surface radioactive waste disposal facilities. However, the ISAM FEP list has not been reproduced in the Status Report, and the only reference provided is to unpublished IAEA working papers. Furthermore, BNFL's augmented FEP list for Drigg is not included in the Status Report, and is not yet available. What is included in the Status Report is an extract from the ISAM FEP list of "external factors", or EFEPs. BNFL has subsequently added further EFEPs to this list, but the process of deriving the initial FEP list and identifying EFEPs is not yet adequately documented.

BNFL notes on page B10 that review of other potentially relevant studies highlighted the need to add at least one further EFEP to the list derived from the ISAM FEP list. The Agency expects BNFL to identify which studies were reviewed and why those studies were selected. Furthermore, the Agency expects BNFL to identify the steps it has taken to ensure that additional EFEPs have not been overlooked.

BNFL highlights on page B11 that "geological resources as a potential motivation for intrusion" should be considered as an EFEP. The Agency expects BNFL to provide information on what is known about the existence of such geological resources at the Drigg site, including information on their spatial distribution (see GRA Paragraph 7.6).

Status Report Table B3 (page B13) lists EFEPs, and provides a summary statement of their relevance to the Drigg PCRSA; this table is supported by descriptive text. The summary statements provided are useful. However, the Agency expects BNFL to provide more detailed supporting rationale for these statements in the 2002 PCSC. The Agency considers that FEP and conceptual model evaluation and screening is an essential part of developing the basis for the PCRSA calculations (see Section 3.2.6, PCRSA Methodology). The Agency will focus its review on both the results of the PCRSA calculations and the rationale provided by BNFL for eliminating FEPs and conceptual models from the calculations. The Agency expects BNFL to provide an adequate justification for its decisions on screening FEPs and EFEPs in the 2002 PCSC. In addition, for each EFEP whose status is "Included", the Agency expects BNFL to provide an indication of how the EFEP is included in the PCRSA.

As an example of the Agency's concerns with the material presented on FEP screening, the Agency refers to the text evaluating the possible importance of seismic events that appears on the bottom of page B20. BNFL states that "...seismic pumping ...is unlikely to happen in the Drigg area because of the current state of regional *in situ* stress. It is also unlikely that the regional stress conditions will change significantly over the next 100,000 years." The Agency notes that these arguments should be supported by references and statements that explain why these may be reasonable assumptions. Several additional examples are provided in Appendix 1.

The Agency welcomes BNFL's use of a conceptual model uncertainty (CMU) form to document conceptual modelling decisions and uncertainties in a systematic manner.

The Agency encourages BNFL to include a statement on the form of which "Included" FEPs are accounted for in the particular assumption or model under consideration, in the same way that a link is provided to key parameters.

In summary, the Agency expects BNFL to document in the 2002 PCSC the derivation and screening of its FEP list, and the rationale for the identification of particular FEPs as EFEPs.

Scenario Development

BNFL's description of the approach to modelling EFEPs and deriving scenarios (Status Report Section B3) is not clear, and the approach itself seems unnecessarily complex. The main problem is that multiple approaches are outlined for presenting related information, and it is unclear whether these approaches are steps in a sequential process or simply an attempt to portray information using multiple formats. Furthermore, if steps within a sequential process, it is not clear how the steps are linked. For example, BNFL refers to the use of a model of environmental states and attributes (Status Report Figure B2, page B17), process influence diagrams (Status Report Figure B3, page B23), landscape models (Status Report Figure B4, page B24), and state-transition diagrams and matrices (Status Report Figures B5 and B6, pages B28-29). The way in which these methods will be used to support the PCSC, and their inter-relationships, are unclear.

However, having noted that BNFL's method for deriving scenarios is not clear, the Agency considers that, at an upper level at least, BNFL has defined an appropriate set of scenario classes (page 90, Status Report Section 4.5.4):

- Environmental evolution scenarios taking account of the natural evolution of the system environment and its subsequent impact on the Drigg disposal facility.

- Future human action scenarios, such as those that may result in intrusion into the Drigg disposal facility.

- Alternative scenarios based on intermittent events, such as those involving explosions, crashes or meteorite impacts, that may result in the gross disruption of the Drigg disposal facility.

The Agency expects BNFL to define individual scenarios within these scenario classes.

Clearing Houses

The role of Clearing Houses is described in Section 4.8.2 of the Status Report. The Agency expects BNFL to provide formally documented records of the work of the Clearing Houses involved in the 2002 PCSC. On page 101, BNFL indicates that the Assessment Clearing House will decide how many scenarios will be required for a sufficiently comprehensive assessment but does not explain how this decision will be taken. The text also indicates that the Assessment Clearing House will assign FEPs to other appropriate Clearing Houses. It is not clear how the Clearing House system will deal with FEPs relevant to more than one Clearing House. For example, it may be necessary to assign radionuclide transport FEPs to the Process System Clearing Houses for the near-field, geosphere and biosphere. It is not clear how the Assessment Clearing House will resolve any divergent advice from the Process System Clearing Houses on particular FEPs. The way in which the Clearing Houses will be staffed is not described in the Status Report, and it is not clear whether there will be overlap in staffing between the different Clearing Houses. In summary, the Agency expects BNFL to document the procedures for establishing and guiding the work of the Clearing Houses.

Representation of Trenches and Vaults in Interaction Matrices

On page B53 (Status Report Section B4.3.3), BNFL describes the rationale for the amalgamation of the trench and vault engineering and the trench and vault waste for the purpose of developing interaction matrices. However, in addition to the rationale put forward by BNFL (that the vaults and trenches only interact through other media), the amalgamation can only be justified if the vault and trench engineering and the vault and trench waste interact in the same way with the other elements considered in the interaction matrix - that is, the off-diagonal elements would have to be the same for the vaults and the trenches. The Agency considers that this assertion needs to be justified before the amalgamation can be used in the PCSC.

Engineering Performance Assessment

BNFL intends to use an engineering performance assessment (Status Report Section B4.3.2), largely based on expert judgement, to help in reaching decisions on the scope and content of the PCRSA. While the use of subsystem analyses and arguments to help support the PCRSA is appropriate, there are presentational difficulties associated with the engineering performance assessment. Examples are provided below:

- BNFL states on page B51 that it intends "...to select the most probable and/or the most disruptive scenarios for more detailed consideration [in the 2002 PCRSA]." The use of "and/or" indicates that BNFL will either choose the most probable scenarios (regardless of consequence), or the most disruptive scenarios (regardless of probability), or both. However, there are significant

differences between these three options. The Agency expects BNFL to clarify which approach it intends to take for the 2002 PCSC. The Agency considers that an appropriate approach might involve examining the most probable scenarios (regardless of consequence) and a range of disruptive scenarios that fall within some probability cut-off. It is also unclear what BNFL means by "most disruptive", and how BNFL can determine *a priori* what the most disruptive scenarios are.

- On page B51, BNFL indicates that expert judgement will be used to estimate the likelihood of scenarios, their consequences, and the uncertainty in likelihood and consequence. The Agency notes that the outcome of such an analysis will hinge on the validity of the expert judgement processes used, and the quality of the experts, and will itself be subject to significant uncertainty. For the 2002 PCSC, the Agency expects BNFL to document the expert judgement process and to consider means of building confidence in the process by conducting scoping calculations and sensitivity studies.

Performance of Engineering

On page 126 (Status Report Section 5.3.1.1), BNFL states that there will be "...a period of at least 300 years when the final engineering will function as designed...." BNFL has not justified the assumption that the final engineering will function as designed for 300 years to limit radionuclide migration. The Agency notes that there are releases of tritium from the trenches that have already migrated off-site over a period of a few decades or less (further comments on the tritium plumes and their potential to lead to future doses via the groundwater pathway are provided in Sections 3.2.7, 3.2.8, 3.2.10 and 3.2.13).

On page 107 (Status Report Section 5.2.1), BNFL states "As the engineered features for physical isolation gradually degrade, engineered drainage will be designed to direct contaminated leachate away from the accessible environment. Irrespective of its role as an infiltration barrier, the cap is expected to survive for thousands of years preventing waste exposure." The Agency has two comments on this statement. First, it is not clear how engineered features will be designed to direct contaminated leachate away from the accessible environment beyond the time at which other engineering features are beginning to degrade. Second, the Agency expects BNFL to justify its assumptions about the survival and performance of the final site cap.

Hydrogeological Interpretation and Modelling

Status Report Section A5.1 (page A37) provides a useful description of BNFL's methodology for interpreting the hydrogeology at Drigg but does not describe how or where the interpretation is documented or mention any procedures for recording such information. The Agency expects BNFL to provide a more detailed account for the 2002 PCSC of how the steps in BNFL's methodology were conducted.

In Status Report Section 3.2.4 (page 57), BNFL discusses its conceptualisation of groundwater flow at the Drigg site and notes that it is testing its conceptualisation by developing continuum groundwater models using the MODFLOW code. On page 58, BNFL distinguishes, in its hydrological conceptual model, between upper and lower groundwaters. The Agency notes that neither the rationale nor the basis for this distinction is presented and, according to BNFL, the two waters are in hydrogeological contact across the whole of the Drigg site.

BNFL intends its continuum groundwater flow models "to aid hydrogeological understanding" and to form the basis for the simplified network models of groundwater flow that will be included in the PCRSA (page 57). The Status Report does not describe how BNFL intends to ensure that the PCRSA network model is consistent with available site characterisation data and the hydrochemical interpretation. The Agency considers that it will be important for BNFL to demonstrate in the 2002 PCSC that the groundwater flow model incorporated in the PCRSA provides a reasonable approximation to actual groundwater flows at the Drigg site. The Agency expects BNFL to demonstrate that the groundwater flow models are appropriately calibrated to relevant site characterisation data. While it may be possible to develop and calibrate an acceptable network model of groundwater flow directly from site characterisation data, it is likely that such a model would necessarily comprise a detailed network with many nodes and legs. The Agency considers that it will probably be easier to justify the simplified PCRSA network models by demonstrating that the continuum model provides a reasonable approximation to actual groundwater flows at the Drigg site and documenting a comparison of the flow velocities and discharge zones calculated using the simplified PCRSA network model with those of the continuum model.

BNFL states on page A109 (Status Report Section A5.9.2) that "...it proved difficult to select representative hydraulic parameters for each model layer [for continuum flow modelling], despite having a large quantity of good quality field and laboratory hydrogeological data." Status Report Table A14 shows values for required hydrogeological modelling parameters that were "...arrived at primarily from examining the statistics of various data sets." The Agency has a number of comments on these statements:

- BNFL does not provide sufficient information (or references to where this information is contained) for the Agency to trace the logic behind the derivation of the values provided in Status Report Table A14. The Agency expects parameter values used in the PCSC to be traceable to source.

- No indication is provided of the uncertainty associated with the values in Status Report Table A14, although BNFL notes that statistical arguments were used to derive these values. The Agency expects BNFL to provide an

indication of the uncertainty associated with parameter values used in the PCSC and an evaluation of their significance.

- BNFL has averaged data collected from spatially heterogeneous units to derive single values for use in modelling. If this approach is followed in the 2002 PCSC, then the Agency expects BNFL to assess the significance of ignoring spatial heterogeneity at scales less than that used for averaging. The Agency expects BNFL to demonstrate that the PCSC takes adequate account of all relevant uncertainties including those arising from spatial variability. If PCRSA results are sensitive to assumptions concerning the hydrogeological parameters, then the Agency requires BNFL to consider the use of available methods, such as geostatistical techniques, to address spatial variability.

Illustrative PCRSA Models, Data and Results

In Appendix D of the Status Report, BNFL describes a series of illustrative PCRSA models, data and results. The Agency notes that due to the illustrative nature of the calculations and lack of supporting references, it is not possible to trace the logic behind the conceptual models and parameter values presented. Further, BNFL generally provides no indication of the uncertainty associated with the modelling assumptions and parameter values used as a basis for the calculations in the Status Report. The Agency expects BNFL to provide an indication of the uncertainty associated with scenarios, models and parameter values used for the 2002 PCSC.

As an example, the Agency notes that the assumed depth of trial pits of 4.5 m (page D67) is likely to be particularly important to the consideration of which human intrusion events can lead to a release and to the estimation of the consequences of possible releases. Similarly, the assumed diameter (and depth) of boreholes (page D69) is likely to be important to evaluation of the risks associated with inadvertent future human intrusion. The Agency expects BNFL to justify the parameters values selected in the 2002 PCRSA for the depths of trial pits and boreholes, and the diameter of boreholes by documenting the range of current practice. Further, the Agency expects BNFL to evaluate the sensitivity of PCRSA results to uncertainty in the values of parameters used to represent the depths of trial pits and boreholes, and the diameter of boreholes (see related comments on the treatment of uncertainty in Section 3.3.7).

3.2.7 Requirement R3 - Use of Best Practicable Means

> *The best practicable means shall be employed to ensure that any radioactivity coming from a facility will be such that doses to members of the public and risks to future populations are as low as reasonably achievable (ALARA).*

The Agency notes that the Status Report has not demonstrated that future engineering options proposed for the Drigg site represent BPM (see Section 3.2.11, Proposed Repository Design). BNFL indicates on page 14 (Status Report Section 1.2.1.2) that the site and facility description will focus on existing site features with minimal associated conceptual uncertainty. The Agency expects BNFL to document in the 2002 PCSC a comprehensive identification of FEPs, and to consider alternative engineering options.

The Agency notes BNFL's proposal to commence waste disposal to Vault 9 in 2003 (Status Report Section 3.4.3, page 67). The Agency considers that future vaults are a "new development" (GRA para 1.13). Therefore, prior to commencing disposals, the Agency expects BNFL to demonstrate that disposals to Vault 9 represent BPM. The Agency also expects BNFL to provide sufficient detail of the design of Vault 9 in the 2002 PCSC so that the Agency can assess the appropriateness of the representation of the vault in the PCRSA calculations.

With regard to the tritium plumes, the Agency notes that the Authorisation for the Drigg site requires BNFL to use BPM to limit the migration of radionuclides. The Agency therefore also requires BNFL to present an assessment of BPM for minimising radionuclide releases via the tritium plumes. Further comments on the tritium plumes are provided in Sections 3.2.6, 3.2.8, 3.2.10 and 3.2.13.

3.2.8 Requirement R4 - Environmental Radioactivity

> *It shall be shown to be unlikely that radionuclides released from the disposal facility would lead at any time to significant increases in the levels of radioactivity in the accessible environment.*

BNFL has provided a discussion of environmental radioactivity and levels of background radiation in Section 5.2.2 of the Status Report. The Agency notes BNFL's emphasis on, and use of, the UK average background dose for making comparisons with calculated doses from Drigg. The Agency considers that BNFL should, to the extent possible, support the use of the UK average value by providing an indication of how the UK average value differs from a regional (e.g., West Cumbria) or local (e.g., Drigg / Sellafield) value.

BNFL states on page 58 (Status Report Section 3.2.5.2) that "...tritium has been detected in both on-site and off-site boreholes drilled as part of the [Drigg Site

Characterisation Programme] DSCP. The tritium does not represent a significant radiological risk and, as described below, is moving seawards representing only a very small fraction of that permitted to be discharged directly to sea via the marine pipeline." The Agency expects BNFL to identify, quantify, monitor and document all radionuclide discharges from the site to allow comparison with background levels (this should include the tritium plumes, further comments on which are provided in Sections 3.2.6, 3.2.7, 3.2.10 and 3.2.13).

3.2.9 Requirement R5 - Multiple-Factor Safety Case

> *The overall safety case for a specialised land disposal facility shall not depend unduly on any single component of the case.*

Assessing the robustness of the Drigg PCSC in terms of GRA Requirement R5 requires understanding of the performance of the Drigg disposal system and, therefore, consideration of the available PCRSA results. BNFL indicates that the PCRSA models, data and results presented in Appendix D of the Status Report were not generated using the systematic PCRSA approach that BNFL has developed for use in the 2002 PCSC. The Agency acknowledges that the results presented in the Status Report are only of an illustrative nature. The PCRSA results in the Status Report can only be regarded as illustrative because BNFL has, for example, only considered a subset of radionuclides and a constant climate change scenario. Further, as noted previously, BNFL has not quantified or assessed the significance of uncertainty. Owing to the illustrative nature of the PCRSA results and the lack of sufficient information on the performance of the various components of the disposal system, it is not possible at this stage to assess whether the Drigg safety case is robust in the sense of GRA Requirement R5.

3.2.10 Requirement R6 – Site Investigations

> *The developer shall carry out a programme of investigations to provide information necessary for the safety case and to demonstrate the suitability of the site.*

Based on its review of the Status Report, the Agency has comments on BNFL's hydrogeological and hydrogeochemical characterisation and expects BNFL to:

- Evaluate whether further site characterisation, perhaps using new techniques, would help to reduce uncertainty and/or increase confidence in the PCRSA.

- Evaluate the potential influence of spatial variability on PCRSA results, and determine whether existing site data sufficiently characterise spatial variability.

On pages 53 to 55 (Status Report Section 3.2.3.2), BNFL discusses the hydrogeological zones of the Drift Aquifer, states that the Lower Diamict and Marine Silt hydrogeological zones are not considered important with respect to contaminant transport but does not present hydraulic conductivity or other characterisation data for these zones. Without further support for BNFL's assumptions, the Agency cannot evaluate their validity. The Agency expects BNFL to demonstrate that the present-day hydrogeology of the site is adequately understood to support the safety case (GRA Paragraph 7.7). The aim of site investigations during repository operation should include improving understanding of site hydrogeology, as well as building confidence in assessments of repository performance (GRA Paragraphs 7.5 to 7.8 and 8.8). The Agency considers that the Marine Silt and Lower Diamict hydrogeological zones may become more important under future climatic conditions when sea level may be lower.

BNFL suggests on page 57 (Status Report Section 3.2.4.2) that the chemistry of groundwaters at Drigg is consistent "...with evaporated rainwater and calcite equilibrium, with redox controlled by reactions of iron minerals." The Agency considers a possible alternative explanation may be that the groundwaters at Drigg reflect some degree of mixing between slightly brackish groundwaters from deeper aquifers and fresher, rainwater-derived groundwaters. In the same section, BNFL also suggests that the "...observed redox behaviour [of the groundwaters] can be modelled by assuming equilibrium between iron oxyhydroxides and siderite [$FeCO_3$] at the carbon dioxide partial pressures calculated from the field data." The Agency notes that according to Section 3.2.4.1 of the Status Report (page 56), siderite is not among the iron-bearing minerals detected at the site.

Status Report Figures A35 and A36 (Status Report Section A5.7.1) indicate that the highest tritium concentrations have been observed furthest from the trenches. This observation may be regarded as counter-intuitive, given that dilution and dispersion generally lead to lower contaminant concentrations at greater distances from the source of contamination. The Agency expects BNFL to:

- Explain why the highest tritium concentrations are observed furthest from the trenches.

- Document an evaluation of the processes that have resulted in development of the existing contaminant plumes and use this information to characterise the nature, distribution and properties of active contaminant transport pathways, and quantify potential future rates and magnitudes of radionuclide transport.

- Where possible, use information from the evaluation of the existing contaminant plumes to help develop and build confidence in the models used to support the PCSC.

Further comments on the tritium plumes are provided in Sections 3.2.6, 3.2.7, 3.2.8 and 3.2.13.

3.2.11 Requirement R7 - Facility Design and Construction

> *The facility shall be designed, constructed, operated and be capable of closure so as to avoid adverse effects on the performance of the containment system.*

Based on its review of the Status Report, the Agency has comments on the proposed repository design, the date of final cap emplacement and the costs of Drigg and the PCSC.

Proposed Repository Design

Pages 67-69 (Status Report Section 3.4.3) describe how BNFL envisages the site at closure. The Agency accepts that the design of the repository will be refined during repository operation (however, see Section 3.2.3, Available Technologies) but notes that BNFL has not explained the basis for the proposed reference design. For example, BNFL has not explained why the future vaults are of the size proposed, or why it is proposed to stack waste containers six high. The Agency expects BNFL to fully evaluate the impacts on safety of future developments at the site, which will include consideration of the bearing strengths of candidate foundation strata for future vaults and calculations that confirm the adequacy of the proposed foundation design.

The Agency encourages BNFL to consider LLW disposal practices and proposals at other sites and in other countries in comparison with the approach proposed for Drigg (see also comments relating to the demonstration of BPM, Section 3.2.7).

Date of Final Cap Emplacement

Table 1 on page 33 (Status Report Section 2.7.2) provides indicative dates for a sequence of events at Drigg. Status Report Table 1 suggests that that the final site cap will not be constructed until sixty years after the end of disposal operations. The Agency notes that substantial delay in the emplacement of engineering measures for closing the disposal facility may be regarded as a burden on future generations (see also Section 3.2.1, GRA Principle No. 1). Whilst BNFL has explained that the delay is to allow waste settlement and monitoring (Status Report, page 69), the Agency expects BNFL to justify the proposed length of the period before final cap emplacement.

Costs of Drigg and the PCSC

BNFL states on page 36 (Status Report Section 2.10) that expenditure for the PCSC "...should be in accordance with other comparable human activities." The Agency

expects BNFL to state clearly what comparable human activities it is referring to, and why those activities are comparable to the Drigg PCSC. The owners of radioactive waste are responsible for bearing the costs of its management and disposal, including the costs of regulation (see GRA Paragraph 7.16).

Table 11 on page 123 (Status Report Section 5.2.7) and associated text provides basic summary information on the overall costs of Drigg and the costs of developing the PCSC. The Agency expects BNFL to present a breakdown and justification of the estimated costs to demonstrate that it has in place a funding plan to ensure that future liabilities can be met.

On page 129 (Status Report Section 6.1.1), BNFL states that a safety case for continued operations might be expected to be different from that for a major decision point (e.g., for the start of disposal operations or final site closure). The Agency does not distinguish between assessments for major decision points and for periodic regulatory review. The Agency expects the PCSC to be developed in accordance with relevant legislation and guidance.

3.2.12 Requirement R8 - Waste Form and Characterisation

> *The developer shall derive waste acceptance criteria consistent with assumptions made in assessments of the performance of the system and with the requirements for handling and transport.*

The Status Report refers only briefly to BNFL's Conditions For Acceptance of waste (CFA) at Drigg, and does not describe in detail the basis for their derivation, although it does discuss (page 103) the potential influence on the CFA of results from radiological capacity assessments. The Agency considers that BNFL's emphasis on assessments of radiological capacity is too narrow, and notes that a range of factors beyond radiological capacity may influence the CFA. The Agency considers that the CFA should be consistent with PCRSA assumptions about the composition and characteristics of waste, as well as being compatible with the final results of the PCRSA in terms of calculations of dose and estimates of risk. For example, if it is assumed in the PCRSA that the waste does not contain a particular substance and the results of the PCRSA depend on this assumption then the CFA should prevent disposal of that substance. The Agency expects BNFL to document the basis for the derivation of the CFA at Drigg and to update the CFA at periodic intervals to ensure that they remain consistent with assumptions, models and parameter values in the most recent post-closure and operational environmental safety cases.

3.2.13 Requirement R9 – Monitoring

> *In support of the safety case, the developer shall carry out a programme to monitor for changes caused by construction of the facility and emplacement of the waste.*

Section 6.3 of the Status Report summarises BNFL's current arrangements for monitoring of the Drigg site. The Agency notes that BNFL's discussion of the monitoring programme is focused on the current monitoring arrangements. The Agency considers that long-term monitoring of the site to build confidence in PCRSA results is insufficiently addressed in the forward programme presented in the Status Report.

Paragraph 7.12 of the GRA states that

> *The developer should show that the methods of construction of the facility are such as to avoid undue disturbance of the geological environment and the containment properties of the host rock. The Agency will need to be satisfied that appropriate investigation and monitoring are carried out during the construction and operational phases to confirm the characteristics of the site, the behaviour of the facility and the extent of disturbance caused by intrusive site investigation procedures and by construction.*

None of the monitoring activities discussed by BNFL appears to address the issue of extent of disturbance caused by construction.

Paragraph 8.26 of the GRA states that

> *In accordance with Requirement R9, the developer will need to establish a strategy and programme for monitoring of the facility to support the safety case. This should include monitoring during the pre-construction period to provide a baseline for future performance, as well as during construction, operation and during any period of control after closure of the facility.*

Beyond a commitment to review the monitoring programme as part of the 2002 PCSC, the Status Report gives no indication of BNFL's strategy for developing and implementing a programme as required by GRA Paragraph 8.26. The Agency expects BNFL to present a more detailed forward programme that includes wider consideration of the need for long-term monitoring.

With respect to the tritium plumes (see also Sections 3.2.6, 3.2.7, 3.2.8 and 3.2.10), BNFL notes (page A77) that there are insufficient data points to the northeast of the trenches to determine groundwater tritium concentrations. Flows to the northeast

have in the past been inferred from the discovery of tritium in the railway cutting drain that runs along the northeast boundary of the Drigg site. Although tritium concentrations in the railway drain have reduced since the installation of the bentonite cut-off wall, the Agency expects BNFL to:

- Continue to assess the need for further monitoring of the contaminant plumes as more information is collected.
- Consider the need for additional monitoring to the northeast of the trenches.
- Discuss with the Agency proposed locations for additional sampling points.

On page A88 (Status Report Section A5.6.4.2), BNFL notes that there are no data on the magnitude of the water fluxes from the trenches to the leachate management system for the period considered in the water balance calculations. The Agency notes that monitoring of the fluxes from the trenches to the leachate management system could provide useful confirmation that the interim cap over the trenches is functioning as designed and early warning of any reduction in its performance. The Agency expects BNFL to confirm that the leachate management system is functioning as intended.

3.2.14 Requirement R10 - System of Records

> *The developer shall set up and maintain a comprehensive system of records for the recording of detailed information on all aspects of the project affecting the safety case.*

In accordance with the Authorisation, BNFL keeps records of disposals at Drigg and these are available for inspection by the Agency. Monthly summaries of disposals are provided to the Agency and copied to the relevant public registers.

BNFL's procedure for developing the PCRSA includes formalised methods for recording information on CMU forms and parameter input forms (PIFs). CMU forms record uncertainties, PCRSA assumptions and their justification, and appraisal of alternative assumptions. PIFs are used as a means of recording supporting information on parameters used in calculations and modelling. The Status Report also describes the information to be recorded by BNFL's Clearing Houses (see Section 3.2.6).

The Agency considers that while disposal records, CMU forms, PIFs, and other PCRSA tools may be regarded as components of an appropriate system of records for the PCSC, the system of records should be broader than this, and will need to cover all aspects of the PCSC, including records of site characterisation data and engineering designs.

3.2.15 Requirement R11 – Quality Assurance

> *The developer shall establish a comprehensive quality assurance programme for all activities affecting the safety case. This shall include supporting activities such as research and assessment.*

Based on the review of the PCSC Development Programme, the Agency is aware that BNFL has a QA regime in place and is continuing to develop procedures controlling the development of the PCSC. However, the Status Report contains insufficient information for the Agency to assess the appropriateness of BNFL's QA system to the PCSC. Based on the review of the Status Report, the Agency has comments relating to the role of QA in the PCSC, QA of historical data, and the use of peer review.

Role of QA in the PCSC

The main components of the 2002 PCSC are briefly described in Section 1.2.1 of the Status Report. The Agency expects BNFL to provide a clear statement in the 2002 PCSC of the requirements for QA and to demonstrate that these requirements have been implemented. This will need to be more detailed than the section on QA included in the Status Report Section 1.3.2, which states that all work carried out within the DTP is conducted in accordance with a project QA programme based on the BNFL management system. The Status Report provides no evidence that the BNFL management system is appropriate for the PCSC, or that QA audits are conducted of the DTP[3].

BNFL refers on page 75 (Status Report Section 4.2.2) to "...the use of formalised procedures to record uncertainties in conceptual models and input parameters..." The Agency expects BNFL to demonstrate that appropriate QA and formalised procedures have been used throughout the PCSC.

BNFL has established a four-tier hierarchy for the documents that will constitute the 2002 PCSC (Status Report Section 1.2.2, page 15). The Agency notes that BNFL has allocated QA documents, including standards and procedures, to the lowest tier, Level 4. BNFL indicates that Level 4 documentation will not normally be published but will be available to the Agency for auditing purposes. The Agency considers that demonstration of an appropriate quality management system and its application will be an essential component of the PCSC. The Agency recommends, therefore, that appropriate QA documents are raised above Level 4.

The Agency welcomes BNFL's statement that "It is planned that only minimal information will need to be classed as commercially confidential." However, the

[3] Since publication of the Status Report, BNFL has presented the Agency with further information on its QA system, including summary results of QA audits.

Agency expects BNFL to clearly justify any claim that information which is part of the 2002 PCSC is commercially confidential.

QA of Historical Data

BNFL notes on page 120 (Status Report Section 5.2.5.3) that some of the historical site characterisation data are "of variable quality." The Agency expects BNFL to take appropriate steps to verify the quality of any historical data on which the PCSC relies. The US Environmental Protection Agency has documented procedures for the qualification of old data (US EPA 1996), and the Agency encourages BNFL to consider application of such procedures in order to build confidence in historical site characterisation, inventory and other data from Drigg.

Peer Review

BNFL's use of peer review is described on page 117 (Status Report Section 5.2.5): "To date the DTP has mainly used peer review for specific aspects of work. Because of the ongoing information exchange and regulatory review with the Agency, a peer review of the entire technical programme has not been carried out." The Agency does not regard its regulatory review of BNFL's documents as peer review. The Agency notes that BNFL has not yet provided any records of peer reviews or evidence that issues raised have been addressed. The Agency expects BNFL to use peer review as one means of building confidence in the assessment codes and PCSC (GRA Paragraphs 8.3 and 8.19). The Agency expects BNFL to fully document such peer reviews, and to provide all peer review reports to the Agency[4].

3.3 Assessment of the Status Report Against the Agency's Specific Review Objectives

In this Section, the Agency summarises its evaluation of the Status Report against the review objectives presented in Section 2.1 of this report.

3.3.1 Quality Assurance

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The Agency notes that BNFL has a QA regime in place and is continuing to develop procedures controlling the development of the PCSC, but considers that the Status Report contains insufficient information for the Agency to assess the appropriateness of BNFL's QA system to the PCSC. (see Section 3.2.15).

[4] Since publication of the Status Report, BNFL has provided further information on its approach to peer review.

3.3.2 Interpretation of Regulatory Guidance

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The Agency has identified three areas in which BNFL's interpretation of the GRA is either incompatible with the regulatory position or is incompletely defined. These areas are the:

- Status of Planned Disposals.
- Criteria for Past and Future Disposals and Intervention.
- Conformity of the PCSC to GRA Principle 1.

Status of Planned Disposals

BNFL indicates on page 24 (Status Report Section 2.3) that Drigg is an "existing facility" rather than a "new development" under the terms of the GRA. While the trenches and Vault 8 are certainly existing, the Agency considers that planned disposals (e.g., future vaults) are new developments.

Criteria for Past and Future Disposals and Intervention

BNFL states on page 24 that "... the appropriate criteria, in particular in terms of risk target, for past disposals to the trenches and to a lesser extent Vault 8, may differ from that for new facilities and disposals..." The Agency regards the entire disposal facility as a single source in the context of dose calculations (see GRA Paragraph 5.11) and as a single entity in the context of risk calculations. Therefore, the Agency expects BNFL to present in the 2002 PCSC risks calculated for the entire disposal facility, including the trenches and the vaults. Furthermore, the Agency expects BNFL to demonstrate, either that risks from the entire disposal facility do not exceed the 10^{-6} per year risk target or that the disposal facility has been, and continues to be, optimised in accordance with GRA Principle No. 3 (see Section 3.2.3) using BPM. In the case of existing disposals, if risks are substantially above the risk target then intervention would need to be considered. In the case of future vault disposals, if risks are above the risk target then such disposals may not be authorised.

The Agency considers that when reporting results from risk assessment calculations, it is important to provide an adequate breakdown of the results in order to illustrate, in a transparent manner, the performance of the different components of the disposal system (see GRA Paragraphs 7.2 and 7.3). Therefore, in addition to presenting risks calculated for the entire disposal facility, the Agency expects BNFL to present in the 2002 PCSC risks calculated for the vaults and trenches separately, and for individual barriers within the disposal system. If risks exceed the target, such information will be required for considering optimisation and intervention.

BNFL also states on page 24 that "...the principle of intervention will be important..." If calculated risks are sufficiently high, the Agency will expect BNFL to consider in the 2002 PCSC how intervention could be applied to Drigg.

Conformity of the PCSC to GRA Principle 1.

Based on its review of the Status Report, the Agency is concerned that BNFL's approach to the PCSC may not be consistent with the aims of GRA Principle 1. The Agency's concern relates to BNFL's assumptions about the effectiveness of, and financial responsibility for, passive institutional controls (see Section 3.2.1).

3.3.3 Comprehensiveness, Integration and Risk Management

The Agency considers that BNFL's assessment methodology incorporates a number of features that should help to ensure that the PCRSA is comprehensive. The success of these methodological tools, such as interaction matrices and FEP lists, will depend upon their effective implementation. Similarly, while the Status Report has for the first time demonstrated how BNFL intends to integrate the components of its programme, the success of the 2002 PCSC in providing a basis for regulatory decision-making has yet to be demonstrated.

Page 16 and Figure 2 (Status Report Section 1.3) describe and illustrate BNFL's structure for the DTP. The Agency notes that there appears to be a distinct, and potentially detrimental, separation between the PCRSA and the Drigg Supporting Studies. Separating the supporting studies programme from the PCRSA may lead to a lack of support for some areas of the PCRSA. The Agency expects BNFL to use the results of post-closure risk assessments to identify and prioritise the Drigg Supporting Studies (see DETR *et al.* 2000).

The Agency is concerned that BNFL is yet to identify and demonstrate an understanding of the processes (and their interactions) likely to dominate radiological risks from Drigg. The Agency expects BNFL to apply the PCRSA iteratively to refine its understanding of system behaviour, identify any necessary risk management measures, and prioritise the PCSC Development Programme. The Agency expects BNFL to focus effort on those FEPs, pathways and scenarios associated with the greatest potential risks (see GRA Paragraphs 6.14, 8.3, 8.15 and 8.17).

3.3.4 Optimisation

The Agency considers that satisfactory demonstration of optimisation is a central requirement of the Drigg PCSC. However, the Status Report has not clearly defined BNFL's intentions for optimisation studies in the 2002 PCSC. The Agency has made several comments on issues relevant to optimisation, including the scope of optimisation studies, and the relationship between inventory and risk (see Section 3.2.3, GRA Principle No. 3).

The Agency encourages BNFL to take a broad view of optimisation and to use the PCSC to consider a range of options, including disposal of the entire UK LLW inventory and, if this is not feasible within the capacity of the site, a reduced inventory. If the results of the PCRSA indicate that the estimated risk is greater than the target, then the Agency expects BNFL to provide quantitative estimates of disposal system performance using alternative engineering measures to support any assertion that risks are ALARA and the reference design represents BPM.

3.3.5 Example PCRSA Results and the Use of Data in the PCRSA

The illustrative PCRSA results provided in the Status Report demonstrate that BNFL has a working methodology for the calculation of post-closure risks. However, the Status Report does not present example results from each of the assessment codes that BNFL intends to use in the 2002 PCRSA. Nevertheless, the Status Report has provided the Agency with an improved understanding of how data will be used in the PCRSA.

The 2002 PCSC will need to include a more extensive presentation of PCRSA results to enable the Agency to assess the robustness of the PCSC (see Sections 3.2.8 and 3.3.7).

3.3.6 Traceable Record of PCRSA Assumptions and Data

BNFL's assessment methodology incorporates a number of features that will help BNFL to document the 2002 PCRSA in a traceable manner, including PIFs and CMU forms. However, the Status Report does not provide sufficient information for the Agency to trace the logic behind the conceptual models and parameter values presented (see Section 3.2.6). The Agency expects BNFL to provide in the 2002 PCSC a traceable record of the assumptions and data used in the PCRSA.

3.3.7 The Treatment of Uncertainties

In discussing its methodology for the treatment of uncertainties in the PCSC, BNFL recognises that "...not all uncertainties can be quantified mathematically or statistically and it is necessary to deal with both the qualitative and quantitative aspects of uncertainty." BNFL's stated approach to the qualitative aspects of uncertainty seeks to make explicit all decisions made and assumptions adopted in the course of an assessment.

BNFL recognises that the quantitative aspects of uncertainty can be managed using a variety of methods ranging from simple calculations, through a number of deterministic modelling approaches to probabilistic simulation studies (Status Report, page 73). However, the Agency considers that BNFL has neither provided an adequate description of its approach to the quantification of uncertainty in the PCRSA

nor evidence that iterative risk analysis has been used to identify the most significant uncertainties.

BNFL suggests on page 92 (Status Report Section 4.5.4) that sensitivities to parameter and conceptual model uncertainty, and optimisation, will be examined using a reference case that neglects environmental change and all other EFEPs. While the Agency considers that such an unrealistic case may have some use in presenting results, it should not be the sole focus of sensitivity and optimisation studies. Use of such a case without also considering sensitivities and optimisation around one or more cases that involve climate change and any other likely EFEPs could lead to misleading conclusions[5].

In Status Report Section D5, BNFL has provided two examples of how conceptual model and parameter uncertainty may be assessed quantitatively in the PCRSA. The Agency has the following comments on these examples:

- The example of conceptual model uncertainty assessment (Status Report Section D5.1) considers an alternative model "...where approximately 10% of the flux from the near field discharges into the Drigg stream..." (page D92). No justification is provided for this alternative, nor for the subsequent statement that "...this is extremely unlikely under present day conditions..." (see also page D95). The Agency expects alternative modelling assumptions and parameter values to be justified and traceable to source in the same manner as the reference case modelling assumptions and parameter values. In addition, for this particular alternative conceptual modelling assumption, any view on the reasonableness of the assumption would have to consider the situation for alternative scenarios, not simply the constant climate scenario.

- The conclusion of the example of parameter uncertainty analysis (Status Report Section D5.2) is that "...uncertainty in cap performance ... ...is not capable of significantly increasing risks such that the risk target is exceeded..." (page D98). While this statement may be true for the particular analysis conducted, the analysis was conducted without considering other parameter values that BNFL might modify, or further alternative modelling assumptions that might be made. The Agency notes that if other parameters were varied, the conclusion may be different. In general, BNFL has not presented a clear picture of how it will deal with potentially complex interactions within the overall system, in its approach to treatment of uncertainty.

In summary, the Agency considers that BNFL's methodology for the treatment of qualitative uncertainties using form-based procedures to record unquantified

[5] Since publication of the Status Report, BNFL has revised its approach toward a reference case that incorporates climate change. The Agency considers this revision to be appropriate.

uncertainties is appropriate. However, the Agency considers that the Status Report has not provided an adequate description of BNFL's approach to the quantification of uncertainty in the PCRSA. The Agency expects BNFL to define and implement in the 2002 PCSC an approach to classify, prioritise and manage uncertainties. In addition, there is a pressing need for BNFL to define its strategy for undertaking PCRSA sensitivity studies, including which model parameters will be varied, which combinations of parameter variations will be examined, how parameter correlation will be considered, and how the results of sensitivity studies will be synthesised for presentation.

3.3.8 Progress Towards the 2002 PCSC and Forward Programme for the PCSC

The Status Report has not provided a means of assessing BNFL's progress toward the 2002 PCSC or a sufficiently detailed forward programme. For example:

- The list of BNFL's achievements (Status Report Section 1.3.1, pages 17-19) is presented with incomplete referencing to support the claims made.

- BNFL's forward programme for completion of the 2002 PCSC is presented in Table 13 on pages 136-138 (Status Report Section 6.2). Table 13 gives the impression that a large majority of the work needed to complete the 2002 PCSC is "complete". The Status Report does not acknowledge that all of the work indicated as "complete" has been subject to review by the Agency. Many of the Agency's review comments question the clarity and completeness of BNFL's work.

This is a significant concern because a primary objective of the Status Report was to provide the Agency with an indication of progress towards developing a PCSC in 2002 that will meet the Agency's expectations (Table 1).

Based on its review of the PCSC Development Programme over the past four years, the Agency acknowledges that BNFL has been responsive to the Agency's concerns with its programme and has made progress in terms of developing its methodology for the PCRSA. However, the Agency also considers that in the period leading up to the 2002 PCSC, BNFL will need to make significant progress in implementing its methodology. As noted above, the Agency expects BNFL to demonstrate that post-closure risk assessment has been used to prioritise work in developing the 2002 PCSC and subsequent PCSCs.

3.3.9 Implications for Practices During the Operational Phase

Based on its review of the Status Report, the Agency has identified two issues that may have implications for practices during the operational phase. These issues relate to the justification and optimisation of repository design (Sections 3.2.3, 3.2.7, 3.2.11 and 3.3.4), and the tritium plumes (Sections 3.2.6, 3.2.7, 3.2.8, 3.2.10 and 3.2.13), as summarised below:

- The Agency will review the Authorisation for the Drigg site periodically and will undertake careful evaluation of proposed revisions to disposal practices in order to ensure that they represent BPM and are appropriate to current regulatory standards. The Agency will review BNFL's assumptions about release pathways, the inventory and other factors that may influence the impact of disposals. The Agency may wish to attach conditions to the Authorisation based on the disposal practices and closure options considered in the PCSC.

- The Agency expects BNFL to present an assessment of the best practicable means for minimising radionuclide releases via the contaminant plumes.

4 CONCLUSIONS

The Agency's evaluation of the Status Report may be summarised as follows:

- **Quality Assurance:** BNFL has a QA regime in place and is continuing to develop procedures controlling the development of the PCSC. However, the Status Report contains insufficient information for the Agency to assess the appropriateness of BNFL's QA system to the PCSC.

- **Regulatory Interpretation:** BNFL's interpretation of available regulatory guidance is incompatible with the regulatory position, or is incompletely defined in three areas:

  - BNFL suggests that planned future vaults are not new developments but are part of an existing facility. The Agency considers that future vaults are new developments.

  - BNFL suggests that different criteria should be applied to past and future disposals. The Agency regards the entire disposal facility as a single source in the context of dose calculations and as a single entity in the context of risk calculations. The Agency expects BNFL to

present risks both for the whole facility, and for the vaults and trenches separately.

- The Agency considers that the approach described in the Status Report is not entirely consistent with Principle 1 of the GRA. The Agency expects BNFL to ensure that the PCSC is consistent with the Principles of the GRA.

- **Comprehensiveness, Integration and Risk Management:** BNFL's assessment methodology incorporates a number of features that should help to ensure the PCSC is comprehensive, and the Status Report has for the first time described how BNFL intends to integrate the various components of its programme into the PCSC. However, the Agency is concerned that BNFL is yet to demonstrate an understanding of which processes are likely to dominate radiological risks from Drigg. The Agency expects BNFL to demonstrate that post-closure risk assessment has been used iteratively to refine understanding of system behaviour, identify any necessary risk management measures, and prioritise the PCSC Development Programme.

- **Optimisation:** BNFL has not clearly defined the optimisation studies to be considered in the 2002 PCSC. The Agency encourages BNFL to take a broad view of optimisation and to use the PCSC to consider a range of options, including, for example, disposal of the entire UK LLW inventory and, if this is not feasible within the capacity of the site, a reduced inventory. If estimated risks are greater than the risk target, then the Agency expects BNFL to provide quantitative estimates of disposal system performance for alternative engineering measures, to demonstrate that risks are as low as reasonably achievable, economic and social factors being taken into account, and that disposal practices and repository design represent BPM. In the case of existing disposals, if risks are substantially above the risk target then intervention would need to be considered. In the case of future vault disposals, if risks are above the risk target then such disposals may not be authorised.

- **Models and Data:** The illustrative modelling results provided in the Status Report demonstrate that BNFL has a working methodology for the calculation of post-closure risks. While the Status Report does not present results from all of the assessment codes that BNFL intends to use in the 2002 PCSC, it has provided the Agency with an improved understanding of how data will be used in BNFL's risk assessment. The 2002 PCSC will need to include a more extensive presentation of the risk assessment models and results.

- **Traceable Record of Assumptions and Data:** BNFL's assessment methodology incorporates a number of features that will help BNFL to document the 2002 PCSC in a traceable manner, including PIFs and CMU

forms. However, the Status Report does not provide sufficient information for the Agency to trace the logic behind the conceptual models and parameter values presented.

- **Treatment of Uncertainty:** BNFL's use of form-based procedures to record unquantified uncertainties is appropriate. However, the Status Report has not adequately described BNFL's approach to the quantification of uncertainty. The Agency expects BNFL to define and implement in the 2002 PCSC an approach to classify, prioritise and manage uncertainties. In addition, there is a pressing need for BNFL to define its strategy for undertaking and presenting results of sensitivity studies.

- **Progress and Forward Programme for the PCSC:** The Agency acknowledges that BNFL has been responsive to its concerns with the PCSC Development Programme and has made progress in terms of developing its methodology. However, the Status Report has not provided a means of assessing BNFL's progress toward the 2002 PCSC or a sufficiently detailed forward programme. The Agency considers that in the period leading up to the 2002 PCSC, BNFL will need to ensure that its methodology is implemented effectively.

In conclusion, the Agency considers that subject to satisfactory resolution of the issues identified during the Agency's review of the PCSC Development Programme, BNFL has the potential to assemble a PCSC in 2002 that will provide a sufficiently comprehensive examination of the relevant issues to inform regulatory decision-making. Unless specifically stated, issues do not necessarily have to be resolved for the 2002 PCSC; however, unresolved issues will be considered by the Agency in determining any future authorisation requirements.

The Agency notes that since publication of the Status Report, BNFL has presented the Agency with further information on the PCSC Development Programme and its QA system, and has revised its approach in several areas. The Agency will continue to review BNFL's PCSC Development Programme and to monitor progress towards the 2002 PCSC.

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APPENDIX 1 ADDITIONAL COMMENTS

This Appendix contains a series of additional comments on the Status Report that are of relatively minor significance, including editorial comments and requests for clarification. The comments are presented by topic, according to the order of material in the Status Report. Comments are provided on the main text of the Status Report, and on Appendices A, B and D.

A.1 Main Text

Document Quality Control

The Status Report contains several obvious typographic and formatting errors. For example, on page 27 the definition of LLW is incorrect: the text should read "...not exceeding *4* $GBqt^{-1}$ alpha emitting radionuclides..."

Throughout the Status Report data are reported and inferences made without proper referencing. For example, on page 35 BNFL states that "...faults in the solid geology are however not of great significance in the context of the Drigg site for which flows within the drift geology dominate potential contaminant movement" but provides no citation. On pages A44 and A45, the following points are made but no citations are provided:

- "Hydrochemical data suggest that groundwater at depth is not derived from groundwater that has migrated down through the overlying water bearing units, rather a complex pattern of older and younger waters exist that can only be explained by higher hydraulic conductivity pathways, which allow some water bearing units to be bypassed."

- "The pumping tests indicate that the Main Diamict behaves as a leaky aquifer with leakage from the uppermost drift."

- "The hydrochemical and hydraulic property data suggest extensive leakage from the perched groundwater to the regional water. Therefore, this zone is extremely important in controlling the movement of leachate within the environment."

Further examples are provided throughout this appendix.

References to the Risk Target

The Agency considers that it would have been appropriate for the Status Report to introduce the numerical value of the risk target at an earlier stage; it is first presented in Status Report Figure 21 on page 81. For example, the text of Status Report Section

1.2.1.3 on page 14 correctly identifies risk as one of the key performance indicators but fails to mention that one purpose of calculating risk is for comparison with the risk target. The risk target could also usefully have been mentioned in Status Report Section 4.1.3 on page 72.

The Agency also considers that in cases where the illustrative PCRSA results suggest that the risk target is exceeded (e.g., page D33), BNFL's comparison of peak dose with the UK average background dose obscures the more important information that the risk target is exceeded.

Impacts on Non-Human Species

BNFL notes on page 22 (Status Report Section 2.2) that it does not plan to consider in the PCSC radiological impacts on non-human species. The assumption that the standard of environmental control needed to protect man will ensure protection of other species derives from the International Commission on Radiological Protection (ICRP 1977, 1991). The Agency notes that this assumption has been questioned in recent years (e.g., Environment Agency 1998), and that the Agency is participating in research on radiological impacts to non-human species and is keeping its position under review. In addition, potential impacts on non-human species may need to be considered in the Drigg PCSC in relation to the Habitats Directive. The Agency would welcome continued dialogue with BNFL on the issue of impacts on non-human species.

Proposed Annual Disposal Limits

On page 31 (Status Report Section 2.5), BNFL states that "The PCRSA results will therefore be used in the PCSC to review the radiological capacity of the site and to put forward appropriate annual disposal limits. These will determine the potential actual future disposals to the site and hence which LLW will not be acceptable for disposal at Drigg." The Agency notes that BNFL's proposals for annual disposal limits will form only one of several inputs to decisions that the Agency will take concerning any future authorisation of waste disposal to Drigg. BNFL should not assume a direct correlation between its proposals and what will be adopted by the Agency.

International Context

BNFL states on page 32 (Status Report Section 2.6, see also the top of page 36 and page 78) that "...assessment methodologies for near surface facilities are significantly less developed than those for deep geological disposal repositories." However, BNFL's argument is not clear, as its assessment methodology is based in large part on methodologies developed for deep geological disposal of high-level radioactive waste (HLW) in Sweden. Furthermore, the risk assessment methodology developed within the IAEA ISAM project (e.g., Status Report Figure 18, page 71), which BNFL also cites as a basis for its methodology, is similar to that which would be applied to deep

disposal. The Agency considers that this is not inappropriate and that assessment methodologies for near-surface and deep disposal should be broadly similar. Furthermore, there is actually more practical experience of applying assessment methodologies to decision making for near-surface disposal (e.g. Dolinar *et al.* 1996; IAEA 1997) than for deep disposal of HLW; as yet there have been no licensing procedures for HLW disposal anywhere in the world. The Agency agrees with BNFL's statement on pages 118-119 that "...many of the general principles, methodologies and problems associated with long-term performance assessments apply equally well to near surface disposal."

Geophysical Surveys

Figure 7 (Status Report Section 3.2.2, page 42) shows that micro-resistivity and ground-penetrating radar surveys were undertaken to the west and south of the Drigg site. The Agency expects BNFL to clarify the purpose of these surveys and why they were located off-site.

Hydrology and Hydrochemistry

In Status Report Section 3.2.3.2 (pages 53 to 55), no values are presented for the hydraulic conductivity of the Lower Diamict, Marine Silt and Holocene Recent (peat) hydrogeological zones, although such information is provided for all of the other zones.

Determination of Hydrologically Effective Rainfall

No explanation or reference is given as to how the loss of water by evapotranspiration is estimated when determining Hydrologically Effective Rainfall (page 58, Status Report Section 3.2.5.1).

Data Precision

As a general comment, parameters in the Status Report are often reported to a level of precision that may not be appropriate given the long-term nature of the calculations, and without an indication of the associated uncertainty. Together this may imply greater knowledge than is actually the case. For example:

- In Status Report Table 5 (pages 63-65), radionuclide inventories for the vaults and trenches are often reported to the same level of precision regardless of the fact that the level of uncertainty is likely to be greater for the trench inventory.

- In Status Report Table D12 (page D28), the use of a fractional occupancy of 0.0014 for a farmer in the estuary seems to imply knowledge of a farmer's whereabouts down to about half a day in any year or 35 days spread over a 70-

year lifetime. The data quoted for the biosphere may be based on present-day habit surveys but it may not be appropriate to take such precise values forward into the PCRSA.

- In Status Report Table D35 (page D75), "inhalation of dust by a laboratory technician" is assigned a value of 0.00109 rather than 0.001.

PCRSA Methodology

On page 71 (Status Report Section 4.1), Figure 18 contains a decision box "Effective to modify assessment components?" that can lead to rejection of an assessment component. It is unclear from the text what is meant by an assessment component or what happens when one is rejected. The Agency notes that the figure appears to imply that an assessment component that cannot be modified may be omitted from the assessment in order to produce an "adequate safety case."

Scenario Identification

On pages 75 and 76 (Status Report Section 4.2.3), BNFL discusses scenario definition. BNFL's text appears to be contradictory. For example, BNFL's statement that "Risks associated with the post-operational phase of the Drigg facility differ from those associated with many other environmental hazards in so far as they are generally not related to events that can arise suddenly, with severe potential effects" appears to conflict with the subsequent statement, "In addition, the facility is itself at risk from aperiodic events, both natural and human-induced, that may lead to loss of containment or enhanced releases" (see also GRA Paragraphs 8.17, 8.21).

Snapshots, Schematics and Scenarios

In several instances, the descriptions in the Status Report of "snapshots", "schematics" and "scenarios" are not sufficiently clear:

- On page 84 (Status Report Section 4.4.6), the statement that "Futures are considered to be time-histories that may be represented within a scenario as a linked sequence of snapshots" is not sufficiently explained. The text fails to explain what a snapshot is or how snapshots are linked within a scenario.

- On page 104 (Status Report Section 4.9.2), the statement that "Sequences of schematics have been adopted to indicate the evolution of the landscape in each scenario" is not sufficiently explained. The text fails to explain the relationship between the sequences of schematics, snapshots and scenarios.

- On page B29 (Status Report Section B3.2.3), the statement that "Snapshot descriptions of system states may be supported by sketches illustrating the

spatial relationships between FEPs and their attributes" is not sufficiently explained.

Terms such as of "snapshots", "schematics" and "scenarios" could usefully be explained in the PCSC glossary.

Definition of Scenario

On page 85 (Status Report Section 4.5.1), BNFL states that "A scenario is a broad description of the evolution of the disposal facility and its surroundings from the time of site closure as a result of natural, waste-related and engineering-related processes." This definition is poor in that, as BNFL implicitly acknowledges in the text that follows the definition, it appears to omit the possible influence of future human actions. BNFL interprets "natural processes" to include future human actions; however, future human actions could be identified separately from natural processes to avoid ambiguity in the definition.

System Environment Model

On page 88 (Status Report Section 4.5.3), Figure 23 illustrates BNFL's EFEPs System Environment Model. While the overall structure of the figure seems appropriate, there are some questionable details. For example, it is not immediately obvious why glaciation is classified as a continuous effect, or why explosions and, particularly, crashes are related to land-use. Status Report Figure 24 on page 89 illustrates the relationship between BNFL's System Environment Model and the Landscape and Process System Models. It is not clear why certain FEPs, such as Tsunami, appear at different levels in Status Report Figures 23 and 24. Also, it is not clear whether all of the inputs (boundary conditions) to the Process System Model illustrated in Status Report Figure 24 have been identified; for example, externally driven hydrochemical changes are not illustrated in the figure.

EFEPs

As noted in the main body of this report, the Agency considers that BNFL has defined an appropriate set of scenario classes. However, Status Report Section 4.5.4 (page 90), which provides further discussion of BNFL's scenario classes, appears to omit some of the EFEPs identified in Status Report Table 7 (e.g., EFEP numbers 1.3.10 and 1.2.07).

Presentation of PCRSA Results by Waste Stream

BNFL indicates on page 103 (Status Report Section 4.9) that it will present a breakdown of PCRSA results by exposure pathway, potential exposure group, time period, and radionuclide or decay chain. The Agency notes that to facilitate

consideration of optimisation, BNFL may, in addition, wish to present results by waste stream.

Dose-Risk Conversion Factor

On page 111 (Status Report Section 5.2.2), BNFL states "Using the International Commission on Radiological Protection (ICRP) recommended dose-risk conversion factor of 0.06 Sv^{-1} (GRA Paragraph 6.16), the average annual dose in the UK due to natural sources of 2210 :Sv, corresponds to a risk of around 1E-04 y^{-1}, equivalent to about 6,000 deaths per year. The Agency considers it is misleading to imply that a direct link can be made between the natural radiation background and this number of deaths.

BNFL also states on page 111 (Status Report Section 5.2.2) that "Although the Drigg PCRSA is based on the current ICRP guidelines and a dose-risk conversion factor of 0.06 Sv^{-1} for stochastic doses below 0.5 Sv, it must be viewed against the background that there is a growing body of opinion that this is a very conservative assessment of the health effects of low radiation doses." The Agency considers that this is a debatable area. BNFL should regard the values of regulatory criteria, including the risk target and the dose-risk conversion factor contained in the GRA and related documents, as part of the assessment context.

Risk Comparisons and Perceptions of Safety and Risk

Sections 5.2.3 and 5.2.4 of the Status Report, which discuss risks from other spheres of human activity (i.e., other than radioactive waste disposal) and perceptions of safety and risk, contain many statements that are not supported by references, such as those at the bottom of page 111, in the second paragraph of page 112, and on page 114.

The Agency also notes that on page 113, BNFL has misquoted the GRA. BNFL indicates that "A risk of one in a million per year is well below that implied by the natural background radiation in the UK which varies from about one in 10,000 to one in 1,000 years." The GRA indicates that "A risk of 1 in a million per year is well below that implied by the natural background radiation in the United Kingdom which varies from about 1 in 10,000 per year to *more* than 1 in 1,000 per year" (emphasis added).

Inclusion of Stakeholders in Confidence Building Activities

The Agency notes that in Section 2.1 of the Status Report (page 21), BNFL identifies a wide range of stakeholders, but that in Status Report Section 5.2.5.2, "Project communication and confidence building activities" (pages 117-119), only a much smaller range of stakeholders (principally the nuclear industry and the scientific

community) is mentioned. The Agency considers that the needs of a wide range of stakeholders should be addressed in communications about the safety case.

Comparison of LLW and HLW

In the last paragraph on page 125 (Status Report Section 5.3.1), BNFL presents a "qualitative argument for LLW disposal sites". The Agency considers that the assumptions on which the argument relies are debatable, and further justification of the assumptions will be needed if they are to be the basis of such an argument.

Projected LLW Arisings

Table 15 on page 145 (Status Report Section 7.1.2.2) compares projected LLW arisings up to ~2050 against radiological capacity calculated assuming that annual individual risks are kept below 10^{-6} per year. This information is useful, and the Agency expects BNFL to present a justification and traceable derivation for this information in the 2002 PCSC.

A2 Appendix A: Drigg Site Characterisation

Geological Characterisation

The description of geological understanding of the Drigg site (Status Report Appendix A) would be clearer if supplemented by figures showing the relationships between units and the extent of the areas being discussed. The Agency expects BNFL to present such information as text and figures in the PCSC. Some of the figures that have been referenced are not completely clear or are missing. For example, in Status Report Figure A3 (page A27), lithologies need to be assigned to the various colours. Status Report Figure A4 (page A30) is not a geological cross-section, but is a duplicate of Status Report Figure A3.

Hydrogeological and Hydrogeochemical Characterisation

The discussions in Status Report Section A5.4.2 (page A62) and related sub-sections would have been easier to follow if illustrations of hydrograph data had been presented. This is particularly necessary where the text discusses and compares information from more than one hydrograph (e.g., Status Report Section A5.4.2.7).

Status Report Section A5.5.1 (page A71) discusses trench groundwater dynamics. BNFL states that "The trench probe water level dynamics appear to respond at two temporal scales:

- a long-term rise, fall or steady state; and

- shorter-term fluctuations that roughly correlate to winter highs and summer lows. The amplitude of these variations contrasts between separate trench probes."

It is unclear whether these statements refer to individual probes or the overall trench system.

On page A73 (Status Report Section A5.5.2.1), the numbering of the trench probes should be more clearly explained. For example, it is not clear what P1.4pl means or whether the "pl" has any meaning.

On page A89 (Status Report Section A5.6.5), there is a potentially confusing shift in units of water flux between the text, where units of m^3y^{-1} are used, and Status Report Table A12, where units of m^3d^{-1} are used. The Agency expects BNFL to adopt standard SI units in the PCSC, as appropriate, and to be consistent in the use of units.

On pages A92-3 (Status Report Section A5.7.1), Borehole F, where the highest tritium concentration has been observed (as well as other observations closer to the trenches), is not shown in Status Report Figure A36, which makes it difficult to correlate between Status Report Figures A35 and A36.

Hydrologically Effective Rainfall Calculations and the WATBAL Model

On page A78 (Status Report Section A5.6.1), BNFL indicates that the WATBAL model has been developed to calculate hydrologically effective rainfall (HER). BNFL refers to Section C5.3 of Appendix C for further description of the WATBAL model. However, the information in Status Report Section C5.3 does not describe in adequate detail the basis of the WATBAL model and how HER has been calculated.

On page A78 (Status Report Section A5.6.1), BNFL presents several equations for estimating the water balance for the "upper water." The terms used in the equations are not clearly defined.

Old Drains

On page A85 (Status Report Section A5.6.4.1), BNFL notes that a component of "drain flow" may not discharge into the streams but may leave the catchment area in drains. BNFL notes the example of an old drain in the south-east corner of the site (Status Report Figure A21) that used to take foul water to an old sewage plant. The Agency expects BNFL to consider existing features, such as old drains, in its evaluation of FEPs, and to assess in the 2002 PCRSA the critical pathways for radionuclide transfer to man and the environment. Where no data exist on the properties of identified features, it may be appropriate to undertake sensitivity studies to assess their potential significance.

A3 Appendix B PCRSA Systematic Approach

FEP Screening

- In Status Report Table B3 (page B13), one EFEP (1.4.05, mining and other underground activities) has been "excluded due to rate or probability relative to other EFEPs". The application of this particular screening criterion, at least in this instance, is unclear.

- It is not clear whether BNFL has considered the possibility of chemical pollution from the Sellafield site affecting geochemical environments associated with the disposal system (FEP 1.4.06, page B20), or whether this is even an issue.

- BNFL states in Status Report Table B5 (page B26) that "...erosion may remove all surface expression [of the cap] within 10,000 years...", but no justification is presented for the assumed erosion rate.

- BNFL states on page B58 "...that the state of the biosphere tends to lag behind changes in the EFEP regime" but provides no justification for this statement.

Climate Change

The Agency has several comments on BNFL's discussions of climate change in the Status Report:

- The Agency expects BNFL to clarify how its climate change scenarios relate to those of the Intergovernmental Panel on Climate Change (IPCC).

- Figure B2 on page B17 (Status Report Section B3.2.1) indicates that BNFL intends to apply a downscaling technique to the results of a global climate model in order to derive suitable data for use in the Drigg PCRSA. The Agency notes that it will be necessary to demonstrate that an appropriate approach has been followed for deriving site-scale information from results calculated at the hemispheric scale using the global climate model. The Agency expects BNFL to provide more detailed information on how it will downscale the output from the global climate model for application at the scale of the Drigg site.

- It is unclear how BNFL intends to account for the variability of climatic conditions within each climate state. The Agency expects BNFL to consider the potential effects of climatic variability within each climate state.

- The Agency expects BNFL to clarify whether the effects of thermal expansion have been included in the sea level rise scenarios.

Engineering Performance Assessment

The engineering performance assessment system map (Status Report Figure B12, page B51) is unclear, both because the text is presented at too small a font and so is difficult to read, and because the figure itself is extremely complex and difficult to interpret.

A4 Appendix D Illustrative PCRSA Models, Data and Results

Clarity of Figures and Tables

Several of the figures and tables in Appendix D are unclear:

- Status Report Table D7 (page D19) shows that the same distribution coefficients have been applied to all of the units considered. However, there is no statement in the text that such an approach has been taken and no justification is given for the selection of distribution coefficients.

- Status Report Figure D6 (page D20), which shows the network topology for the consented area and the Pebbly Clay and Lacustrine Fluvial Formations, is unclear because it is not possible to relate the network topology to the geological and hydrogeological site description. The same comment applies to some of the other figures showing network topology.

- Status Report Figure D10 (page D23), which is intended to show the "location of components of the physical biosphere for a non-evolving climate scenario", requires further explanation as, for example, the significance of the area within the brown dashed line is not clear.

- Status Report Table D9 (page D26) provides mean and 97.5 percentile consumption rates for a range of foodstuffs. This is the only table where some indication of uncertainty has been provided, but it is not clear how or whether the uncertainty has been carried through the assessment calculations (other than as indicated at the bottom of page D25).

- Status Report Table D10 (page D27) shows the fractional source of supply by compartment number; however, different compartment numbers are shown in

Status Report Tables D11 and D12 (page D28). It is unclear why these numbers differ.

- In Status Report Table D12, consumption of water is shown as zero for all potential exposure groups. The Agency assumes that the basis for this is that BNFL is assuming that no exposed group obtains water from a local (contaminated) source. For example, Status Report Table D28 (page D65) indicates that water abstraction is only expected up-gradient of any waste under the present-day climate. The Agency has commented on the need for BNFL to justify these assumptions in its review of earlier documents from BNFL's PCSC Development Programme. The Agency expects BNFL to consider a potentially exposed group, such as a subsistence farming community, that would consider obtaining water from a local source, or to justify why such a group does not need to be considered.

Conservatism in the PCRSA

BNFL notes on pages D84 and D91 that elevated risks arising from long-term occupancy of agricultural buildings (up to 10^{-4}) are "...due to the conservative approach taken..." However, it is not clear exactly why BNFL believes the approach is conservative. Also, BNFL indicates on page D91 that calculated risks from the vaults from long-term occupancy of agricultural buildings remain above the risk target for the assessment period; however, this is not the case for the vaults (see Status Report Figure D49), only for the trenches.

APPENDIX 2 ISSUE RESOLUTION FORMS

This Appendix contains Issue Resolution Forms that carry forward new expectations of BNFL into the Issue Resolution Process. The Appendix contains the following IRFs:

DP112	Derivation of Radiological Capacity.
DP113	Clearing Houses.
DP114	Proposed engineering measures and BPM.
DP115	Forward Programme and Use of Risk Assessment
DP116	Derivation of Conditions for Waste Acceptance
DP117	Criteria for Past and Future Disposals

Drigg Review Issue Resolution Form			
Agency Reference No:	DP112	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	-		

Issue Statement

Issue Title: Derivation of Radiological Capacity

Issue Description: BNFL's proposed methodology for calculation of radiological capacity has not been fully explained or justified.

Section of the GRA:	5.8, 9.5
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

BNFL states that "The PCRSA results will therefore be used in the PCSC to review the radiological capacity of the site and to put forward appropriate annual disposal limits. These will determine the potential actual future disposals to the site and hence which LLW will not be acceptable for disposal at Drigg" (Status Report, page 31).

BNFL states that "For a limited number of radionuclides, it is reasonable to assume that there is a direct [linear] correlation between the disposed inventory and the risk resulting from [the inventory]" (Status Report, page 157). BNFL acknowledges that for a limited number of radionuclides, there may not be a direct correlation between inventory reduction and risk reduction." In such cases BNFL will apply "...more complex considerations".

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position
BNFL's proposed methodology for calculation of radiological capacity has not been fully explained or justified. The Agency considers it essential to examine the relationship between inventory and risk, if radiological capacity is used as one approach to managing risk. Although BNFL indicates that "...more complex considerations... ...will be applied" in cases where there is no direct correlation between inventory and risk, BNFL has provided insufficient information about how such radionuclides would be considered.

Supplementary Review Criteria	
The Agency expects BNFL to :	
DP112.1	Justify and explain clearly its approach for calculating radiological capacity in the 2002 PCSC.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

Drigg Review Issue Resolution Form

Agency Reference No:	DP113	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	DP022, DP024, DP038, DP040		

Issue Statement

Issue Title: Clearing Houses

Issue Description: BNFL intends to use Clearing Houses in developing the PCRSA but has not fully described procedures for establishing and guiding the work of the Clearing Houses. The Agency expects BNFL to document a comprehensive record of the judgements and assumptions on which the PCRSA is based.

Section of the GRA:	6.12, 8.21
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

BNFL intends to use Clearing Houses in developing the PCRSA. A Clearing House is essentially a working group made up of project staff with expertise in the area of concern. BNFL has identified two sets of clearing houses; the Assessment Clearing House and Process System Clearing Houses, comprising:

- The Near-Field Clearing House.
- The Geosphere Clearing House.
- The Biosphere Clearing House.
- The Future Human Actions and Disruptive Events Clearing House.

The Assessment Clearing House will decide how many scenarios will be required for a sufficiently comprehensive assessment. The Assessment Clearing House will assign FEPs to other appropriate Clearing Houses (Status Report, page 101). Section 4.8.2 of the Status Report describes the roles of the Clearing Houses in greater detail.

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position

BNFL has not explained sufficiently how the Assessment Clearing House will decide how many scenarios will be required for a sufficiently comprehensive assessment. It is not clear how the Clearing House system will deal with Features, Events and Processes (FEPs) relevant to more than one Clearing House. For example, it may be necessary to assign radionuclide transport FEPs to the Process System Clearing Houses for the near-field, geosphere and biosphere. It is not clear how the Assessment Clearing House will resolve any divergent advice from the Process System Clearing Houses on particular FEPs. The way in which the Clearing Houses will be staffed is not described in the Status Report, and it is not clear whether there will be overlap in staffing between the different Clearing Houses.

Supplementary Review Criteria

The Agency expects BNFL to:

DP113.1	Document its procedures for establishing and guiding the work of the Clearing Houses.
DP113.2	Provide formally documented records of the work of the Clearing Houses involved in the 2002 PCSC.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

Drigg Review Issue Resolution Form

Agency Reference No:	DP114	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	DP054, DP061		

Issue Statement

Issue Title: Proposed Engineering Measures and BPM

Issue Description: Best Practicable Means (BPM) shall be employed to ensure that any radioactivity coming from a facility will be such that doses to members of the public and risks to future populations are as low as reasonably achievable (ALARA). BNFL has not demonstrated that the engineering options proposed for the Drigg site represent BPM.

Section of the GRA:	6.23, 7.10, 8.10
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

Pages 67-69 (Status Report Section 3.4.3) describe how BNFL envisages the site at closure. BNFL indicates on page 14 (Status Report Section 1.2.1.2) that the site and facility description will focus on existing site features with minimal associated conceptual uncertainty.

BNFL proposes to commence waste disposal to Vault 9 in 2003 (Status Report Section 3.4.3, page 67).

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position

While the Agency considers that it would be inappropriate to base the PCRSA on unproven or futuristic technologies, the Agency accepts that the design of the repository will be refined during repository operation. The Agency notes, however, that BNFL has not explained the basis for the proposed reference design. For example, BNFL has not explained why the future vaults are of the size proposed, or why it is proposed to stack waste containers six high.

The Agency also considers that the Status Report has not demonstrated that future engineering options proposed for the Drigg site represent BPM. The Agency encourages BNFL to consider LLW disposal practices and proposals at other sites and in other countries, in its demonstration that BPM has been used.

Supplementary Review Criteria

The Agency expects BNFL to :

DP114.1 Provide sufficient detail of the proposed design of Vault 9 in the 2002 PCSC so that the Agency can assess the appropriateness of the representation of the vault in the PCRSA calculations.

DP114.2 Demonstrate that disposals to Vault 9 represent BPM prior to commencing disposals.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

Drigg Review Issue Resolution Form			
Agency Reference No:	DP115	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	-		

Issue Statement

Issue Title: Forward Programme and Use of Risk Assessment

Issue Description: The Agency considers that BNFL has provided insufficient information on its forward programme. The Agency expects BNFL to demonstrate that risk assessment has been used to prioritise work in developing the 2002 PCSC and subsequent PCSCs.

Section of the GRA:	-
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

BNFL's forward programme for completion of the 2002 PCSC is presented in Table 13 on pages 136-138 (Status Report Section 6.2).

BNFL considers that the information in Table 13 shows that many key tasks have been completed. In particular, in recent years, concurrent with the information exchange process with the Agency, the principal methodologies and tools to be used in the 2002 PCSC have been developed and trialed. The required databases to support assessment modelling have been compiled. Furthermore, completion of the illustrative assessment calculations presented in Appendix D has enhanced confidence that the set of assessment calculations required for the 2002 PCSC will be completed to programme (Status Report, page 132).

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position
The Status Report has not provided a means of assessing BNFL's progress toward the 2002 PCSC or a sufficiently detailed forward programme. Table 13 gives the impression that a large majority of the work needed to complete the 2002 PCSC is "complete". The Status Report does not acknowledge that all of the work indicated as "complete" has been subject to review by the Agency. Many of the Agency's review comments question the clarity and completeness of BNFL's work.

Supplementary Review Criteria	
The Agency expects BNFL to :	
DP115.1	Present a more detailed forward programme and demonstrate that post-closure risk assessments have been used to prioritise work in developing the 2002 PCSC and subsequent PCSCs.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

Drigg Review Issue Resolution Form

Agency Reference No:	DP116	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	-		

Issue Statement

Issue Title: Derivation of Conditions for Waste Acceptance

Issue Description: The developer shall derive waste acceptance criteria consistent with assumptions made in assessments of the performance of the system and with the requirements for handling and transport.

Section of the GRA:	7.17, 7.18, 7.19
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

In support of waste disposal operations, BNFL has in place a system of waste controls, including waste acceptance criteria (Status Report, page 31). The limitations set out in BNFL's Conditions For Acceptance (CFA) of waste include the nature of wastes that may be disposed, activity concentrations and annual disposal limits (Status Report, page 23). There are also specific controls on concentrations of fissile material and the amounts of certain non-radioactive waste components such as putrescibles, complexants, oxidising agents, etc. These may affect the general biogeochemical evolution of the site, and specifically radionuclide behaviour and transport (Status Report, page 106).

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position
Although the Status Report discusses the potential influence on the CFA of results from radiological capacity assessments, it does not describe in detail the basis for the derivation of the CFA or indicate how consistency is maintained between those parts of the CFA that relate to post-closure performance and the PCRSA.

Supplementary Review Criteria
The Agency expects BNFL to : DP116.1 Document the basis for the derivation of the Conditions For Acceptance (CFA) of waste at Drigg and to update the CFA at periodic intervals to ensure that they remain consistent with assumptions, models and parameter values in the most recent post-closure and operational environmental safety cases.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

Drigg Review Issue Resolution Form

Agency Reference No:	DP117	BNFL Reference No:	
Antecedent Form(s):	-		
Related Issue Form(s):	-		

Issue Statement

Issue Title: Criteria for Past and Future Disposals

Issue Description: The Agency regards the entire disposal facility as a single source in the context of dose calculations and as a single entity in the context of risk calculations. The Agency expects BNFL to present risks for the whole facility, and for the vaults and trenches separately.

Section of the GRA:	5.11, 7.2, 7.3, 7.17, 7.18, 7.19
Supplementary Review Criteria:	-

Interpretation of BNFL's Position

BNFL states that "... the appropriate criteria, in particular in terms of risk target, for past disposals to the trenches and to a lesser extent Vault 8, may differ from that for new facilities and disposals..." (Status Report, page 24). The Agency understands that BNFL considers that different criteria should be applied to past and future disposals.

BNFL also states that "Decision making on the nature of any intervention will depend on an assessment of the associated benefits and detriments separate from the PCSC. BNFL will progress developments on this in the coming years as appropriate, depending on the assessed impact of the trenches in the 2002 PCSC, noting that in closing the Drigg site it will need to demonstrate that risks to future populations from past disposals to the trenches are as low as reasonably achievable" (Status Report, page 24).

References:

BNFL (2000) Status Report on the Development of the 2002 Drigg Post-Closure Safety Case.

Evaluation of BNFL's Position

The Agency regards the entire disposal facility as a single source in the context of dose calculations and as a single entity in the context of risk calculations. In the case of existing disposals, if risks are substantially above the risk target intervention would need to be considered. In the case of future vault disposals, if risks are above the risk target then such disposals may not be authorised.

The Agency considers that when reporting results from risk assessment calculations, it is important to provide an adequate breakdown of the results in order to illustrate, in a transparent manner, the performance of the different components of the disposal system (see GRA Paragraphs 7.2 and 7.3). If risks exceed the target, such information will be required for considering optimisation and intervention.

Supplementary Review Criteria

The Agency expects BNFL to :

DP117.1 Present in the 2002 PCSC risks calculated for the entire disposal facility and for the vaults and trenches separately.

Approved by: Signature:	Dr J Irwin (Head – NCRAOA) Date:
Approved by: Signature:	I J Streatfield (Drigg Site Inspector) Date:

ENVIRONMENTAL POLICY - RISK AND FORECASTING

Position Paper Number 26

Assessment of the Post-Closure Safety Case Development Programme for the Drigg Low-Level Radioactive Waste Disposal Site: Phase II Overview

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Title: Assessment of the Post-Closure Safety Case Development Programme for the Drigg Low-Level Radioactive Waste Disposal Site: Phase II Overview		Report No: PP26 Version: 1.0 Issue Date: January 2003
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Mr I Streatfield Nuclear Regulator	Ian Streatfield	13 January 2003
Dr C Williams Policy Developments Manager, Radioactive Substances Regulation		8 February 2003
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Copy Number		

This document is provided as part of the exchange of information between BNFL and the Environment Agency, under BNFL's Drigg Post-Closure Safety Case Development Programme. It refers to information, which was still in the course of completion by BNFL.

PREFACE

Drigg is an operational facility for the near surface disposal of solid, low-level, radioactive waste (LLW). The site is owned and operated by British Nuclear Fuels plc (BNFL) and is located on the West Cumbrian coastal plain, south of BNFL's Sellafield site.

Disposals at Drigg are carried out under the terms of an authorisation granted under the Radioactive Substances Act 1993. The authorisation is subject to periodic review by the Environment Agency. In September 2002, BNFL submitted a Post-Closure Safety Case for Drigg, which is required by the Agency as part of the next authorisation review. Before submission of the Post-Closure Safety Case, BNFL provided a series of documents on the development of the Post-Closure Safety Case. These 'Interim BNFL Reports' assisted the Agency in determining whether the scope and quality of BNFL's programme was likely to provide adequate support for the Post-Closure Safety Case and in determining their adequacy with respect to requirements for authorisation.

This report summarises comments and views expressed by the Agency based on 'Interim BNFL Reports', prior to September 2002. The report does not refer to BNFL's Post-Closure Safety Case, which will be subject to separate detailed review by the Agency. Comments and views expressed in this report represent the Agency's expectations of any formal submissions by BNFL required under the terms of an authorisation for disposals at the Drigg site. They are provided as guidance to BNFL for consideration in the preparation of the Post-Closure Safety Case and any future documents arising from BNFL's Drigg Programme.

Provision of comments and views by the Environment Agency, based on 'Interim BNFL Reports', does not place the Agency under any obligation to approve the Post-Closure Safety Case, nor bind the Agency in any way to grant an authorisation for continued operation of the Drigg site by BNFL.

R A Yearsley
I J Streatfield
Environment Agency of England & Wales

EXECUTIVE SUMMARY

This report presents an overview of Phase II of the Environment Agency's review of the Post-Closure Safety Case Development Programme being undertaken by British Nuclear Fuels plc for its solid, low-level radioactive waste disposal facility at Drigg in Cumbria. The work is a continuation of the Phase I of the Environment Agency's review programme, which was reported in an overview published in 1999. The Environment Agency has undertaken the review programme in preparation for submission by British Nuclear Fuels plc of a Post-Closure Safety Case for Drigg in September 2002.

British Nuclear Fuels plc (BNFL) is currently authorised by the Environment Agency (the Agency) to dispose of solid low-level radioactive waste (LLW) at a disposal facility near the village of Drigg on the Cumbrian coast in Northwest England. The Drigg disposal facility is the UK's primary specialised disposal facility for LLW and, as such, is a significant component of the UK's arrangements for the management of radioactive waste. The LLW disposed of at Drigg arises from all phases of the nuclear fuel cycle (e.g. uranium enrichment, fuel manufacture, power generation and reprocessing) as well as industry, hospitals, universities, and the defence industry. BNFL estimates that LLW disposal at Drigg is likely to continue until about 2050 when the site will be full. After waste emplacement at Drigg is complete, a final site cap will be constructed over the entire disposal area and the site will be closed.

In accordance with Government policy, the Agency periodically reviews the authorisation of the Drigg disposal facility. A condition of the current authorisation requires BNFL to provide two safety cases for the site by 30 September 2002:

- The Operational Environmental Safety Case (OESC) will consider the impacts of the facility on the environment and the public in the period up to the completion of site operation, currently estimated by BNFL as approximately 2050.
- The Post-Closure Safety Case (PCSC) will consider the long-term impacts of the facility after 2050.

The Agency will review the OESC and PCSC to inform the next authorisation review, which will commence in 2003.

The Agency has been preparing for review of the 2002 PCSC by reviewing BNFL's PCSC Development Programme. The PCSC Development Programme includes the wide range of provisional work undertaken and documented by BNFL as interim working documents, in order to obtain feedback from the Agency. Throughout this process the Agency has provided detailed guidance to BNFL on its expectations of the PCSC, taking care to avoid being overly prescriptive or compromising any future regulatory decisions.

The Agency has reviewed BNFL's PCSC Development Programme in two phases and is implementing a third phase of work to review BNFL's PCSC. The three phases of work comprise briefly:

Phase I — Review of early documents from BNFL's PCSC Development Programme (December 1996 - March 1999). The Agency published an overview of Phase I in 1999.

Phase II — Review of later documents from BNFL's PCSC Development Programme, including BNFL's March 2000 Status Report on the Development of the 2002 PCSC (the Status Report), and BNFL's responses to the issues raised in Phase I and some from Phase II. The Agency's review of the Status Report was published in 2001. This report provides an overview of Phase II.

Phase III — Review of the 2002 PCSC. The Agency will review the 2002 PCSC against the UK regulatory guidance, the "Guidance on Requirements for Authorisation" and the Government guidelines for environmental risk assessment and management. The review of the PCSC will inform the authorisation review that is planned to start in 2003.

During Phase II, the Agency undertook detailed reviews of 30 documents from BNFL's PCSC Development Programme, including the Status Report. During these reviews, a wide range of supporting reports provided by BNFL were examined where the Agency required further information to clarify or improve the Agency's understanding of BNFL's work. Based on its reviews of BNFL's Phase II documents, the Agency has documented review comments and expectations of BNFL's PCSC in a series of eight further Position Papers, and 32 Issue Resolution Forms (IRFs). In Phase II, the Agency also assessed BNFL's responses to the IRFs from Phases I and II. Where issues remain to be addressed, the Agency has developed successor IRFs that will be carried forward to the Phase III review.

Overall, the documents from Phase II of BNFL's PCSC Development Programme and BNFL's presentations at Technical Exchange Meetings indicate that BNFL has made demonstrable progress towards the PCSC and in implementing a systematic approach to risk assessment. At this stage, however, the detailed justification and basis for the 2002 PCSC itself remain to be assessed; this will be one of the important tasks for Phase III of the Agency's review.

As a result of its reviews during Phase II, the Agency considers that BNFL has defined the scope of the PCSC more clearly than it had in Phase I. However, the Agency still considers that BNFL has not clearly defined the optimisation studies to be considered in the 2002 PCSC.

The Agency has greater confidence in BNFL's Quality Assurance (QA) of document production than at the end of Phase I. However, it is important for BNFL to apply strict QA and quality control to all aspects of the work that supports the PCSC. Assessing the quality of BNFL's PCSC will be a central part of the Agency's Phase III review.

At the end of Phase I, few of the issues raised by the Agency had been resolved to the Agency's satisfaction, and BNFL had only provided written responses, setting out their intentions for addressing or resolving the issues, to about 7% of the IRFs. By the end of Phase II, BNFL had provided written responses to about 94% of the IRFs and planned to address the remainder in the 2002 PCSC. At the end of Phase II, about 15% of the issues have been resolved. Where BNFL was not in a position to address an issue during Phase II, it has indicated its intent either to address the issue in the 2002 PCSC, or to include appropriate further studies in its forward work programme.

Based on its review of the PCSC Development Programme, the Agency has identified twelve key issues related to the regulation and long-term impact of the Drigg disposal facility. These key issues concern:

1. Optimisation and BPM.
2. Risk assessment and management.
3. Climate change impacts.
4. The status and nature of the trench and vault wastes.
5. Future human intrusion.
6. Potentially exposed groups.
7. Radionuclide transport and retardation.
8. Hydrogeological models.
9. Radionuclide release.
10. Engineered features.
11. BNFL's forward programme.
12. The provision of funding.

These issues will form priority topics for consideration by the Agency when it reviews the 2002 PCSC. The Agency recognises that these key topics provide a starting point for the PCSC review and that further topics might arise during the review.

The focus of the review of BNFL's PCSC Development Programme has been on potential future environmental impacts although there are some immediate improvements that have arisen from the work. For example, the Agency has required BNFL to improve existing disposal practices on the Drigg site, which will ultimately lead to a reduction in both the operational environmental and post-closure impact from the site. In the longer term, the review of the Drigg PCSC will be an important component of the Agency's work to protect the environment by ensuring the safe disposal of low-level radioactive waste from the nuclear industry and also from other users of radioactive materials such as hospitals and universities.

Since December 1996, the Agency has been undertaking review and assessment of BNFL's Post-Closure Safety Case development programme. By applying lessons learnt from past assessments of a similar nature and lessons arising from the

current review programme, improved procedures and better working practices have been implemented that have increased regulatory effectiveness. These lessons will be applied in the detailed review and assessment of BNFL's Post-Closure Safety Case (2002 PCSC) for the Drigg site, which was submitted to the Agency in September 2002. In addition, appropriate management structures and review procedures have been put in place in readiness for the review of BNFL's Drigg PCSC. The preparations undertaken by the Agency in Phases I and II will ensure its review of the 2002 PCSC is efficient, robust and effective. The results from the review of the 2002 PCSC will be considered by the Agency in the authorisation review that is planned to start in 2003 and may, for example, assist in establishing appropriate authorisation conditions.

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LIST OF ACRONYMS

ALARA	As Low As Reasonably Achievable
BNFL	British Nuclear Fuels plc.
BPM	Best Practicable Means
DETR	Department of the Environment, Transport and the Regions
DEFRA	Department for Environment, Food and Rural Affairs (successor to DETR and MAFF)
DoE	Department of the Environment
DTI	Department of Trade and Industry
EPA 90	Environmental Protection Act 1990
FEP	Feature, Event, Process
GRA	Guidance on Requirements for Authorisation
HMIP	Her Majesty's Inspectorate of Pollution
IRF	Issue Resolution Form
LLW	Low-Level Radioactive Waste
MAFF	Ministry of Agriculture, Fisheries and Food
NCRAOA	National Centre for Risk Analysis and Options Appraisal (now: Environmental Policy - Risk and Forecasting)
NRA	National Rivers Authority
OESC	Operational Environmental Safety Case
PCRSA	Post-Closure Radiological Safety Assessment
PCSC	Post-Closure Safety Case
QA	Quality Assurance
RSA 60	Radioactive Substances Act 1960
RSA 93	Radioactive Substances Act 1993
TRC	Technical Review Criteria

1 INTRODUCTION

1.1 The Agency's Regulatory Role

On 1 April 1996, Her Majesty's Inspectorate of Pollution (HMIP), the National Rivers Authority (NRA) and the Waste Regulatory Authorities merged to form the Environment Agency of England and Wales (the Agency). At that time the Agency became responsible for the authorisation of radioactive waste disposal under the Radioactive Substances Act 1993, as amended (RSA 93).

British Nuclear Fuels plc (BNFL) is currently authorised by the Agency to dispose of solid low-level radioactive waste (LLW) at a disposal facility near the village of Drigg on the Cumbrian coast in Northwest England. The current Certificate of Authorisation for Drigg was originally granted by the Department of the Environment (DoE) and the Ministry of Agriculture Fisheries and Food (MAFF) in accordance with the Radioactive Substances Act 1960 (RSA 60). RSA 60 was consolidated in the Radioactive Substances Act 1993. RSA 93 provides the current framework for controlling the disposal of radioactive waste so as to protect the public and the environment.

RSA 93 does not provide for statutory review of existing authorisations. As a matter of Government policy, however, the Agency conducts periodic reviews of authorisations for nuclear licensed sites in order to ensure that they are appropriate to the operating practice and that the Certificate of Authorisation continues to reflect current regulatory standards. The current Certificate of Authorisation for the Drigg site requires BNFL to use Best Practicable Means to compact relevant waste, and to limit the migration of any radionuclides from relevant waste.

In December 1996, the Agency initiated a review programme based on voluntary submissions by BNFL of documents arising from its Post-Closure Safety Case (PCSC) Development Programme for the Drigg disposal facility. BNFL's PCSC Development Programme included the wide range of provisional work undertaken and documented by BNFL as interim working documents. Many of these documents were submitted to the Agency for review in order to obtain feedback from the Agency. Throughout the process of dialogue with BNFL, the Agency has provided detailed guidance to BNFL on its expectations of a PCSC taking care to avoid being overly prescriptive or compromise any future regulatory decisions.

In January 2000, the Agency formalised the arrangements with BNFL and issued a variation to the authorisation that included requirements for BNFL to provide two safety cases for the site by 30 September 2002:

- The Operational Environmental Safety Case (OESC) will consider the impacts of the facility on the environment and the public in the period up to the

completion of site operation, currently estimated by BNFL as approximately 2050.

- The Post-Closure Safety Case (PCSC) will consider the long-term impacts of the facility after 2050.

The Agency will review the 2002 PCSC against the principles for the protection of the public and the radiological requirements previously published by the Agency (Environment Agency *et al.* 1997) and in accordance with existing guidelines for environmental risk assessment and management (DETR *et al.* 2000). Application of the guidelines has been endorsed by DEFRA (DEFRA 2002). The OESC will also be subject to review by the Agency to ensure that the Drigg site continues to meet relevant dose limits.

The Agency's reviews of the OESC and PCSC will be used to inform the next authorisation review, which will commence in 2003. During its review of the authorisation, the Agency will consult with relevant Government Departments and other organisations, including the Nuclear Installations Inspectorate of the Health and Safety Executive, and the Food Standards Agency. A period of public consultation will also be included, and responses to the consultation will be used to inform the Agency's decision-making with regard to the future of the Drigg disposal facility.

The Agency has reviewed BNFL's PCSC Development Programme in two phases, and is implementing a third phase of work to review BNFL's PCSC. The three phases, identified in Figure 1, comprise:

Phase I. Review of early documents from BNFL's PCSC Development Programme. This phase was initiated in December 1996 and was completed at the end of March 1999. At the end of Phase I, the Agency published an overview of its review (Environment Agency 1999a), which included a summary of the Agency's general and technical comments on the information presented by BNFL. These comments were the basis for a list of expectations of the 2002 PCSC. It also presented recommendations for a series of regulatory actions by the Agency.

Phase II. Review of later documents from BNFL's PCSC Development Programme, including BNFL's March 2000 Status Report on the Development of the 2002 PCSC (the Status Report, BNFL 2000), and BNFL's responses to the issues raised. This phase, which began at the start of 1999 and continued until submission of the PCSC in September 2002, is the subject of this report. The Agency's review of the Status Report was published in 2001.

Phase III. Review of the 2002 PCSC. The Agency will review the 2002 PCSC against the principles for the protection of the public and the

radiological requirements published in 1997 by the UK environment agencies in the "Guidance on Requirements for Authorisation" (GRA). The review will also take account of the existing Government guidelines for environmental risk assessment and management (DETR *et al.* 2000).

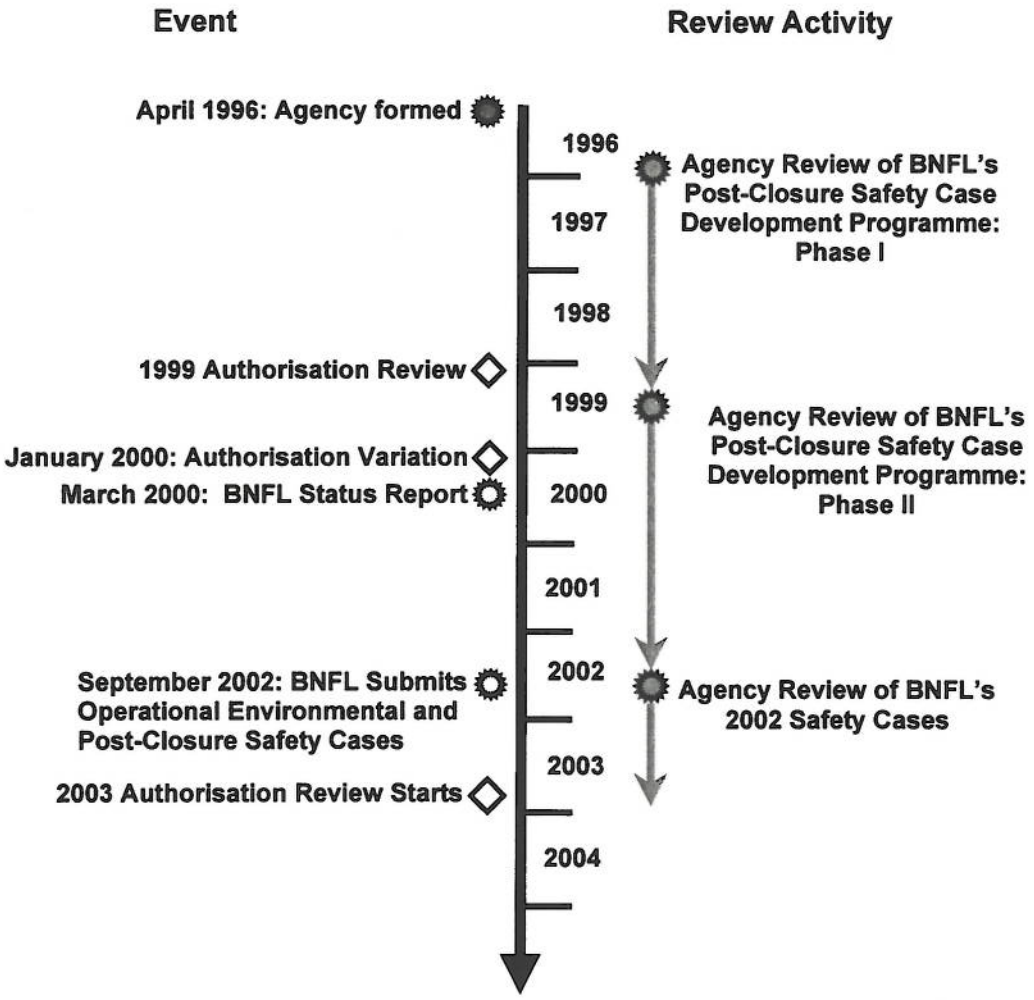


Figure 1 **Timeline showing key stages in the Agency's ongoing regulation of the Drigg disposal facility.**

The preparations undertaken by the Agency in Phases I and II will ensure its review of the 2002 PCSC is efficient, robust and effective.

1.2 Waste Disposal at the Drigg Disposal Facility

The Drigg disposal facility is the UK's primary specialised disposal facility for LLW and, as such, is a significant component of the UK's arrangements for the management of radioactive waste. The wastes disposed of at Drigg arise from all phases of the nuclear fuel cycle (e.g. uranium enrichment, fuel manufacture, power generation and reprocessing) as well as industry, hospitals, universities, and the defence industry.

The Drigg disposal facility comprises two parts:

Trenches: Between 1959 and 1995, about 800,000 m^3 of LLW was tipped into a series of seven shallow clay-lined trenches and covered with soil. This practice was similar to that used by the landfill industry for the disposal of non-radioactive wastes. Waste disposal to the trenches ceased in 1995; the trenches are now covered by a temporary cap that incorporates a plastic membrane to minimise water ingress.

Vaults: Since 1988, waste has been high-force compacted and placed in steel waste containers, similar to those used for transporting goods by lorry, and these have been disposed in a concrete vault. Before placing the containers in the vault, the waste is further conditioned by filling voids within the containers with a cement-based grout. Waste items that are too big for the containers are grouted directly into the vault. The capacity of the existing vault is about 200,000 m^3 and, currently, the vault is approximately two-thirds full. BNFL plans to build additional vaults to accept a further 750,000 m^3 of conditioned waste and estimates that this will provide sufficient capacity for the site to remain operational until about the year 2050.

After waste emplacement at Drigg is complete and following a period of further monitoring, BNFL's plans are that a final site cap will be constructed over both the trenches and the vaults and the site will be closed.

1.3 Report Structure

This report is structured as follows:

- Section 2 describes the objectives of the Agency's review of BNFL's PCSC Development Programme for the Drigg disposal facility.
- Section 3 outlines the range of review tasks undertaken.
- Section 4 summarises the results of the review.

- Section 5 summarises achievements of the Agency's review of the PCSC Development Programme and identifies the environmental outcomes of the work.
- Section 6 presents conclusions.
- Section 7 contains a list of references.

2 REVIEW OBJECTIVES AND MANAGEMENT

2.1 Review Objectives

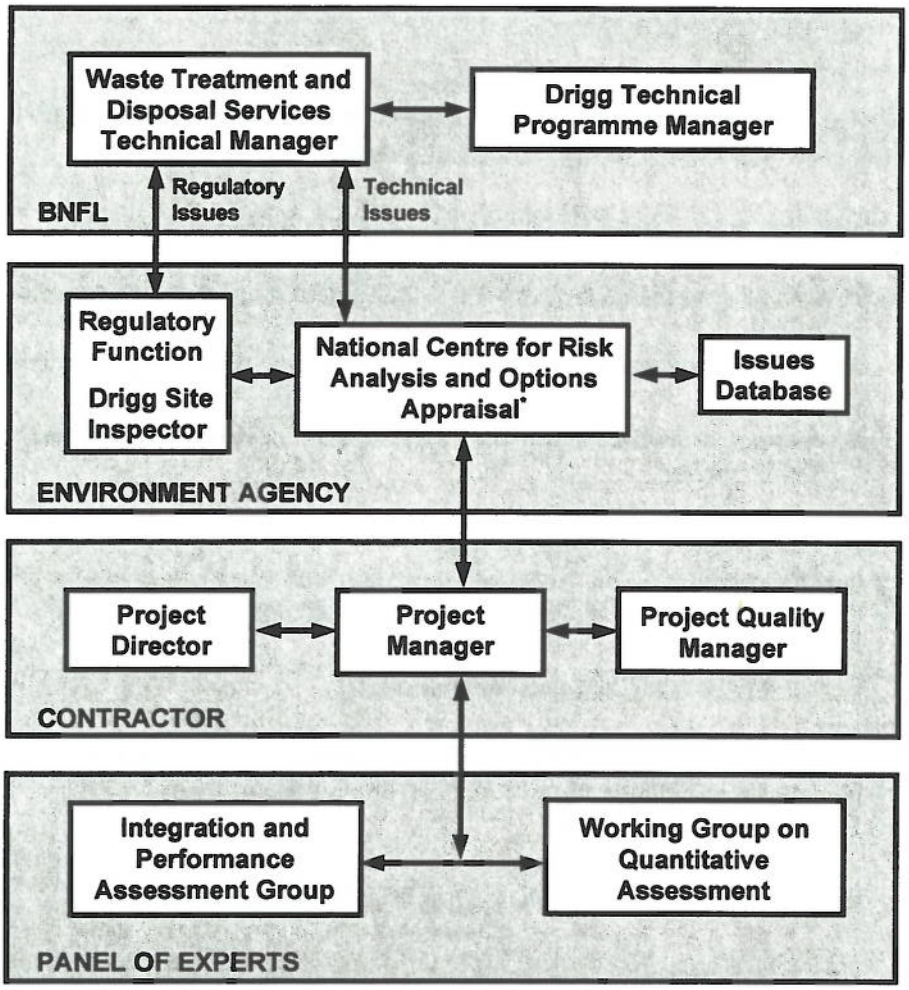
The Agency's review of documents voluntarily provided by BNFL from the PCSC Development Programme has had two principal objectives:

- To assess the information supplied by BNFL against the GRA (Environment Agency *et al.* 1997) and to provide further guidance to BNFL on the future direction of its programme.
- To identify the need for additional assessments by the Agency, such as the examination of further BNFL documents, or the conduct of independent calculations, in order that the Agency can efficiently assess the 2002 PCSC.

To further guide the review, the following more detailed objectives were developed:

- To evaluate the documents from BNFL's PCSC Development Programme using relevant review criteria, and to provide constructive review comments to BNFL on a time scale that will allow appropriate revisions to the developing safety case.
- To identify issues that may affect the assessment of site impact and to develop suitable criteria against which any responses made by BNFL may be assessed.
- To identify the need for more detailed reviews of issues raised and to specify appropriate criteria to be applied in these reviews.
- To identify the need for further quantitative assessment by BNFL and/or the Agency.
- To identify the need for other further work by the Agency, such as review of BNFL's site characterisation and interpretation programmes, or quality audits of BNFL's work programme.
- To provide a preliminary view on whether BNFL's PCSC is likely to constitute a sufficiently comprehensive examination of the relevant issues and whether it is likely to provide adequate estimates of future radiological impacts, which could be used as a basis for regulatory decision-making.

These objectives have been applied throughout the review tasks described in Section 3. Phase II of the Agency's review included review of BNFL's March 2000 Status Report on the Development of the 2002 Drigg PCSC (BNFL 2000). A further series of specific objectives were developed for the review of BNFL (2000) - see Section 3.1 and Environment Agency (2001a, b).



Note: Internal communications and wider technical involvement within the Agency have been omitted for clarity.

Figure 2 Project structure diagram showing the principal routes of information flow.

2.2 Review Management

The Agency commissioned a Contractor, Galson Sciences Limited, to assist in its review of BNFL's PCSC Development Programme. In consultation with the Agency, the Contractor assembled a panel of experts to undertake assessments on behalf of the Agency. This panel included staff from the Agency, the Contractor, and several additional experts under sub-contract. The Contractor established groups of reviewers, as necessary, to assist with the assessment of particular technical aspects of the PCSC Development Programme. The relationships between the Agency, BNFL, the Contractor, and the panel of experts are shown in Figure 2. Their roles are described in Environment Agency (1999b).

3 SUMMARY OF REVIEW TASKS

This section provides a summary of the four main technical and regulatory tasks performed during Phase II of the Agency's review:

- Establishment and maintenance of review procedures and guidance.
- Review of documents from BNFL's PCSC Development Programme.
- Development of recommendations for further quantitative assessment.
- Assessment of issue resolution and further development of the Agency's "Issues Database".

The aim of this section is to provide an overview of what was done. Section 4 summarises the results of the work and assesses both BNFL's progress towards the 2002 PCSC, and the Agency's progress towards its review.

3.1 Review Procedures and Guidance

The procedures and guidance developed during Phase I of the Agency's review were set out in Agency Guidance Note 1 (GN1, Environment Agency 1997). Important aspects of the procedures include:

- The ability to deal with a phased supply of documents for review.
- The implementation of an "Issue Resolution Procedure." This is a mechanism for recording a dialogue between the Agency and BNFL in a transparent and traceable manner, based on the use of an Issue Resolution Form (IRF) - see Section 3.4.
- The definition of General Review Guidance to assist reviewers when undertaking reviews of documents from BNFL's PCSC Development Programme, and definition of the form of output from the review. Reviews of BNFL's documents have been documented in Position Papers from the Agency's National Centre for Risk Analysis and Options Appraisal (NCRAOA)[1]. The NCRAOA Position Papers present the Agency's comments on BNFL's documents and the Agency's expectations of the PCSC.

[1] The Agency's National Centre for Risk Analysis and Options Appraisal has changed its name to Environmental Policy - Risk and Forecasting.

- The use of supplementary Technical Review Criteria (TRC) to guide reviewers when assessing documents from the PCSC Development Programme.

These procedures were refined during Phase II (see Environment Agency 1999b) but the process of review has remained largely unchanged since Phase I. New review guidance was developed specifically during Phase II for the review of BNFL's Status Report (BNFL 2000) and this new guidance was published as Environment Agency (2001a). Key aspects of the Status Report review (Environment Agency 2001b) included an assessment of the Status Report against the Principles and Requirements of the GRA (Environment Agency *et al.* 1997) and against the document-specific review objectives. These document-specific review objectives were designed to determine whether the 2002 PCSC was likely to provide an adequate input to a future authorisation decision by evaluating whether the Status Report:

1. Provided assurance that BNFL was developing the PCSC under a suitable quality assurance (QA) regime.
2. Provided assurance that BNFL was developing the PCSC based on an interpretation of available regulatory guidance that was acceptable to the Agency.
3. Provided evidence that the PCSC would be sufficiently comprehensive, would adequately integrate all of its component parts, and would be based on a methodology that identified and prioritised the issues of most significance to assessment results.
4. Documented an acceptable approach for demonstrating optimisation in the PCSC.
5. Presented example results from each of the assessment codes that BNFL intended to use in the 2002 Post-Closure Radiological Safety Assessment (PCRSA), that demonstrated how the various parts of BNFL's PCRSA would be assembled, and how data would be used in the PCRSA.
6. Provided assurance that BNFL was developing a traceable record of assumptions and data on which to base the 2002 PCSC.
7. Described an acceptable methodology for the treatment of uncertainties in the PCSC, including a clearly defined and comprehensive approach to quantification of uncertainty in the 2002 PCRSA.
8. Provided assurance that BNFL was making adequate progress towards the 2002 PCSC and indicated that BNFL had an appropriate forward programme for developing the 2002 PCSC and any subsequent updates of the safety case.
9. Contained information on post-closure safety that might have implications for the operational phase of the repository.

3.2 Review of BNFL's Documents

During Phase II of the Agency's review, 30 documents submitted voluntarily by BNFL from its PCSC Development Programme were reviewed in detail. These documents covered the following topics:

- Information provided by BNFL to the Environment Agency for the 1999 Review of the Authorisation (BNFL 1999).
- A revised outline of the PCSC.
- BNFL's interpretation of how the GRA applies to Drigg.
- Quality assurance of BNFL's Drigg Technical Programme.
- The use and verification of BNFL's assessment codes.
- BNFL's model of the Drigg source-term and provisional modelling results.
- BNFL's Engineering Risk Assessment methodology.
- BNFL's sorption database and its derivation.
- BNFL's hydrogeological modelling of the Drigg site.
- BNFL's March 2000 Status Report on the development of the Drigg 2002 PCSC.

In addition, a wide range of supporting reports provided by BNFL were examined where the Agency required further information to clarify or improve the Agency's understanding of BNFL's work.

3.3 Key Actions and Recommendations From Phase I

At the end of Phase I, a wide ranging set of recommendations for ten Key Actions by the Agency was identified as an outcome of the review process (Environment Agency 1999a). These have been considered by the Agency during Phase II and a summary of how the Agency has addressed, or is in the process of addressing, the Key Actions is presented in Section 4.2. One of the Key Actions was a recommendation for the Agency to undertake several scoping calculations to assess the potential significance of certain key risk drivers, or features, events and processes (FEPs), that could influence the performance of the Drigg disposal facility. Under Phase II, there was ongoing consideration of whether there was a need to carry out further quantitative assessment calculations, possibly including independent risk assessment calculations

by the Agency. To date, the Agency has not implemented any independent quantitative assessment since the information being provided by BNFL was of an interim nature and thus liable to change as BNFL's understanding developed. The recommendations arising from the Phases I and II of the review work might be used to define and implement independent calculations as part of the Agency's review of BNFL's PCSC.

3.4 Issue Resolution and Issues Database

During Phase I, the Agency established and implemented an Issue Resolution Procedure (Figure 3) based on the use of a standardised Issue Resolution Form (IRF) and an associated electronic Issues Database. This procedure has been designed to:

- Record the Agency's concerns, comments, expectations and/or requirements of a developing PCSC. In particular to record and retain the corporate memory where the process may span a considerable number of years (throughout the authorisation period and up to closure)
- Ensure traceability and transparency throughout the Agency's reviews and during dialogue with BNFL.
- Facilitate easy access for project staff to approved project documentation.
- Provide detailed site-specific review criteria.

The Issue Resolution Procedure is described in more detail by Yearsley *et al.* (2001).

During Phase II, the Issue Resolution Procedure and IRF were refined and the Issues Database significantly upgraded. The Issues Database has been transferred to a more capable and modern software platform, ™FolioViews, which has enabled development of a more useable and flexible database with improved search capabilities. Information held within the Issues Database has been continually updated. The Issues Database is currently available to relevant Agency staff, the review team, and BNFL.

Eighty-six IRFs were raised during Phase I, each of which required BNFL to respond to one or more TRC. Thirty-two new IRFs were raised during Phase II, bringing the total number to 118, and the total number of TRC to approximately 500. Assessing BNFL's responses to issues raised, and providing further Agency comment to BNFL, has been a considerable task. Where issues remain to be addressed, the Agency has developed successor IRFs containing appropriate TRC that will be carried forward to the Phase III review.

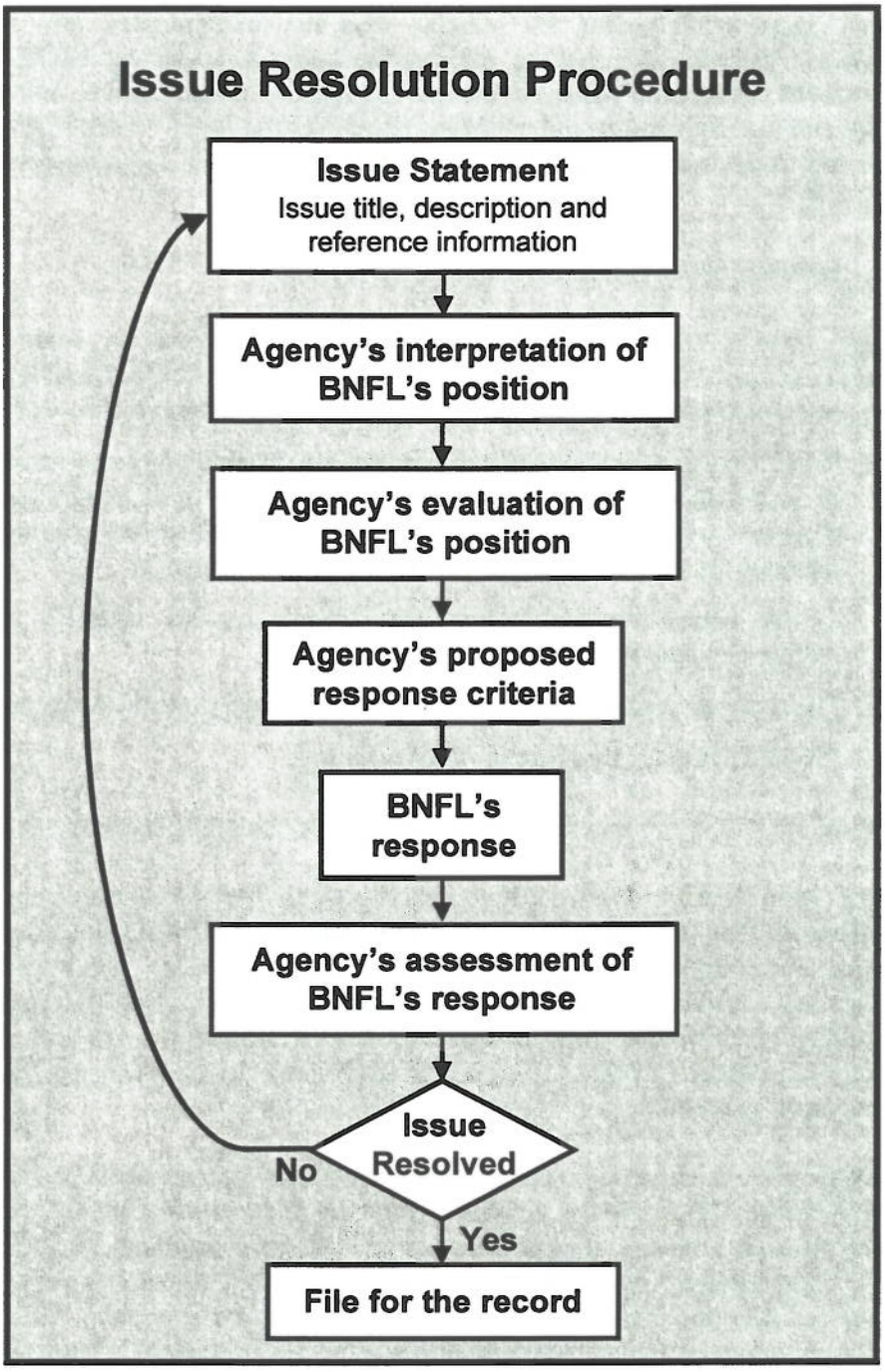


Figure 3 **Flowchart for the Issue Resolution Process.**

4 SUMMARY OF REVIEW RESULTS

This section provides a summary of the results from Phase II of the Agency's review of the PCSC Development Programme. The review results are summarised by way of a commentary on BNFL's progress during Phase II towards the 2002 PCSC and the Agency's progress towards its review. The results are also considered in terms of key issues identified during the Agency's reviews that will form priority topics for consideration when the Agency reviews the 2002 PCSC.

4.1 BNFL's Progress

The Agency considers that the documents from Phase II of BNFL's PCSC Development Programme and BNFL's presentations at Technical Exchange Meetings provide evidence that BNFL has made demonstrable progress towards the PCSC since the end of Phase I, including progress in implementing a systematic approach to risk assessment.

The following paragraphs compare the Agency's evaluations of BNFL's programme at the end of Phase I and at the end of Phase II. The topics discussed were originally identified in the Phase I Overview Report (Environment Agency 1999a – to avoid repetition, this is the standard reference for Phase I in sections 4.1.1 to 4.1.6.):

4.1.1 Quality Assurance

At the end of Phase I, the Agency noted that BNFL had not demonstrated that appropriate QA measures had been applied to all areas of the PCSC Development Programme. During Phase II, the Agency identified many problems in BNFL's assessment code reports, which added to the Agency's concerns over BNFL's QA. As a result of the Agency's comments, BNFL reviewed the implementation of its QA programme and implemented corrective actions, including enhanced procedures for checking PCSC documentation. Thus, at the end of Phase II, the Agency has greater confidence in BNFL's QA of document production than it did at the end of Phase I.

The Agency has made it clear that it will be important for BNFL to apply strict quality assurance and control to all aspects of the work that supports the PCSC. Assessing the quality of BNFL's PCSC will be a central part of the Agency's Phase III review.

4.1.2 Scope of the PCSC and Optimisation

At the end of Phase I, the Agency noted that BNFL had not fully defined the scope of the PCSC, and had not defined how certain key issues, such as optimisation, would be treated. As a result of its reviews during Phase II, the Agency considers that BNFL has now defined the scope of the PCSC more clearly. Throughout Phases I and II of the review, the Agency has encouraged BNFL to address thoroughly issues such as

treatment of uncertainty and optimisation. There has been progress in BNFL's approach to treatment of uncertainty but the Agency still considers that BNFL has not clearly defined the optimisation studies to be considered in the 2002 PCSC. The Agency has encouraged BNFL to take a broad view of optimisation and to use the PCSC to consider a range of options. For example, if disposal of the entire UK LLW inventory is not feasible within the capacity of the site, a reduced inventory could be considered. If estimated risks are greater than the risk target, then the Agency expects BNFL to provide quantitative estimates of disposal system performance for alternative engineering measures and to demonstrate that risks are as low as reasonably achievable (ALARA), economic and social factors being taken into account.

BNFL will also need to show that disposal practices and repository design represent Best Practicable Means (BPM). In the case of existing disposals, if risks are substantially above the risk target, then some form of intervention might need to be considered. In the case of future vault disposals, if risks are above the risk target, then such disposals may not be authorised.

4.1.3 Risk Assessment Results

At the end of Phase I, the Agency noted that BNFL was yet to present any results from calculations of the performance of the Drigg site. During Phase II, BNFL provided the Agency with the Status Report (BNFL 2000), which contained illustrative results from performance assessment calculations for the Drigg disposal facility. However, these calculations were performed following a different methodology to that which BNFL plan to use for the 2002 PCSC.

During Phase II, BNFL also provided illustrative results from a set of initial calculations made using its model of the Drigg source-term, DRINK. The Agency considers that the provision of these modelling results was beneficial to the regulatory dialogue.

At a Technical Exchange Meeting held in June 2002, BNFL made a presentation to the Agency of a summary of provisional performance assessment results that may form the basis of the results to be included in the 2002 PCSC. Based on BNFL's presentation, the Agency considers that BNFL has made demonstrable progress during Phase II in the conduct of the risk assessment. The Agency considers BNFL's progress is, in part, a result of the regulatory dialogue during the PCSC Development Programme.

4.1.4 Draft of the PCSC

Throughout Phase I, the Agency noted that it would be important for BNFL to provide an early first iteration of the PCSC for review. Despite several such requests in the period since December 1996, BNFL has not provided the Agency with a draft of the

PCSC. The Agency considers that the Status Report (BNFL 2000), rather than being a draft of the PCSC, was more a statement of intent by BNFL (Environment Agency 2001b). Thus, despite BNFL's progress, as discussed in Section 4.1.3, the Agency remains concerned that BNFL has adopted an essentially one-pass approach to developing the post-closure risk assessment within the 2002 PCSC, rather than adopting a clearly documented iterative approach to identifying the key factors that influence risk. The Agency would expect BNFL to adopt a more iterative approach in updates of the PCSC to support future authorisation reviews.

4.1.5 Regulatory Interpretation

At the end of Phase I, the Agency noted that BNFL should document its interpretation of how the GRA applies to the Drigg site. BNFL provided its interpretation early in Phase II and this interpretation formed one input to the Status Report (BNFL 2000). The Agency considers that BNFL's interpretation is incompatible with the regulatory position, or incompletely defined, in three areas (Environment Agency 2001b):

- status of the future vaults;
- radiological criteria for past and future disposals; and
- influence of passive institutional controls on the post-closure risk assessment.

4.1.6 Issue Resolution

At the end of Phase I, only a few of the issues raised by the Agency had been resolved, and BNFL had provided written responses to only 6 of the 86 (about 7%) IRFs (Environment Agency 1999a). At the end of Phase II, BNFL has made progress and provided written responses to 111 of the 118 (about 94%) IRFs. Where BNFL has not been in a position to address an issue during Phase II, it has indicated an intention either to address the issue in the 2002 PCSC or to include appropriate further studies in its forward work programme.

4.2 The Agency's Progress

During Phase II, the Agency documented its comments on BNFL's documents in a series of eight Position Papers containing 32 Issue Resolution Forms. The Agency also:

- Assessed BNFL's responses to over 100 IRFs issued during both Phases I and II.
- Developed appropriate regulatory guidance on specific issues, such as collective radiological impacts.
- Developed a strategy on how to link its review of PCSC results to future authorisation conditions (Bennett *et al.* 2002).

- Prioritised the review of the 2002 PCSC on a series of key issues. These key issues are identified in Section 4.3.
- Identified how BNFL's PCRSA relates to the Departmental Guidance on environmental risk assessment and management (DETR *et al.* 2000)
- Implemented an updated Issues Database based on FolioViews software.

The Agency's overall progress may also be evaluated by considering the current status of the Key Actions identified at the end of Phase I (Environment Agency 1999a) (Table 1). Note that it was always intended that the Key Actions should be conducted at appropriate stages of the Agency's Review, not necessarily during Phase II, and several of theses actions are ongoing or under consideration.

Table 1 The status of Key Actions at the end of Phase II.

No.	Key Action	Status at the end of Phase II	
1	The Agency to establish a legal requirement for BNFL to prepare a PCSC.	Achieved through the 2000 variation to the Authorisation.	Achieved
2	The Agency to establish a requirement for BNFL to respond to the Agency's comments.	Achieved through the exchange of information with BNFL to an agreed schedule.	Achieved
3	The Agency to require BNFL to clarify, at an early stage, its PCRSA in terms of data flow and its approach to the treatment of uncertainty.	Achieved through establishing a requirement in the 2000 variation to the Authorisation for BNFL to supply a Status Report on the development of the 2002 PCSC. The Status Report was partially successful in clarifying data flow through the PCRSA and BNFL's approach to the treatment of uncertainty (see Environment Agency 2001a).	Achieved
4	The Agency to conduct quality audits of BNFL's PCSC Development Programme.	The Agency decided not to commission audits during Phase II but plans to undertake them during the PCSC Review.	Planned for Phase III Review
5	The Agency to undertake detailed review and assessment of selected aspects of BNFL's PCSC Development Programme.	At the end of Phase I, recommendations were made to the Agency for more detailed assessment work in a number of the technical areas discussed in BNFL's documents: FEP screening and scenario development, climate change, hydrogeological modelling, human intrusion and BNFL's treatment of uncertainty in the PCRSA. The Agency decided not to commission this work during Phase II since the information being provided by BNFL was of an interim nature and thus liable to change as BNFL's understanding developed. The Agency will reassess the need for independent studies during the PCSC Review.	Under consider-ation for Phase III review

No.	Key Action	Status at the end of Phase II	
6	The Agency to undertake an assessment of BNFL's computer codes and calculations.	At the end of Phase I, the Agency was recommended to gain experience of using BNFL's codes before September 2002 in order to be ready to assess the calculations presented by BNFL in the 2002 PCSC. This work was not commissioned during Phase II, partly because BNFL were revising their codes. It will be reconsidered during the PCSC Review.	Under consider-ation for Phase III review
7	The Agency to undertake an assessment of the need for independent calculations.	As discussed in Section 3.3 of this report, assessments were made during Phases I and II and these led to recommendations for independent calculations. The Agency also commissioned an R&D project to review the capabilities of available performance assessment codes. To date the Agency has decided not to conduct independent risk assessment or scoping studies since the information being provided by BNFL was of an interim nature and thus liable to change as BNFL's understanding developed. The Agency might undertake independent calculations as part of the PCSC Review.	Under consider-ation for Phase III review
8	The Agency to consider further how the outputs from the review of the PCSC and the PCRA may be used to establish authorisation conditions.	The Agency is developing its strategy on risk-informed decision-making with respect to the Drigg disposal facility. To inform development of its strategy, the Agency has commissioned an R&D project to investigate the linkage between post-closure safety case review and the authorisation process for radioactive waste disposal facilities (Bennett *et al.* 2002).	Ongoing
9	The Agency to ensure integration of post-closure safety considerations with wider considerations influencing the regulation of the Drigg disposal facility, including operational issues, funding, waste acceptance criteria, and environmental protection and pollution control (e.g., from non-radioactive substances).	This action will be addressed through the Agency's Site Inspector as part of the Authorisation review. The Site Inspector has responsibility for ensuring integration of the reviews of the PCSC, OESC and any other environmental issues that might arise with regard to the Drigg site.	Ongoing
10	The Agency to consider further involvement of the public and other stakeholders with an interest in the safety of the Drigg disposal facility.	The Agency undertook initial steps in 2000 to develop a stakeholder communication strategy for the review of the Status Report. Further work has been done in support of the PCSC Review, and the Authorisation review will involve a period of formal consultation.	Ongoing

In conclusion, the Agency considers it has made significant progress during both phases of the review of the PCSC Development Programme. Through its review of

the PCSC Development Programme, the Agency has put in place appropriate management structures and review procedures for the review of the 2002 PCSC and subsequent support of the authorisation review, which is planned to start in 2003. The Agency is committed to the use of risk-informed approaches, and to transparency and public scrutiny in its regulatory decision-making.

The review of the PCSC Development Programme and the PCSC is an essential component of the Agency's activities to ensure continued safe operation and appropriate regulation of the Drigg disposal facility.

4.3 Key Issues for the PCSC Review

The following paragraphs identify twelve key issues, which have been derived from the Agency's reviews (see, for example, Environment Agency 2001b). These key issues will form priority topics for consideration when the Agency reviews the 2002 PCSC:

1. **Optimisation and Best Practicable Means**: The Agency will assess whether the Drigg disposal facility has been designed in accordance with sound engineering principles and is being operated using BPM to ensure that impacts from the facility are As Low As Reasonably Achievable (ALARA). Determining what represents BPM will include considering a range of alternative engineering designs.

2. **Risk Assessment and Management**: The Agency will assess whether the PCSC and the risk assessment it includes has a sound scientific basis and whether risk assessment has been used to evaluate thoroughly the uncertainties associated with estimates of long-term disposal system performance. This will entail assessing:

- The risk assessment approach.
- The comprehensiveness of the risk assessment, for example in terms of its consideration and treatment of scenarios and features, events and processes that may affect the performance of the disposal facility.
- The plausibility of any assigned scenario probabilities.
- The conceptual and computer models used.
- The data and parameter values used.
- The quality assurance procedures and quality control measures applied to the PCSC, including the traceability of decisions and assumptions on which the risk assessment is based.

The Agency will also assess whether the risk assessment has been applied appropriately to identify risk management options. This will entail assessing the links between risk assessment results and potential risk management measures.

3. **Climate change impacts**: The Agency will assess the implications of future climate change impacts, for example, site glaciation or coastal erosion.

4. **Trench and vault wastes**: The Agency will take into account the presence, status and nature of the wastes in the two parts of the disposal facility (i.e., the trenches and vaults). The Agency will assess the appropriateness of BNFL's estimates of the waste inventory. Derivation of the waste inventory for the trenches is a key issue because existing records of the trench disposals are of a lower standard than those expected for current and future disposals.

5. **Future human intrusion**: The Agency will assess the approaches and data used in BNFL's risk assessment to consider future human intrusion.

6. **Potentially exposed groups**: The Agency will assess BNFL's arguments regarding the identity and habits of potentially exposed groups, including the possible use of water from contaminated areas in the far-future as sea-level falls in response to climate cooling.

7. **Radionuclide transport and retardation**: The Agency will assess the approaches and parameter values used in BNFL's risk assessment to consider radionuclide transport and retardation.

8. **Hydrogeological models**: The Agency will assess the appropriateness and validity of BNFL's hydrogeological models of the area surrounding the disposal facility. In particular, the Agency will assess the appropriateness of the hydraulic conductivities assigned by BNFL to the disposal facility and surrounding geological strata at the site, and of BNFL's approaches for considering potentially more conductive hydrogeological features.

9. **Radionuclide release**: The Agency will assess the approaches used in BNFL's risk assessment to consider the migration of water through the wastes in the repository and the release of radionuclides from them.

10. **Engineered features**: The Agency will assess the appropriateness of the approaches used in BNFL's risk assessment to represent the various engineering features at the site, including in particular the disposal areas, the final site cap, and any proposals for aiding long-term drainage of the site.

11. **Forward programme**: The Agency will assess the appropriateness of BNFL's plans for implementation of a forward programme of waste management, risk assessment and supporting research, and monitoring.

12. **Funding**: The Agency will assess the adequacy of BNFL's arrangements for the provision of funds for site operation, for its future development and for control and eventual closure of the disposal site. Assurance of adequate funding is an essential pre-requisite for granting a disposal authorisation - to ensure that present-day disposals do not lead to unacceptable future costs if funds were not available to manage, close and control the site as envisaged.

The Agency recognises that there may be implications for the future funding of Drigg arising from the recent announcement by the Government of the planned formation of a Liabilities Management Authority (DTI 2002).

5 ACHIEVEMENTS AND ENVIRONMENTAL OUTCOMES

5.1 Achievements and Benefits

This section identifies further regulatory achievements (see also Section 4.2) made as a result of Agency's ongoing review of BNFL's PCSC Development Programme. The achievements fall in two related areas, increased efficiencies and improved working practices, and influences on BNFL's programme.

5.1.1 Improvements in Working Practices, Efficiency and Regulatory Effectiveness

At the beginning of the Drigg review, the Agency recognised that the review process could be improved, by comparison with earlier work of a similar nature undertaken by Her Majesty's Inspectorate of Pollution (a predecessor of the Environment Agency). The main changes involved more closely targeting the review to the principles and requirements of the regulatory guidance, rather than conducting a peer review covering the broad context of existing scientific and technical knowledge. Thus, reviewers were asked to judge whether the arguments presented were adequately supported by the underlying science and technology, to meet the regulatory guidance. This change did not detract from the quality of the reviews; rather it focused reviewers on issues of potential regulatory concern, and this improved the efficiency of the review process.

The efficiency of the review process was also improved by developing specific guidance to reviewers, which clearly defined the review procedures, identified the scope of the review required, and set out a standard format for reporting reviewer's comments. The use of a clearly defined process resulted in shorter timescales for conduct of reviews.

Early in the Drigg review programme, the Agency decided to take ownership of the outputs from the review, and to present review comments as Agency-approved reports rather than contractor reports. This meant that Agency staff had to fully understand reviewers' comments and their implications in the context of the regulatory guidance, and they also had to recognise and agree an approach to any policy or legal issues arising from the comments. The Drigg review reports therefore required an integrated approach from a team of staff across the Agency, including Operations, Policy, Legal, National Centres and National Services. This has improved regulatory effectiveness, in that the Agency's reports represent regulatory comment rather than simply the views of the contractor or particular expert reviewer. It has also increased awareness among relevant Agency staff of issues raised, which places the Agency on a firmer foundation for conduct of the PCSC review and, in the longer term, for future reviews of updated Drigg safety cases.

A further improvement to the review process was the development of an Issue Resolution Process and an associated Issues Database to record, for example, regulatory comments and BNFL's responses, in a standard format. The Issues Database provides a clear traceable record of issues and concerns, which is a necessity over the long duration of the project (some 6 years). The Issue Resolution Process has provided an effective mechanism for information exchange with BNFL and has proved to be a good basis for dialogue. It also provides a starting point for retaining corporate memory for the process of regulatory reviews that is likely to continue well into the future.

Overall, the improvements in the review process have resulted in greater regulatory effectiveness by allowing provision of earlier responses by the Agency to BNFL's submissions, thus providing a better basis for dialogue with BNFL on issues of concern. A significant contribution to regulatory effectiveness has also been made by the Agency taking ownership of review outputs rather than presenting contractor reports to BNFL. In the current review work, and in the longer term, development of the Issue Resolution Process and the associated Issues Database has proved to be an effective tool for efficient recording of issues and concerns, and for promoting dialogue with BNFL.

5.1.2 Influences on BNFL's Programme

The following points identify some of the main changes to BNFL's programme that have come about as a result of the Agency's review:

- At the beginning of the Phase I review process, BNFL proposed a relatively limited range of scientific and technical work that would be used to update an earlier PCSC. The Agency pointed out that the approach proposed by BNFL was not consistent with recognised practice in systematic risk assessment. As a result of the Agency's comments, BNFL undertook a very significant restructuring of its programme and adopted and implemented a systematic approach to the development of the PCSC.

- BNFL replaced its original source-term code, VAULT, with the more advanced and justifiable DRINK model.

- BNFL dropped its suite of human intrusion codes, known as HICODES, and has adopted a simpler and more justifiable approach.

- BNFL significantly revised its representation of the biosphere.

- BNFL commissioned a new programme of hydrogeological and contaminant transport modelling to replace its original water-balance models.

In summary, review of BNFL's PCSC Development Programme has led BNFL to undertake a more appropriate range of studies to increase its understanding and provide an improved basis for the PCSC. This should result in a PCSC that reflects current best practice. The improvements in BNFL's programme have been significant, and the 2002 PCSC is expected to be one of the most comprehensive assessments undertaken for a low-level radioactive waste disposal facility.

5.1.3 Benefits Arising from the Agency's Review Programme

A number of benefits arise from the preparatory work that the Agency has undertaken in Phases I and II that will aid review of BNFL's PCSC. These include:

- **Clarification of Expectations of the Drigg PCSC.** Early dialogue between the Agency and BNFL has been necessary to clarify, for BNFL, the Agency's expectations of the PCSC and, where possible, to encourage resolution of certain issues before the Agency reviews the PCSC.

- **Scope of the PCSC.** In its dialogue with BNFL, the Agency has made clear that the GRA sets out a framework which will require the 2002 PCSC to be a more comprehensive analysis than any previous assessment of the Drigg site.

- **Agency Review Approach.** The Agency's preparatory work has established appropriate internal expertise and enabled development and implementation of procedures to facilitate an efficient, robust and effective assessment of the PCSC against the Guidance on Requirements for Authorisation [GRA] (Environment Agency *et al.* 1997) and other relevant guidance (DETR *et al.* 2000).

- **Review Outputs and Decision-making.** The review and the associated dialogue with BNFL has provided a sound basis for future regulatory decision-making through development of Agency positions on a wide range of issues such as treatment of human intrusion, non-human species and risk-informed decision-making. On the basis of experience from the Phase I and II review programmes, the Agency has also commissioned R&D on linking review outputs with regulatory decision-making.

- **Timescales.** The review of the 2002 PCSC will need to be completed in a relatively short period in order to feed into the Agency's review of the authorisation. Given the volume and complexity of the technical information that will need to be assessed, the conduct of preparatory work has been vital to ensure that the Agency is able to undertake a review of appropriate quality, scope and depth.

- **Issues Database.** The Issues Database has been developed to provide a full record of the issues raised by the Agency during the review and the subsequent

BNFL responses. It also includes other relevant material such as the Guidance on Requirements for Authorisation and meeting minutes. The Issues Database thus provides an important record for the current Drigg review process. In the longer term, it will provide benefits to the Agency and BNFL in terms of retaining corporate memory of issues that might need to be taken forward to future updates of the PCSC for Drigg, possibly up to final closure in approximately 2150. This does not mean that the Issues Database will be kept in its present format but rather it might provide a starting point for implementation of future systems for long-term retention of information related to the Drigg safety case.

5.2 Environmental Outcomes

Although the focus of the review of the Drigg PCSC is on potential future impacts, there are more immediate environmental outcomes from the work. The Agency's review has encouraged BNFL to adopt improved waste disposal practices at the Drigg disposal facility. For example, the Agency's review has influenced BNFL's planning for interim capping of the existing Vault 8, and for construction of a possible new waste disposal vault, Vault 9.

The Agency's review has led to recommendations to BNFL for improved and better targeted environmental monitoring, which should assist in the Agency's evaluation of options for reducing environmental discharges from the site.

There are potential present-day environmental outcomes of the Agency's review at locations away from the Drigg site itself. Review of the 2002 PCSC, and future updates of the PCSC, will act as a risk management tool to define and regulate the types and volumes of wastes that might be accepted at the Drigg site. Any required changes in the types and volumes of wastes considered acceptable for disposal at Drigg would be driven principally by the need to ensure current and long-term environmental protection. Such changes could influence waste management at waste producers' sites and might require revision of a producer's waste management strategy.

In the longer-term, the review of the Drigg PCSC will be an important component of the Agency's work to ensure the safe disposal of low-level radioactive waste from the nuclear industry and also from other users of radioactive materials such as hospitals and universities.

Finally, synergies developed between the Agency's Drigg review team and others within the Agency has led to an improved capability within the Agency for assessing the long-term impacts of other, non-radioactive, hazardous waste disposals.

6 CONCLUSIONS

The Agency's review of the PCSC Development Programme has indicated that BNFL has made progress in developing a new PCSC for the Drigg site. At this stage, the detailed justification and basis for the 2002 PCSC itself remain to be assessed; this will be an important task for the Agency's review of BNFL's PCSC.

Documents from Phase II of BNFL's PCSC Development Programme and BNFL's presentations at Technical Exchange Meetings indicate that BNFL has made demonstrable progress towards the PCSC and in the area of implementing a systematic approach to risk assessment. However, the Agency still considers that BNFL has not clearly defined the optimisation studies to be considered in the 2002 PCSC.

At the end of Phase II, the Agency has greater confidence in BNFL's Quality Assurance (QA) of document production than it had at the end of Phase I. It will be important for BNFL to apply strict QA and quality control to all aspects of the work that supports the PCSC. Assessing the quality of BNFL's PCSC will be a central part of the Agency's PCSC review work.

BNFL has made progress in addressing issues raised in Phase I and II, having provided written responses to about 94% of the Issue Resolution Forms. Where BNFL was not in a position to address an issue during Phase II, the Company has indicated its intent either to address the issue in the 2002 PCSC, or to include appropriate further studies in its forward work programme.

Based on its review of the PCSC Development Programme, the Agency has identified a set of twelve key issues related to the regulation and long-term impact of the Drigg disposal facility. These are:

1. Optimisation and BPM.
2. Risk assessment and management.
3. Climate change impacts.
4. The status and nature of the trench and vault wastes.
5. Future human intrusion.
6. Potentially exposed groups.
7. Radionuclide transport and retardation.
8. Hydrogeological models.
9. Radionuclide release.

10. Engineered features.
11. BNFL's forward programme.
12. The provision of funding.

These issues will form priority topics for consideration by the Agency when it reviews the 2002 PCSC. Further topics might arise during the review.

The review of BNFL's PCSC Development Programme has focused on potential future environmental impacts - but there are also some immediate improvements that have arisen from the work. For example, the Agency has required BNFL to improve existing disposal practices on the Drigg site, which will ultimately lead to a reduction in both the operational environmental and post-closure impact from the site. The ongoing review of the Drigg PCSC will be an important component of the Agency's work to protect the environment by ensuring the safe disposal of low-level radioactive waste from the nuclear industry and from other users of radioactive materials such as hospitals and universities.

The preparations undertaken by the Agency in reviewing BNFL's PCSC Development Programme will ensure its review of the 2002 PCSC is efficient, robust and effective. Improved procedures and better working practices have been implemented that have increased regulatory effectiveness. Review of BNFL's PCSC will provide input to the authorisation review, which is scheduled to begin in 2003.

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PROPOSED WASTE DISPOSAL FACILITY AT WINSFORD ROCK SALT MINE, BOSTOCK, MIDDLEWICH, CHESHIRE

Planning Inspectorate Reference: APP/Z0645/V/01/000273

PROOF OF EVIDENCE

By

DR SIMON JAMES TRENT POLLARD
ENVIRONMENT AGENCY – NATIONAL CENTRE FOR RISK ANALYSIS AND OPTIONS APPRAISAL

1 INTRODUCTION

1.1 Biographical information

My name is Simon James Trent Pollard. I am the Environment Agency's Risk Analysis Manager at the National Centre for Risk Analysis and Options Appraisal. I am a chartered chemist, a Fellow of the Royal Society of Chemistry and a Fellow of the Chartered Institution of Water and Environmental Management. I obtained my doctorate in environmental engineering in 1990. I have 14 years professional experience in waste management, contaminated land and risk assessment, having worked in university research, consultancy and regulation.

1.2 Declaration

I am a former employee of Enviros Aspinwall, having worked as a senior consultant in their Edinburgh office between 1994 and 1996. I have had no company connection with Enviros Aspinwall's advice to Minosus on the proposed facility.

1.3 Purpose of this proof

My colleague David Newberry will address the regulatory context of the Pollution Prevention and Control (England and Wales) Regulations 2000 (PPC). My proof explains the general approach the Agency would expect to take in reviewing the applicant's environmental risk assessment for the proposed facility. The approach described is therefore without prejudice to the Environment Agency's consideration of any application.

2 ENVIRONMENTAL RISK ASSESSMENT AND MANAGEMENT

2.1 General Duty

The Environment Agency is required, by Ministerial Guidance issued in support of section 4 of the Environment Act 1995, to apply principles, procedures and techniques, in particular risk assessment, economic and policy appraisal to support its decisions made in the context of sustainable development. The Ministerial guidance directs the Agency to take an holistic and long-term perspective to the protection and enhancement of the environment.

2.2 General Guidance on Environmental Risk Assessment and Management

To support the Agency's work in environmental risk assessment, and that of others in this field, the Department of the Environment, Transport and the Regions (DETR) and the Environment Agency published "Guidelines for Environmental Risk Assessment and Management" in July 2000[1]. This revised Departmental guidance sets out the general expectations of environmental risk assessment work, a structured approach to the assessment, and a set of high level principles to which environmental risk assessments in the public domain can refer. In addition to guiding the work of the Agency and others, the guidelines are intended as a reference point for the development of more specific environmental risk assessment guidance for individual areas of legislation, such as that on contaminated land, waste management and major accident hazards[3].

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[1] Department of the Environment, Transport and the Regions, Environment Agency, Institute for Environment and Health (2000) *Guidelines for Environmental Risk Assessment and Management. Revised Departmental Guidance*, The Stationery Office, Norwich

2.3 **Environmental Assessment under the Pollution Prevention and Control (England and Wales) Regulations 2000**
Regulation 11 of the Pollution Prevention and Control (England and Wales) Regulations 2000 require that installations are operated such that all appropriate preventative measures are taken against pollution using best available techniques and that no significant pollution is caused. Operators are required to demonstrate that necessary measures are taken to prevent accidents, limit their consequences and, upon cessation of operations, to put measures in place to avoid any pollution risk.

2.4 The means by which the Agency assesses these and the specific requirements of the regulations is, in part, by reference to an environmental assessment and a best available techniques (BAT) appraisal for the proposed installation. Draft guidance has been prepared by the Agency and issued for consultation[2]. BAT for the management of risk extends beyond technology to management practice.

2.5 Under PPC, certain hazardous waste installations are regulated by reference to the European Framework Directive on Waste. The Agency intends to meet its regulatory responsibilities for such installations using the PPC framework and its duties and powers under the European Landfill Directive.

2.6 The environmental assessment requirements applicable to underground rock salt caverns taking hazardous waste will derive from both the PPC regulations and accompanying guidance. Specific waste acceptance criteria for underground disposal, including standard risk assessment requirements, will be set out in European Union documents[3] and Environment Agency guidance prepared in support of the Landfill Directive. Working drafts of the European Commission Decision relating to waste disposal in rock salt caverns are in preparation for ratification by member states in 2002/3. Current drafts make it clear that the Agency should expect risk assessments to consider periods of geological time and associated geological events (seismic activity, glaciation, flood etc.) as appropriate.

2.7 **Environment Agency review of environmental risk assessments**
Operators and developers of a wide range of facilities and schemes are required to submit environmental risk assessments to the Agency in support of their operations. Risk assessments help the operator and the Agency identify risk management measures required to reduce risks to and from the environment and to human health, where appropriate. The Agency stipulates these measures as conditions in the permit to operate. Preparation of the environmental risk assessment is the applicant's responsibility. It is a "living document" requiring updating as and when modifications to an operation are proposed, or when new or additional information, relevant to the operation, becomes available.

2.8 The Agency expects the operator to adhere to the general and specific guidance issued on environmental risk assessment and management, as appropriate. In reviewing an

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[2] Environment Agency, Scottish Environment Protection Agency and Northern Ireland Environment and Heritage Service (2000) *Horizontal Guidance Note IPPC H1. Integrated Pollution Prevention and Control (IPPC). Environmental Assessment and Appraisal of BAT, Version 2 Internal Consultation and Working Draft,* Environment Agency, Bristol

[3] A European Commission Decision Document is being drafted with the assistance of the sub-group of the EU Technical Adaptation Group for Waste Related Directives that is working on the Landfill Directive.

applicant's submission, the Agency evaluates it from a regulatory and technical perspective, assessing the quality and suitability of the submission, by reference to the Agency's general duties and powers and those prescribed under specific legislation.

2.9 The Agency has substantial experience in assessing risk assessments for facilities ranging in complexity from nuclear disposal facilities through to individual septic tanks. He Agency established a National Centre for Risk Analysis and Options Appraisal in 1997 to lead its activities in this area. Depending on the type of facility and quality of submission, on receipt of the operators risk assessment, the Agency will normally:

- conduct a technical and regulatory review of the submission, consulting internally and externally as required, and probing the submission for its technical soundness and completeness by reference to the legislation;
- request further work of the operator, if deemed necessary;
- consider the need for an independent review of the risk assessment;
- consider the need for an independent risk assessment for any operation or proposal; and
- determine any risk management measures required, or which should be considered, to mitigate the risks to an acceptable level of residual risk.

3 ASSESSING RISKS FOR THE PROPOSED FACILITY AT WINSFORD ROCK SALT MINE

3.1 The proposed facility at Winsford is unique in this country and is being put forward under a new legislative regime. My colleague David Newberry refers to additional work the Environment Agency may wish to undertake in support of its consideration of any application it may receive.

Approach

3.2 Complex facilities such as those proposed at Winsford require commensurate greater detail of, and specialist expertise within the environmental risk assessment. The Environment Agency's approach to review (para. 2.9 above) is to use the expertise of its in house staff and, where required, to commission additional expertise from external experts. Depending on the complexity of the review, the Agency may nominate a dedicated project manager to manage the review and / or an external project manager to co-ordinate specialist inputs for consideration by the Agency inspector.

3.3 The Agency has a firm view on the risk assessment approach that it would expect of this PPC application. Expectations include, but are not restricted to, the following:

- a comprehensive "cradle-to-grave" approach to the risk assessment, considering risks from waste receipt to final placement, closure and performance of the facility forward in time over geological timescales and under various scenarios of operational, institutional and post-institutional control;
- consideration of risks to, and via air, water, soil and biota, including to people, taking into account the identification, due consideration and assessment of the features, events and processes likely to influence the performance of the facility, and associated risks, in the short and long (geological) term;
- due consideration and assessment of a small range of reasonable worst case (including major accident) risk scenarios;

- detailed assessment of the physical suitability and long-term geotechnical stability of the site and any associated engineering, including the long-term risks of subsidence of land above the facility (para. 3.5, below);
- assessment of the hydrological and hydrogeological regimes, evolution with time and potential implications, including the specific assessment of potential water ingress, flood risk and its potential implications;
- the efficacy of quality control and assurance procedures, including for any proposed treatment to manage risks to or from the environment;
- a detailed assessment of waste types, waste quantities and waste acceptance criteria considered suitable for disposal and the demonstrable validation of procedures proposed to assess waste suitability;
- consideration of the effectiveness of controls (security, monitoring, safety assessment and maintenance) to be implemented during the post-operational control periods and the role of these controls in assuring the avoidance of long-term risks of pollution;
- consideration of potential risk management options with regard to BAT and application of the principle of ALARA (as low as reasonably achievable) to managing risk, as appropriate.

3.4 In considering any environmental risk assessment, Agency practice is to:

- consider any submission with close reference to the statute, any statutory guidance and existing published guidance on how requirements can be fulfilled;
- consider international best practice in the assessment and regulation of such facilities;
- be proportionate and reasonable in its requirements by reference to the risks posed and likewise in its own assessment of any submission;
- establish transparent and defensible decisions based on the applicant's science and engineering;
- refer to relevant risk criteria, objectives, quality standards and environmental quality criteria in characterising the significance of risks.

Geotechnical issues

3.5 Clearly, for a facility such as that proposed, geotechnical issues (e.g. physical suitability and stability) are paramount. The Agency would consider the matter of mine stability as part of any PPC application and would expect to consult other relevant regulatory authorities (the local planning authority and the Mines and Quarries Inspectorate) accordingly. We would expect to consider, in consultation with others:

- whether infilling of the mine would compromise its stability;
- the capacity of the operator to monitor for changes in stability; and
- the operator's ability to undertake any remedial actions at a future date.

3.6 The Agency would look to the operator to address these issues in full within the body of the risk assessment, additional matters including, but not being restricted to:

- the potential threat to the integrity of the mine and the waste deposit arising from the ingress of water from above, both (i) during the operation of the mine and the waste disposal facility, via the mine shaft entries or by other pathways (e.g. via roof collapse or borehole penetration); and (ii) following closure of the waste disposal facility, by failure of any of the bulkheads;

- the potential deterioration in performance of such engineered measures over the timescale in which the risk is addressed;
- a demonstration of adequate controls being in place to ensure operations elsewhere in the mine, outside the direct control of any PPC permit, would not detrimentally affect the proposed operation;
- proposals for monitoring the integrity of the site, including the means of measurement of settlement or convergence. A permit, if issued, would include a programme of appropriate monitoring and this would be linked into an appropriate action plan that would cover contingency plans in the event of an unpredicted or unforeseen event occurring.

Experience of regulatory review

3.7 Environment Agency guidance on environmental risk assessments prepared in support of process facilities and various land disposal facilities under a range of regulatory regimes has been published [3,4,5], though specific Agency guidance for hazardous waste installations under PPC has not been prepared. The risk assessment requirements placed on operators and applicants vary proportionately in their level of detail, in part according to the nature, extent and complexity of the hazards posed. Where appropriate, the Agency places on the public record both the operator's risk assessment and the Agency's internal and independent review of the risk assessment. For example, the Agency has recently done this for the developing post-closure safety case[6] at Drigg, the near surface, low-level radioactive waste disposal facility in Cumbria operated by British Nuclear Fuels Limited[7].

4 CONCLUSION

4.1 In determining whether a permit would be issued and any conditions we might attach, the Agency would expect adherence to existing and developing guidance and would itself undertake a comprehensive and critical regulatory review in support of the permitting process to ensure present and future risks are managed accordingly.

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[4] Environment Agency, Scottish Environment Protection Agency, and Department of the Environment for Northern Ireland (1997) *Radioactive Substances Act 1993 - Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation*; Environment Agency: Bristol

[5] Environment Agency and Health and Safety Executive (1999) *Guidance on the Environmental Risk Assessment Aspects of COMAH Safety Reports*, Environment Agency, Bristol

[6] BNFL (2000) *Status Report on the Development of the 2002 Drigg Post-Closure Safety Case*, BNFL, Risley

[7] Environment Agency (2001) *Assessment of the Post-Closure Safety Case Development Programme for the Drigg Low-Level Radioactive Waste Disposal Site: Phase II*, National Centre for Risk Analysis and Options Appraisal, Position Paper Number 25, Environment Agency, London

1. SAFETY PHILOSOPHY FOR UNDERGROUND DISPOSAL FACILITIES

The safety case philosophy for underground disposal facilities has been set out by the Committee for the Adaptation to Scientific and Technical Progress of EC-Legislation on Waste[2] (the Technical Adaptation Committee). This will be brought into force via Annex A to a European Commission Decision (attached) that will amend the Landfill Directive. The Commission consulted on the previous draft of this document dated 1 May 2002.

The isolation of deposited wastes from the biosphere is the primary objective for waste disposal in underground facilities. The wastes, the geological barrier and the cavities, including any engineered structures, constitute an overall disposal system that, together with all other technical aspects, must minimise potential environmental impact and provide long-term safety.

For salt caverns, the salt provides the primary geological barrier to ensure containment and, together with the over and underlying impermeable rock, it prevents groundwater entering the disposal facility and, where necessary, stops the escape of liquids and minimise release of gases from the disposal area. The wastes are only likely to make contact with the biosphere in the case of accident or an event in geological time such as earth movement, or erosion (for example, associated with sea-level rise). The waste is unlikely to change under the conditions of storage, and the consequences of such failure scenarios must be considered as part of the safety case.

Where the geological barrier is pierced by shafts and boreholes, these must be sealed during operation to secure against ingress of water, and must be sealed after the underground landfill ceases to operate. If mineral extraction continues after the cessation of waste disposal, the disposal area must be sealed with a hydraulically impermeable dam. The dam should be constructed according to the calculated hydrostatic pressure corresponding to the depth so that water, which may seep into the still operating mine, cannot penetrate through to the waste disposal area.

With final closure of the disposal facility and the withdrawal of controls, the continued isolation of the waste from the environment shall not depend on actions by future generations to maintain the integrity of the disposal system.

2. RISK ASSESSMENT APPROACH TO UNDERGROUND FACILITIES

a) **General.** A risk assessment provided by the developer is an important part of the safety case for a disposal facility, although the relative importance of quantitative and qualitative arguments will change as uncertainties increase with the evolution of the disposal system over time. One particular value of a risk assessment conducted in a thorough manner lies in the disciplined and systematic approach it imposes. The totality of an assessment will be complex and the expressions of the outcome as a single value of risk does not convey the implications and assumptions and logic, which underpin it. Therefore, the contribution that a risk assessment makes to the safety case for the disposal facility needs to be judged at least as much by its assumptions and logical structure as by the risk estimates it provides.
In this case the risk assessment needs to focus on the likelihood of the breach of total containment rather than the consequences of that breach. If there is a likelihood of a breach, a permit should not be issued.

In a risk assessment, all the features of the disposal system that can be shown to contribute significantly to long term safety, or which may be adverse to safety, will need to be disaggregated, analysed in depth in a manner which achieves overall consistency of approach. Where appropriate, such features might need to be mathematically modelled. In this process, very many assumptions will be made, each of which needs to be recorded. Only if each assumption is separately identified can it be adequately tested and, as appropriate, the effect of making a different assumption explored.

b) **Risk Assessment under PPC.** Under the Landfill Regulations 2002, operators are required to demonstrate that necessary measures are taken to protect the environment and human health and to prevent accidents. In doing this the operator should have regard to

1) the generic Government guidance on environmental risk assessment and management[3];
2) he specific technical requirements for landfills falling under the Landfill Directive;
3) the European Commission's decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 and Annex II of the Landfill Directive (1999/31/EC) if agreed (due to be published Summer 2002).
4) the requirements of the EU Water Framework Directive (2000/60/EC) requiring the demonstration of the long-term safety of the installation by reference to the prohibition of direct discharge of pollutants into groundwater;
5) Agency Guidance on *Hydrogeological Risk Assessments for Landfills and the Derivation of Groundwater Control and Trigger Levels.*

Risk assessment for a disposal facility must be carried out for both the operational and post operational phases. A risk assessment should include, for example, assessment of the geological, hydrogeological, geochemical and geomechanical conditions that influence the containment of the waste, particularly over the long-term. The risk assessment should include in its evaluation, the environmental impact of any surface facilities required for handling and storage of waste prior to disposal, and the potential long-term environmental impact within the biosphere and on any potentially exposed group of humans.

c. **Exercise of Judgement.** Forming a judgement about the level of safety afforded by a disposal facility will involve assessment of the means by which contaminants might move from the wastes through the immediate physical and chemical environment of the facility, and through the surrounding host rock to the biosphere. This is likely to entail considering the potential behaviour of contaminants over and extended period. The safety case provided by the developer will have to address these issues. The Agency will need to be satisfied that good engineering practice has been used in developing proposals for the design, construction, operation and eventual closure of the facility. In addition, the Agency will need to be reassured that good science has been applied in investigating the suitability of the site, in any supporting research and development, in interpretation of the resulting data and in development of safety assessment techniques.

The Agency considers that a risk assessment is unlikely to be sufficient on its own to provide a satisfactory demonstration of safety. The risk assessment is likely to form only part of the overall safety case. Sufficient assurance of safety over the long timescales which may need to be considered is likely to be achieved only through multiple and complementary lines of reasoning. All such supporting arguments, whether qualitative or quantitative, will, in different ways and to different degrees, inform the regulatory decision.

Unless the Agency is satisfied that the technical support for safety from the various lines of reasoning offered by the developer results in a safety case of sufficient quality overall, disposal of waste in the facility will not be allowed.

To support its judgements, the Agency may need to make safety assessments of its own, based on information supplied by the developer. This might include independent investigations of matters of particular importance to the safety case and studies relating to the completeness of the case.

d. **Supporting Information and Quality Assurance.** The developer is responsible for all information necessary to support the risk assessment. This will need to be provided to the Agency within an agreed documentation structure so that its relevance to the formal application document is apparent.

Quality assurance arrangements, which permit all classes of information to be traced back to their source, are of particular importance. In cases that the Agency may identify from time to time, it will need access to the original data and associated methods of collection in entirety so that the provenance and interpretation of the data can be examined. There may be circumstances in which the Agency will wish to gather its own information, or will request the developer to gather information for it.

e. **Facility-related Information and Accident Scenarios.** The developer should demonstrate that the proposed location of the facility within the site is of sufficient extent to accommodate the categories and quantities of waste to be disposed of whilst maintaining adequate separation from geological media of less suitable characteristics.

The facility shall be designed, constructed, operated and be capable of closure so as to avoid adverse effects on the performance of the containment system. The developer should show that the methods of construction of the facility are such as to avoid undue disturbance of the geological environment and the containment properties of the host rock. The Agency will need to be satisfied that appropriate investigation and monitoring are carried out during the construction and operational phases to confirm the characteristics of the site, the behaviour of the facility and the extent of disturbance caused by intrusive site investigation procedures and by construction.

f. **Site Investigation and the Geological Environment.** The developer shall carry out a programme of investigations to provide information necessary for the safety case and to demonstrate the suitability of the site. A thorough site investigation of the geological setting of a site will be required. This includes investigation, analysis and interpretation of the host geological structure and detailed examination of the surface environment, for example, soils, hydrological features, and topography.

Information on the geological characteristics of the site will be progressively extended through the site investigation and during operation of the facility. Information supplied by the developer to the Agency may include results from research, from continuing environmental and geotechnical investigations, and from monitoring during the site investigation, construction and operating phases of the facility. These investigations should be aimed at improving understanding of the geology, hydrogeology, geochemistry and other relevant characteristics of the site and at improving confidence in assessments of the long-term performance of the system. They should also allow the effects of disturbance to the site from construction of the facility and related activities to be assessed.

As part of this demonstration, the developer will have to show that the geological environment is adequately characterised, understood and capable of analysis necessary to support the safety case. This will involve consideration of the lithology, the stratigraphy, the geochemistry and the local and regional hydrogeology. The location, frequency and structure of any faulting or fracturing in surrounding geological strata and the potential impact of seismic activity on these structures should be included. The developer will also need to assess the potential for, and effects of, dynamic processes such as seismic events and ground subsidence. Knowledge of the characteristics of the site should increase progressively through the site investigation and the facility development phase.

The developer should show that the physico-chemical and geochemical characteristics of the geological environment are such as to prevent the migration of contaminants. The developer should show that the hydrogeological characteristics of the region and the site under present and possible future conditions are such as to allow the safety case for the facility to be made.

Information will also be required on the surface environmental characteristics of the geographical area of the site including land use, surface waters, soils and sediments, as well as environmental factors that could influence their evolution.
For example the normal patterns of weather and climate and any history or expectation of extreme disturbance to the normal patterns.

g. **Geo-mechanical information.** The geo-mechanical stability of the cavities within the host geological structure must be demonstrated by appropriate investigations and supporting modelling predictions. The deposited waste must be part of this assessment. The process should be analysed and documented in a systematic way.

h. **Hydrogeological and Hydrological Assessment.** A thorough investigation of the hydrogeological properties is required to assess the groundwater flow pattern in the surrounding strata based on information, such as the hydraulic conductivity of the rock mass, knowledge of relevant fracture systems and the hydraulic gradients.

i. **Geochemical Assessment.** A thorough investigation of the rock and the groundwater composition is required to assess the present groundwater composition and its potential evolution over time, the nature and abundance of fracture filling minerals, as well as a quantitative mineralogical description of the host rock. The impact of variability on the geochemical system should be assessed.

j. **Biosphere Impact Assessment.** An investigation of the biosphere that could be impacted by the underground storage is required. Baseline studies should be performed to define local natural background levels of relevant substances. Current levels of stress to critical compartments of the ecosystems should be determined and critical biological endpoints should be identified. Critical pathways of relevant substances should be identified and risks for biomagnification should be evaluated. The impact of variability on the biosphere system should be assessed.

k. **Safety Assessment Timescales.** In order to comply with the objectives of sustainable waste management, risk assessment should cover the long-term. Long term containment of the wastes must be demonstrated within the safety case such that potential impacts in the biosphere and among potentially exposed human groups will be minimised and remain with levels acceptable in the present day.

Demonstration of long-term safety of underground disposal in a salt rock should be principally undertaken by designating the salt rock as the barrier rock. Salt rock waste because of its convergent behaviour and to confine it entirely at the end of the transformation process. The convergent behaviour of the salt rock thus does not contradict the requirement to have stable cavities in the operation phase. The stability is important, in order to guarantee the operational safety and in order to maintain the integrity of the geological barrier over unlimited time, so that there is continued protection of the biosphere.

Controlled subsidence of the overburden or other defects over the long-term time will be only acceptable if it can be shown that only rupture-free transformations will occur such that the integrity of the geological barrier is maintained. No pathways should be formed by which water would be able to contact the waste or the wastes or components of the waste migrate to the biosphere.

The performance of these various features should be quantitatively assessed over the long-term. They should be evaluated on the basis of site-specific data or sufficiently conservative assumptions, taking into account, for example, groundwater flow, barrier efficiency, natural attenuation as well as leaching of the deposited wastes. Containers and cavity lining should not be taken into account when assessing the long-term risks of waste deposits because of their limited lifetime.

In general, assessments of the environmental impact of a disposal facility should cover the timescale over which the models and data by which they are generated can be considered to have some validity. The timescales over which the Agency will expect to see detailed estimates of risk will therefore depend on the site and the facility and is a matter for the developer to justify. At times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed, scoping calculations or qualitative arguments may be used to indicate the continuing level of safety.

No definate cut-off time is prescribed for the period over which the risk should be assessed. The timescales over which assessment should be presented is a matter for the developer to consider and justify as adequate for the wastes and disposal facility concerned.

l. **Treatment of Uncertainty.** The treatment of uncertainty is central to the establishment of the safety case for a waste disposal facility. Uncertainties are not of themselves obstacles to establishing the safety case, but rather matters requiring consideration in a variety of ways and assimilation into the structure of the case as appropriate. They arise from, among other things, natural variability, the practical limitations on sampling relevant processes and data, alternative interpretations of data, and natural events and human activities that may affect transport and exposure pathways.

Some uncertainties may be eliminated from further consideration by making simple deterministic assumptions based on reasoned arguments. For example, to deal with future human behaviour the developer could present assessments in terms of the impact on potentially exposed groups based on observed past and present human behaviour, justifying the particular groups chosen. Some uncertainties may be quantified and incorporated into numerical assessments of probability or risk. Quantification of other uncertainties may be inappropriate. Where such uncertainties are important to the case, they may be treated by making deterministic assumptions and exploring the effects of varying these.

m. Modelling Studies. The developer may provide results from mathematical modelling studies together with details of the models and methodologies used. The aim of the studies would be to assist an understanding of the characteristics and behaviour of the overall system and its components.
Candidate processes for modelling might include, for example, hydrogeology and groundwater flows, chemical and physical processes affecting contaminant transport, and gas generation and migration behaviour within the facility.

A systematic programme of work will be needed to provide validation of models (including the interpretation of raw data, conceptual models, mathematical models and computer programs). Validation is an iterative and progressive process of building confidence. The measures adopted in a validation programme should include:

- systematic approaches to model building and considerations of alterative models;
- iteration between model building, safety assessments and data collection;
- continuing peer review of model development.

In some areas, e.g. seismic survey data, there may be alternative interpretations of the data and therefore no conceptual model of the system, which can be regarded, as uniquely valid.

n. Future Human Actions. A range of future human actions can be envisaged having the potential to breach the natural barrier provided by the salt and the host geological environment or significantly impair the performance of the disposal system. These may be deliberate, i.e. taken with knowledge of the location and hazardous nature of the facility, or inadvertent because the location or purpose is unknown. The Agency considers that it is not necessary to undertake quantitative risk assessment of deliberate human actions, since it is assumed that no such action would be taken without due regard to the safety implications and the economic and environmental values of the time.

The developer may advance arguments to justify a very low probability of inadvertent actions affecting the disposal system for a period following closure by reference to the proposed post-closure management plans. However, in the longer term, institutional controls cannot be relied upon and the developer will be expected to assess the likelihood and consequences of possible future human actions.

o. Operational Phase Assessment. When demonstrating operational safety, a systematic analysis of the operation of the facility must be made on the basis of specific data on waste inventory, facility management and the scheme of operation. It is to be shown that the waste will not react with the rock in any chemical or physical way, which could impair the strength and tightness of the rock and endanger the storage itself. For these reasons, in addition to wastes that are banned by Article 5.3 of the Directive, wastes that are liable to spontaneous combustion under the storage conditions (temperature, humidity), gaseous products, volatile wastes, wastes coming from collections in the form of unidentified mixtures should not be accepted.

Particular incidents that might lead to the development of a pathway between the wastes and the biosphere in the operational phase should be identified. The different types of potential operational risks should be summarised in specific categories. Their possible effects should be evaluated. It should be shown that there is no unacceptable risk that the containment of the operation will be breached. Contingency measures should be provided.

p. **Risk from Surface Reception Facilities.** Although the wastes taken at the site may be destined for subsurface disposal, wastes will be unloaded, tested and possibly stored on the surface, before reaching their final destination.
The reception facilities must be designed and operated in a manner that will prevent harm to human health and the local environment. They must fulfil the same requirements as any other waste reception facility.

q. **Assessment of Other Risks.** For reasons of protection of workers, wastes should only be deposited in areas where there is no human activity and which are securely separated from areas of mining operation.

3. WASTE ACCEPTANCE CRITERIA.

It should be noted that the facility must be classified as hazardous, non-hazardous or inert. The waste acceptance procedures set out in the Commission Decision should be adhered to and, for inert and non-hazardous waste, the waste acceptance criteria given in that document apply.

If the intention is to accept a mix of hazardous and non-hazardous wastes the facility may need two separate licences unless the criteria for non-hazardous wastes set in the Commission Decision are adhered to. The Agency is likely to set additional waste acceptance criteria for the underground storage of hazardous wastes. These will include, as a minimum, the criteria given in Section 2.4.2 of the Commission Decision and the Dissolved Organic Carbon (DOC) value given in Section 2.4.1. These conditions apply regardless of the conditions that emerge from a consideration of the following upon which the Agency will provide further guidance on this issue in due course.

Acceptance criteria for underground storage are to be derived from, *inter alia*, the analysis of the host rock, so it must be confirmed that no site-related conditions specified in Annex I of the Landfill Directive (with an exemption of Annex I para 2 and para 3) have relevance.

The acceptance criteria for hazardous waste intended for underground disposal can only be obtained by referring to the local conditions. This requires a demonstration of the suitability of the host rock for development of a disposal facility. This will require an assessment of the risks to the long-term containment of the wastes, which will require taking into account the performance of the overall disposal system, including, for example, the waste; any engineered structures and cavities; the host geological structure and the hydrogeological environment.

The developer shall derive waste acceptance criteria consistent with assumptions made in assessments of the performance of the system and with the requirements for handling and transport. Acceptance criteria should be based on a site-specific risk assessment. The site-specific risk assessments for the wastes to be accepted at a disposal facility are necessary to demonstrate that the level of isolation from the biosphere is acceptable.

The factors affecting the performance of the waste before and after disposal, and which need to be covered by the acceptance criteria, include the chemical and physical composition. The chemical and physical form of the waste should be such as to limit detrimental chemical or microbial interactions. The waste package should have sufficient mechanical stability to withstand the conditions of transport and handling.

Wastes that might react with each other must be defined and classified in groups of compatibility; the different groups of compatibility must be physically separated in the disposal facility.

When waste is accepted for disposal, the physical and chemical composition of waste consignments transferred to the facility will need to be sufficiently well characterised to ensure compliance with the conditions of the permit.

Wastes can only be deposited in areas where there is no current mining activity involving the use of men or machinery, and which are securely separated from such areas and from areas with mining/ore potential.

a. Excluded wastes. Wastes that may undergo physical, chemical or biological transformation or that generate gases after they have deposited must not be disposed of in an underground facility. This includes the following:

a) Wastes listed in Article 5.3 of the Directive
b) Wastes and their containers, which might react with water or with the host rock under the storage conditions and lead to:
   - a change in the volume;
   - generation of auto-flammable or toxic or explosive substances or gases; or
   - any other reactions which could endanger the operational safety and/or the integrity of the barrier.
c) Wastes that are biodegradable
d) Wastes that have a pungent smell.
e) Waste that can generate a gas-air mixture which is toxic or explosive. This particularly refers to wastes that:
   - cause toxic gas concentrations due to the partial pressures of their components;
   - form concentrations when saturated within a container, which are higher than 10% of the concentration which corresponds to the lower explosive limit.
f) Wastes with insufficient stability to correspond to the geo-mechanical conditions.
g) Wastes that are auto-flammable or liable to spontaneous combustion under the storage conditiosn, gaseous products, volatile wastes, wastes coming from collections in the form of unidentified mixtures;
h) Wastes that contain or could generate pathogenic germs of communicable diseases (already provide for by Article 5.3c of the Directive)

b. Lists of waste suitable for underground disposal. Inert wastes, hazardous and non-hazardous wastes, not excluded by the above, may be suitable for underground storage, but see the first two paragraphs of this section on Waste Acceptance Criteria.

References

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3. Water Framework Directive

4. Agency Guidance on Hydrogeological Risk Assessments for Landfills and the Derivation of Groundwater Control and Trigger Levels.

Participatory Risk Assessment for Environmental Decision-Making

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1. Introduction

Recent research, discussion and practice in the role environmental decision-making as an integral part of a democratic society have resulted in legislation, policy and guidance that encourage, and indeed may require, greater participation. The focus of this research paper is to explore these participatory ideas in the context of environmental risk assessment. Participation methods have generic application. However, the importance of fitting method to purpose requires that different contexts and issues relative to the objectives be addressed. In relation to environmental risk assessment these issues include:

- the complexity of risk issues *per se;*
- the inherent uncertainty that dominates any risk assessment;
- the quantitative nature of many risk assessments and the difficulty of dealing with low probability-high consequence outcomes;
- the possibility of controversy in relation to decisions involving risk and thus the careful attention needed to the process and identification of participants;
- the traditional role and culture of experts in risk decisions and the challenge of reconciling this with the role of lay knowledge and the potential for the public to act as quality assurors in the risk decision process;
- the tendency for people to need reassurance when confronted with risk, even during a participation process;
- the need to acknowledge the public's ability to deal with complex technical issues and the need for information and data to respond to their questions, and
- the fact that 'risk' *per se* will often not be the only issue of public concern.

2. Risk Assessment in the Environment Agency

The Environment Agency is required to address a very wide range of risk issues throughout its regulatory and supervisory work. Environmental risk assessments supporting the Agency's work generally fall into one of two categories [1, 2], with the majority of activity being associated with the latter.

- regulatory risk assessment, where the Agency *per se* undertakes the risk assessment (the design of flood defence schemes, assessment of existing production chemicals under EC legislation); and
- applicant risk assessment, where the Agency is involved in reviewing risk assessments that operators, dischargers, developers or abstractors are required to undertake to support environmental permits [2].

Agency risk assessments may apply at specific stages of the development, permitting, operation or decommissioning of an activity, or they may parallel other decision processes. Arguably, risk assessment at the strategic planning stage is most valuable in preventing adverse environmental impacts and in ensuring that appropriate risk reduction is considered early on. At the strategic level, however, the Agency is often not the primary decision-maker and seeks to influence activities through its input to, and consultation on, strategic environmental plans.

3. Pressures for Participation in the UK

A summary of national and international pressures for enhanced public participation in decision-making can be found in [3]. In the legislative context, most UK requirements have been limited to consultation to gain people's opinions on already drafted plans and proposals. The concept of representative democracy has underpinned these requirements. Legislative change could be precipitated by the Aarhus Convention (and the draft EU Directive giving effect to the Convention) that stresses the need for early public participation "when all of the options are open". National guidance and advice of relevance to public participation by the Environment Agency is available in documents [4] and [5].

4. Participatory Risk Assessment

Recent literature [8-15] has reflected the drive to pubic participation and identified it as an essential aspect of risk assessment. Of particular relevance are [6,7] and [10]. These reports stress the need for direct methods to ensure that people's values, lay knowledge and understanding are articulated and taken into account alongside technical arguments. Participation is no longer being presented as an optional add-on to policy-making but as an integral part of the process.

In particular, it has been acknowledged that the risk assessment process should be open, accountable, credible and inclusive [10, 16]. Underlying the recent changes in approaches towards participation generally, and risk assessment specifically, is the need to view the process in a more holistic way [12]. Within the risk context the need to 'find a process that facilitates the involvement of all affected parties and at the same time produces a prudent and informed judgement based on expertise and knowledge' is one of the major challenges of a modern democratic society [8]. The success of such a process depends on a number of factors including time; openness of result; equal position of all parties; willingness to learn; resolution of allegedly irrational responses; and demoralisation of positions and parties. Furthermore, the practicality depends on the availability of resources, the existing degrees of freedom in the decision-making processes and the capacity for change, where needed. The concept of analytic-deliberative processes has gained increasing importance, being identified as one of the key ways to move forward with regard to participatory risk assessment [11, 17-19]. This approach to environmental decision-making suggests that to achieve a process that is both transparent and trusted requires the involvement all parties from the outset. Experts and lay people are involved in defining and reflecting upon the pertinent issues throughout the risk assessment. This requires that both the *analysis* (the specific and more specialised processes associated with risk assessment) and the *deliberation* (the interactive means by which ideas are deliberated upon by wider stakeholders) be seen as inextricably linked and equally influential.

Some general objectives of participation [3] are identified in Table 1. All of these are relevant to participatory risk assessment. Objectives limited to satisfying regulatory requirements in isolation are unlikely to accord with the public's objectives. They may also be unlikely to provide for the most effective participatory methods in terms of optimising deliberation and discussion and opening science to public understanding and debate. Additional objectives relevant to participatory risk assessment have also been identified (Table 1) [8, 15, 17, 20].

General objectives	Additional objectives for risk assessment
To satisfy regulatory requirements To resolve conflicting views To increase transparency and defensibility (of professional judgements and decisions) To change people's views To improve services To determine needs and desires To empower citizens to take action To enable social learning To optimise trust and credibility To elicit values relevant to the decision	To ensure: - problem scoping is comprehensive and in-line with public and stakeholder concerns; - that hazards of concern to the public are scoped into the assessment; - that 'local' information and understanding of environmental conditions, exposure patterns, etc is included; - development of stakeholder and public understanding and technical capability; - that uncertainty is discussed and understood; - that alternatives and risk reduction options are discussed and the interests and concerns of the public incorporated; and - the public can act as a quality assurance mechanism in the risk assessment process. To assist in identification of appropriate standards and criteria by which risks will be evaluated To provide for public challenge of assumptions and scenarios considered relevant to the hazard assessment and risk estimation

Table 1 Objectives of public participation applied to environmental risk assessment

There are also some important issues that need to be considered at the outset. For example: (i) assessing the attitude of the convenor; (ii) evaluating potential alternatives to a participatory process; (iii) determining whether the decision has already been made (in which case, participation beyond information provision will not be relevant); and (iv) identifying potential stakeholders and public with an interest.

5. Challenges for Participatory Risk Assessment

Risk management decisions are often enormously complex, replete with technical uncertainties and perplexing value tradeoffs. Making and implementing wise policy choices is difficult, even for risk management experts. Given this, 'how can members of the interested lay public hope to understand and play a meaningful role in making such complex, high stakes choices?' [19]. One solution could be to engage different people at different stages – informed stakeholders in the more technical elements, the lay public in problem definition and risk evaluation – while not losing sight of the need to inform people in general throughout. Whilst it is important that consultation forms a 'level playing field' it is also important not to ask too much of participants. A further concern is that in focusing so heavily on issues of deliberation and 'smoothing out differences' between stakeholders, technical issues can become neglected or inadvertently left alone to experts [21].

At a most basic level, experts often have a different language to other stakeholders to describe risk. Three different 'types' of risk language have been identified: colloquial, technical and insurance [22]. It has been suggested that the colloquial view of risk is that of danger, venture and opportunity; the technical view one of hazard, probability and consequence; and the insurance view one of chance and uncertainty. Proceduralised risk assessment frameworks [10] used by regulators run a potential danger of implicitly assuming that the technical view is somehow pre-eminent. In many regulatory settings, there is a potential disparity between the need to define operational procedures for regulation and a desire to engage the public in risk decisions where 'technical' language will compete with the colloquial language of the public; hence the initiation of our study. Some commentators have expressed this in terms of a 'deficit model' whereby the expert 'elite' tend to view 'the public' as starting from a position of ignorance and the expert from 'the correct position' [23-25]. Whilst experts and lay people are likely to construct a risk issue differently, this does not mean that one kind of knowledge is more or less valid. Instead, it should be the case that both parties have the opportunity to contribute. As noted in much of the research on risk and democracy, the analysis that takes place is conducted by experts in various scientific disciplines each operating within a defined scientific culture [26]. This project does not suggest that this could be otherwise: risk assessment undoubtedly needs input from specialist advisors and a clear reference to the legislative setting - indeed, it has been observed that the public welcome advice from experts [23, 27]. What needs to be considered is the part that lay knowledge, understandings and perceptions can play in defining the agenda for risk assessment; provision of feedback into the analytical process and in interaction with the experts conducting the analysis early on in the process.

Uncertainty is critical to risk characterisation [11] and a problematic area with respect to increased public participation in risk assessment. It is clear that people do not respond well to uncertainty and that it frequently increases confusion and anxiety. Indeed, in a recent study on risk literacy, i.e. trying to ascertain what it is about an issue that either increases or decreases people's propensity to learn about it, it was found that uncertainty can have a negative impact upon knowledge acquisition [27]. However, there is also evidence that when people are faced with issues of uncertainty in participatory processes they are able to recognise and deal with it, if they are provided with opportunities to understand the reasons for the uncertainty and to question different expert views [17].

A major problem with regard to managing the concept of uncertainty is whether or not it is acknowledged explicitly in the risk assessment process. It is frequently the case that various stakeholders tend to suppress or push aside the information on uncertainty in order to maintain the guise of trust and authority. The sometimes covert nature of uncertainty therefore makes it all the more difficult to deal with and increases public alienation [28]. Uncertainty needs, therefore, to be presented as something that has pragmatic ramifications as opposed to being something that is abstract and theoretical. This might require considerable effort and imagination on

the part of the convenor of the decision-making / participatory process but could result in a more successful and fulfilling outcome for all parties.

A related problem is that of data availability, both in terms of 'does it exist' and 'can it be made available'. Most risk controversies are distinguished by information scarcity, with some data, regarded as indispensable by at least one stakeholder, usually not available [29]. The essential trade-offs that are necessary in the face of such data unavailability require that these are conducted in as open as manner as possible. This forces people to confront their assumptions and to seek common ground [17, 30]. Both published and unpublished may need to be revealed. For some issues, data may be evolving. Participants need time to become equated with technical information and an opportunity to understand what is still not known and then weigh up alternatives [17]. This requires that people can access the base data, not just summaries or overviews. Confidentiality, or perceived commercial confidentiality by private sector developers/proponents can also have a significant impact on public involvement. Legislative requirements for public consultation are relatively limited and have been time-limited once proposals are made public. To encourage public participation in assessment processes requires a willingness to engage with people while proposals are developing and assessment is underway. At the current time it seems more likely that participatory processes will be able to be used where public sector development or regulatory functions are also involved.

6. Criteria for Effective Participatory Risk Assessment

General criteria for increasing effective participation in environmental decision-making processes within the Environment Agency are presented in [3]. These include issues such as clarity of objectives, the clarity of the legal process, representativeness, inclusivity and transparency. Often effectiveness has been defined in terms of the outcome – particularly the legitimation of the decision. However, constructs of 'discursive' and 'deliberative' democracy demand a broader definition of effectiveness which, rather than focussing on working to ensure that everyone will be happy with the outcome (unrealistic), concentrate on matching the 'right science' with the 'right participation' [11]. 'Fairness' and 'competency' criteria [31, 32] have underpinned many international evaluations of participatory processes. Also evident is the importance of ethical and value-based dimensions [33] including the extent to which a process is honest, equitable, impartial and respectful.

In practice, multiple methods of information provision, consultation and also deliberation may be required if the overall effectiveness of a programme of participation is to be considered. Matching methods to overall objectives, and the adaptation of methods to meet local conditions or to enable a less costly method to be used is likely to improve effectiveness.

It is suggested that participatory risk assessment might provide for:

- Stakeholder and public engagement in the problem definition and framing stage, including the identification of hazards, identification of information needs, and definition of criteria relevant to the risk characterisation.
- Stakeholder, at least, (and possibly the public where local issues are important) engagement in the hazard identification and risk estimation stages to allow for questioning of technical assumptions, model use, and uncertainty management and to ensure that all relevant information is available to the assessment process or commissioned where missing.
- Stakeholder and public engagement in the risk characterisation stage.
- Open access to information relevant to the risk assessment process.
- Participation to act as a quality assurance mechanism in the risk assessment process.
- Integration of the risk assessment with other assessments and with the decision process (i.e. not just participatory risk assessment but a participatory decision process).

A distinction is made here between stakeholders who may represent particular interests (industrial, regulatory, conservation, etc) and the public who may be representative of particular interests within a community, but who would not take part in a participatory process as a representative of these interests, but as individuals. The distinction is drawn to ensure that the right people are asked to participate to meet the objectives. The stress is placed on the importance of early engagement, in the problem definition stage. Given the objectives of participatory risk assessment, it is not evident that radically different criteria of effective participation are appropriate, rather it is necessary to consider whether any additional criteria need to be included to ensure that the staged process of participation suggested is effectively managed.

From our initial work, some specific criteria in relation to the risk assessment process have also been identified as the following:

- Is there opportunity for participants to engage in the problem scoping – including agreement on the definition of the problem and the issues which will need to be addressed?
- Is there opportunity for participants to discuss likely data and information deficiencies in the assessment process and to agree how these will be rectified?
- Is a formal process involved that allows for the concerns and values of participants to be captured and recorded such that the criteria that will be relevant to the risk evaluation are agreed?
- Are the technical experts involved able to communicate and explain complex science and risk data, and willing to be open about limitations in current knowledge?
- Does the process make a difference to participants in terms of their understanding of the issue and knowledge gained, in particular their understanding of the risk assessment process and its role in decisions?

- If the process leads to challenge to existing Agency risk assessment methods and/or decision criteria is the Agency prepared to revisit these?
- Does the process lead to an enhancement of the Agency's credibility as an environmental regulator and promote trust in its risk decisions?

7. Conclusions

The contributions to the risk debate from the social sciences are having considerable influence on the practice of environmental decision-making. Calls for increased stakeholder involvement [6,7,28,34] in risk decisions are requiring greater access to and engagement with environmental risk assessments. Mechanisms for this level of involvement, however, are not well defined. For these aspirational calls to be realised in practice, decision-makers need to work alongside other stakeholders to establish at what stages, and in what ways involvement can be meaningfully incorporated. Future outputs from this work will help establish the practical applicability of these mechanisms for the Environment Agency.

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www.environment-agency.gov.uk

Communicating Risk Assessment Involving Lay Audiences: Environmental Decisions on Risk

R&D Technical Report E2-043/TR/01

ENVIRONMENT AGENCY

Participatory Risk Assessment – Involving Lay Audiences in Decisions on Environmental Risk

R&D Technical Summary E2-043/TS

The Department of the Environment, Transport and the Regions (DETR), the Environment Agency ("the Agency") and the Medical Research Council (MRC) Institute for Environment and Health published revised departmental Guidelines for Environmental Risk Assessment and Management in July 2000. This guidance, which sets out an overarching philosophy and framework for environmental risk management in England and Wales, signals a desire for risk practitioners to consider stakeholder involvement in decisions on risk. The Agency therefore initiated this research in order to explore in detail the practicalities of this shift in approach.

Specifically, the research objective is to inform the Agency's developing approach to the practical involvement of non-specialist stakeholders (lay audiences) in environmental risk assessment work. It reflects the desire of the Agency to improve stakeholder (including public) engagement in key decisions involving risk issues whilst, and importantly, having due regard to regulatory and operational demands and constraints.

The work was conducted by the University of Birmingham's Centre for Environmental Research and Training with support from PDA International. It was undertaken in close collaboration with the Agency's Environmental Policy – Risk and Forecasting unit (formerly known as the National Centre for Risk Analysis and Options Appraisal) and with active research input from the Agency's Project Board.

The research has the following specific objectives:

- Understanding what participatory risk assessment is
- Identifying relevant stakeholders
- Exploring the contexts in which the Agency makes decisions concerning risk
- Evaluating the potential to open up the process of risk assessment to public involvement

The following have been undertaken:

- An extensive review of the published and 'grey' literature and practical experience of participatory risk assessment.
- Completion of a 'needs analysis' for key Agency staff and non-specialist stakeholders in terms of participation in risk assessment.
- A detailed characterisation of the Agency's regulatory context for decisions involving risk in terms of the potential for, and barriers to, participation in risk assessment.
- The design and execution of a simulation exercise to test a possible method of participatory risk assessment.

The work has identified a need for the Agency to develop more deliberative techniques for involving the public in the decision-making process. This would bring benefits in terms of the quality of decisions reached and the trust of the public. It also has the potential to increase scientific literacy amongst the public and to enable them to have greater ownership of decisions made. Whilst doubt is frequently expressed about the ability of the public to participate in technical debate, interviews clearly demonstrated that this is a misconception - it is the presentation of this material that causes the problems rather than the material *per se*.

The research results indicate that a staged process that optimises participation at key stages in the assessment process – i.e. problem definition and framing, assessment and evaluation – is favoured by potential stakeholders and reflects developing international best practice.

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Characterisation of the contexts in which decisions involving risk are taken has shown that the methods used to this end need to be tailored for different contexts. It is important to consider factors such as the nature of the issue (e.g., the extent of a potential adverse impact); the role of the Agency and of other parties; the volume and nature of technical information; and the timescale on which the decision will be taken. It is also important to achieve a careful balance between the desire to be open (i.e., to seek to actively engage interested parties) and the need for meaningful participation. Thorough scoping, including gauging the level of interest in a particular issue, is important before embarking on any participatory process.

Wishing to explore the practicalities of the proposals generated in this research, the project successfully tested a method to involve the public in the problem definition and framing for a hypothetical 'authorisation' decision. This involved small group deliberation about the nature of the issues presented by a proposal to burn waste as fuel at a cement kiln and the identification of data and information needs. The individuals who participated in the simulation were evidently interested in the process and able to deal with complex technical issues when given sufficient time to assimilate information and to ask questions. The workshop identified a requirement that participants must be able influence the decision if they are to feel that their participation is worthwhile.

This R&D Technical Summary relates to information from Project E2-043 contained in the following research outputs:

1. **R&D Technical Report E2-043/TR/01** – Participatory Risk Assessment: Involving Lay Audiences in Decisions on Environmental Risk. Literature Review and Stakeholder Interviews, ISBN 185705 9131
2. **R&D Technical Report E2-043/TR/02** – Participatory Risk Assessment: Characterising Environment Agency Decisions on Risk, ISBN 1844321630
3. **R&D Project Record E2-043/PR** – Workshop Simulation: Participatory Risk Assessment Project Record, ISBN 1844321622
4. Homan, J., Petts, J., Pollard, S.J.T. and Twigger-Ross, C. (2001) Participatory Risk Assessment for Environmental Decision-Making. In: *Proceedings VALDOR 2001 - The 2nd VALDOR Symposium Addressing Transparency in Risk Assessment and Decision-Making*, K.Anderson (ed.), 10-14 June, Stockholm, Sweden, 2001: 398-406
5. Petts, J., Pollard, S.J.T., Gray, A-J, Orr, P., Homan, J. and Delbridge, P. (2003) Involving Lay Audiences in Environmental Risk Assessments. In: *ConSoil 2003, Proceedings 8th International FZK/TNO Conference on Contaminated land*, 12-16 May 2003, Ghent, Belgium: Theme D: 2969-2978

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PARTICIPATORY RISK ASSESSMENT -

INVOLVING LAY AUDIENCES IN ENVIRONMENTAL DECISIONS ON RISK

Literature Review and Stakeholder Interviews

The University of Birmingham

R&D Technical Report: E2-043

PARTICIPATORY RISK ASSESSMENT -

INVOLVING LAY AUDIENCES IN ENVIRONMENTAL DECISIONS ON RISK

Literature Review and Stakeholder Interviews

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This work is a piece of preliminary research to inform Environment Agency views on the practical involvement of lay audiences in environmental risk assessment work. It does not necessarily commit the Environment Agency to the recommendations herein, though the findings will be of use in developing a dialogue between operators, developers and regulators on the application of environmental risk assessment within regulation.

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EXECUTIVE SUMMARY

Risk assessment is increasingly viewed in participatory terms, in response to the 'risk society'[1] debate, evidence from the risk communication literature, the environmental justice agenda, and a growing understanding of scientific values. There are official calls for increased stakeholder involvement from 'problem definition' or 'framing' through to the evaluation of risk estimates. Further, the transition to a 'right-to-know' society is requiring greater public access to these assessments that are used to inform environmental decisions.

This report is one element of a project, the primary objective of which, is to provide the Environment Agency and other risk assessment practitioners with piloted best practice on workable mechanisms for involving non-specialists in appropriate aspects of risk assessment work. To this end, this preliminary report includes a review of the literature and practical experience of participatory risk assessment, potential criteria for evaluating effective participatory processes and it presents the results of a 'needs analysis' of key Agency staff and specialist and non-specialist stakeholders in terms of participatory risk assessment. The review complements a previous review for the Environment Agency (project E2-030[2]) and, therefore, does not seek to duplicate the more general discussion of the driving forces behind increased public participation in environmental decision-making.

There is evident difficulty in defining risk decisions, and in practice, caution is needed in viewing public participation as being limited to the risk assessment contribution to a decision, in isolation. It is rare that risk issues can be separated from the broader environmental, social and economic elements of decisions. Furthermore, as examination of the decision contexts in which the Agency is involved reveals, it is rare that the Agency is the sole decision-maker or is itself using risk assessment as the only decision tool (Section 2).

Generally at present, the Agency neither routinely nor directly involves people in deliberative processes related to decisions that involve formal risk assessments, although it has engaged people widely in standard consultation and information provision exercises. For the Agency, there are a number of key issues that the 'analytic-deliberative'[3] process raises relating both to the science and procedures of risk assessment and to the institutional and regulatory culture in which assessments are applied. For example:

(i) Is the Agency clear what its objectives are in opening assessments to participation?
(ii) Are the decision processes involved open to public engagement at the early problem-formulation and scoping stage?
(iii) Do regulatory requirements promote public participation, particularly where the assessment is applicant driven?, and if not is there scope for the Agency to encourage or support applicant-driven participatory assessment?
(iv) Is the Agency willing to engage people in technical discussion where its science, and approach to risk assessment may be challenged?
(v) Do its staff have the ability to explain and discuss complex risk issues and data in lay public fora?

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[1] Beck, U. (1992) *Risk Society. Towards a New Modernity.* Sage, London
[2] Petts, J and Leach, B. (2000) Evaluating Methods for Public Participation: Literature Review. R & D Technical Report: E2-030, Environment Agency , Bristol
[3] Stern, P.C. & Fineberg, H.V. (eds) (1996) Understanding Risk: Informing Decisions in a Democractic Society. Washington DC: National Academy Press

(vi) If a deliberative process leads to a significant challenge to existing risk acceptability criteria is the Agency prepared to consider the need to change these criteria?
(vii) Is it able to integrate any participatory processes with activities by other decision-makers?
(viii) To what extent will the Agency's assessment be viewed as independent? And if not how can independent review be applied?
(ix) Is the Agency willing to be open about limits to current knowledge and able to demonstrate continued attention to the science, data and models that underpin the assessments?
(x) Is the Agency able to support cumulative and comparative risk assessments even where there may be no regulatory requirement?

Considering the United States' (US) definition of the analytic-deliberative process in risk management terms, and the Royal Commission on Environmental Pollution's environmental policy decision process, participatory risk assessment needs to be considered in terms of four stages:

(i) the initial framing or definition of the issue or problem;
(ii) the identification of data and information needs and how uncertainty will be managed;
(iii) oversight of the assessment itself, and
(iv) the evaluation of the risk estimates.

The research challenge this project addresses is to establish at which of these stages, and in what ways participation can be meaningfully incorporated. The challenge is to develop *informed* and practical processes that enable decisions involving science to be debated widely in a social context.

At present the public tend to become involved in the later stages of decision processes, i.e. at the point of evaluating risk assessment output before the final decision is taken. Even then, it may not be possible for the public to influence the decision that is made. This review indicates that involvement of the public needs to be much earlier in the decision-making process.

Mechanisms for stakeholder involvement in risk decisions, while understood, have to-date not been adopted widely and still require evaluation in practice. Even at the international level, experience is limited, although there are increasing attempts to apply participative processes to policy, plan and project-level decisions. Participatory processes have been demonstrated to be effective in reaching decisions, as discussed in Section 6, although it would be naive to assume that a more inclusive and deliberative process automatically results in lack of contention. Indeed, as raised in our interviews with stakeholders, involving the public may result in more diverse opinions as opposed to consensus.

This report reviews the Agency's different decision responsibilities and develops criteria for effective participatory decision processes where risk is an important issue within the decision (Section 7). These reflect broader criteria for effective public participation incorporating key principles of, clarity of objectives; representativeness; inclusivity; openness; deliberation; social learning and decision responsiveness. The criteria were tested in the interviews with stakeholders (Section 9), and the majority agreed that they were very important.

A key aspect of the decision-making process is to ascertain the role that stakeholders can realistically have. If there is genuinely a limited potential to influence a decision, then

participation can create false hopes. In some cases, it is clear that consultation, as opposed to participation, is required. It is important to establish the risk decisions that can be made using more deliberative techniques. This will form the basis of the next part of the project. Amongst Environment Agency staff interviewed, awareness of methods of participation is generally quite low (Section 8). Some stakeholders also suggested that they had met with Agency reluctance to engage with, and assimilate, ideas from third parties and the approach and attitude taken towards participation was not perceived to be consistent.

What is clear is the need for the Environment Agency to develop more deliberative techniques for involving the public in the decision-making process. This would benefit the Agency in terms of quality of decisions reached and the trust it would gain with the public, it would also have the potential to increase scientific literacy amongst the public and enable them to have greater ownership of decisions made. Quite clearly and importantly, such a need can not be applied universally and would need to be fully costed and implemented according to business need and resource availability.

The literature review establishes the following requirements for participatory risk assessment:

(i) the integration of information provision, consultation and participation methods for all risk-based decision purposes if the key criteria of representativeness, inclusivity, potential decision responsiveness and enhancement of trust, are to be achieved;
(ii) use of methods that optimise opportunities for deliberation and multi-criteria assessment must be included;
(iii) a staged process that optimises stakeholder and public participation at key stages within the assessment process – i.e. problem definition and framing; assessment; evaluation;
(iv) adaptation of methods and process to meet the different decision contexts and timescales over which regulatory assessments have to be conducted;
(v) achievement of a careful balance between consultation overload where multiple participation activities might be organised, - for example, by the Agency, the local authority and a developer/applicant, - and
(vi) meaningful participation in the public's mind which will require evaluation of participation activities.

1 INTRODUCTION

1.1 Need for study

This study comes at a time when there is increasing research, discussion and practice in relation to public participation in environmental decision-making. Recent focus tends to view participation as being inextricably linked with, and fundamental to, democracy. As such there are increasing amounts of legislation and guidance that encourage, and may require, participation to be a significant part of environmental decision-making. Such participation can operate over a range of scales and achieve different levels of detail: the key is to find the method, or combination of methods, that is most effective for the particular objectives.

This study explores these developments as relevant to decisions where environmental risk assessment is important. Discussion of the need for participatory risk assessment follows not only the democracy argument, but also the need for the science that underpins decisions to be exposed to questioning. Participation methods have generic application. However, the importance of fitting method to purpose requires that different contexts and issues relative to the objectives be addressed. In relation to risk assessment these issues include:

- the complexity of risk issues *per se;*
- the inherent uncertainty that dominates any risk assessment;
- the quantitative nature of many risk assessments and the difficulty of dealing with low or small probability events or outcomes which may have large consequences;
- the possibility of controversy in relation to decisions involving risk issues and thus the careful attention needed to both the process and the identification of participants;
- the traditional role and culture of experts in risk decisions and the difficulty of reconciling this with the role of lay knowledge and the potential for the public to act as quality assurers in the risk decision process;
- the tendency for people to need reassurance when confronted with risk, even during a participation process;
- the need to recognise the public's ability to deal with complex technical issues and the need for provision of information and data to respond to their questions, and
- the fact that 'risk' *per se* will not be the only issue of public concern.

Whilst some of these issues relate also to other environmental assessments requiring public participation, combined they raise particular considerations for participatory risk assessment. In the light of the increasing pressures for participation (Pollard *et al.*, 2002), this study addresses the pertinent issues for a participatory project generally and specifically one where the assessment of environmental risk is important.

1.2 Purpose and limits of the review

Recent years have seen a burgeoning literature on risk; the assessment and management of risk, and life in the 'risk society'. This literature has pervaded a number of subject areas in science, engineering and social science disciplines. It is an issue that has attracted increasing attention from public bodies and Government Departments keen to explore the implications and understandings of risk amongst the public. Paralleled to this has been the rise in concern about the need for consultation and interaction with the public. This review does not attempt to evaluate risk issues or participatory processes in their broadest sense. Other reports and

reviews discuss and critically evaluate participatory methods *per se* (e.g. Petts *et al.,* 1996; Downs, 1997; Kemp *et al.,* 1997; Petts and Leach, 2000).

Participatory risk assessment is in its infancy and so this is a preliminary review. There are few available studies in the open literature that consider the process-specific issues. There are examples of case studies that have been termed a 'participatory risk assessment' (Section 6) when in fact they include a technology assessment or impact assessment. It is important to define what is a 'risk assessment' and what might make a participatory process that includes a risk assessment different from others where other assessment tools are relevant. Certainly, useful evidence can be drawn from participatory processes that have dealt with broader scientific and technical issues than just risk.

Therefore, this review draws upon two literatures: firstly, in relation to participation, and, secondly on risk assessment. It considers how they can be meaningfully combined to produce criteria for effective participatory risk assessment. The review also reports the findings of interview surveys of Agency staff and of stakeholders exploring the need for, and potential form of, public participation in Agency risk-related decision-making.

Risk relates to a wide range of situations and a wide variety of decision contexts. As such this review attempts to provide generic 'guidance' as to how participatory risk assessment might proceed in different decision contexts but does not attempt to provide decision-specific guidance. This will only be possible following the second stage of the project that this report informs. The second stage of the project, reported upon separately under Environment Agency project E2-043, will test participatory techniques in specific decision contexts that are informed, in part, by the output of a risk assessment.

1.3 Structure of the review

The next section considers the definition of risk assessment, its role in the risk management process, and the different management contexts in which the Agency undertakes risk assessments. Section 3 briefly refers to the pressures for public participation and revisits key definitions in this context. Section 4 discusses the pressures for, and definition of, participatory risk assessment and the implications for Agency practice.

Section 5 examines the problems and challenges for participatory risk assessment, not least dealing with uncertainty. Section 6 discusses experience, drawing upon the risk literature but also other participatory approaches to complex decisions. Section 7 defines criteria of effective participatory risk assessment drawing on the generic criteria of effective process presented in other work (Petts and Leach, 2000). Sections 8 and 9 summarise the interview surveys. Section 10 presents conclusions on how to optimise participatory risk assessment.

2 RISK ASSESSMENT

2.1 Definitions and process

The word *risk* has a number of meanings. In everyday usage it is often synonymous with 'danger'. In economic appraisal it is the 'possibility of more than one outcome occurring' (The Treasury, 1997), where the other outcomes considered may be more rather than less desirable than the base case. In environmental protection the concept of risk derives from engineering and emphasises both an undesirable outcome and the attachment of some sort of probability to that outcome. The definition of risk in engineering is 'a combination of the probability or frequency of occurrence of a defined hazard and the magnitude of the consequences of the occurrence' (Royal Society, 1992). *Hazard* is defined as a 'property or situation that in particular circumstances could lead to harm'. It is possible to have a hazard but no risk, particularly where there is either no 'pathway' by which the hazard may be transferred or no targets or receptors which could be harmed (Environment Agency, 2000c).

In the public domain, we know that risk has broader connotations than those presented by these definitions. The concept of risk has been identified as meaning more to individuals than measurable fatalities or injuries. Risk is socially constructed. A broad range of qualitative characteristics contribute, related not only to the source and nature of potential harm (delayed effects, effects on children, catastrophe potential etc), but also to the potential for control, the extent to which institutions can be trusted to manage the risk and concern over equity in risk bearing (Fischhoff *et al.*, 1981; Slovic, 1987, 2000). We return to the importance of these differing definitions in Section 5.

The systematic analysis of risk has long been part of human activity, and has been formalised in the chemical and nuclear industries and in relation to occupational chemical risks since the 1930s. In the UK, risk assessment in environmental protection has had a shorter period of application than in the US, being formalised in official Government guidance since the mid-1990s (DOE, 1995; DETR *et al.,* 2000). In 1994, the UK Sustainable Development Strategy stated that as far as is possible decisions should be based on the best possible scientific information and analysis of risks (Pollard *et al.*, 2002).

Risk assessment has been defined in a number of ways in Agency literature, but largely following the engineering concept of risk. For example, it has been described as a means by which it is possible to determine 'how significant the probability of harm is and, usually, the options available to manage the harm' (Environment Agency, 2000c). Similarly, the HSE define a risk assessment 'as a tool for extrapolating, from available data, our experience of harm or for compressing a large amount of scientific information and judgement into an estimate of the risks' (ILGRA, 1998b, p. 27). These definitions reflect practical experience of the difficulties of risk assessment in a range of decision-making contexts, as well as acknowledgement of the decision purpose of risk assessment (POST, 1996).

In the technical and engineering literature risk assessment is normally defined as typically comprising four stages:

(i) Hazard identification – i.e. defining the source and nature of the possible problem
(ii) Hazard analysis or assessment – i.e. assessing the nature of the consequences of a hazard being realised

(iii) Risk estimation – i.e. estimating the extent of the actual harm to humans and/or the environment and the probability of this level of harm occurring
(iv) Risk evaluation – i.e. evaluating the acceptability of the assessed level of harm

Risk management has been defined as:

> The process whereby decisions are made to accept a known or assessed risk and/or the implementation of actions to reduce the consequences or probability of occurrence (Royal Society, 1992)

At this point it is relevant to note that the definition of risk assessment in the US is different although the principles of the process are the same as in the UK. The US, in focusing since the 1970s on health risk assessment, has defined the process as:

(i) Hazard identification or indicator chemical selection
(ii) Exposure assessment – determination of magnitude of human exposure
(iii) Toxicity assessment – i.e. the estimation of intakes and evaluation of toxicity
(iv) Risk characterisation – i.e. risk evaluation

In recent years variable definitions of the risk assessment process have appeared to meet different decision contexts. Thus, for example the guidance on contaminated land (DETR, 2001) has defined risk assessment differently to that of the engineering literature. The DETR and Environment Agency's guidance on risk assessment and management for environmental policy decisions (DETR *et al.*, 2000) presents an updated definition of the process (Figure 2.1), replicated in the Agency's guidance on risk assessment related to waste management licensing (Environment Agency, 2000a). The overarching DETR/Environment Agency guidance is acting as a means for converging approaches to environmental risk assessment across Government (Pollard *et al.*, 2002).

Figure 2.1 identifies risk management as being comprised of four distinct stages: problem formulation; tiered risk assessment; options appraisal and risk management. The Figure is based in the regulatory context of risk assessment, which requires certain decision stages.

Figure 2.2 taken from the Royal Commission on Environmental Pollution's 21st Report on *Environmental Standard Setting* (RCEP, 1998) situates risk assessment in a broader policy-making process emphasising the need for 'the articulation of people's values' throughout the process. It also serves to remind us that risk assessment is rarely the only form of assessment that is being undertaken in any decision. It is usually only one tool that is being used to inform the decision. This has important implications for the participation process.

Figure 2.1 Risk Management Process (DETR *et al.*, 2000)

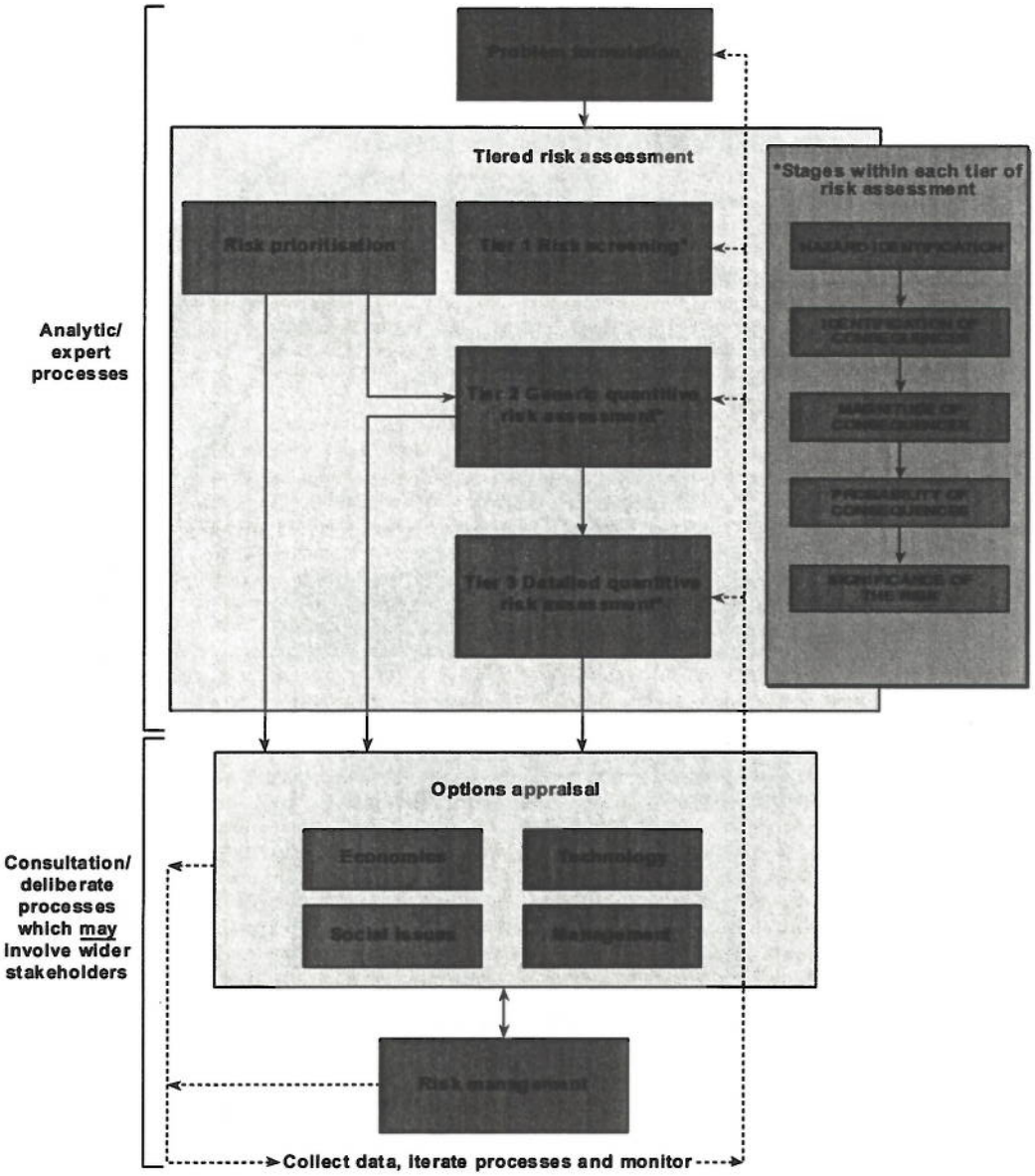
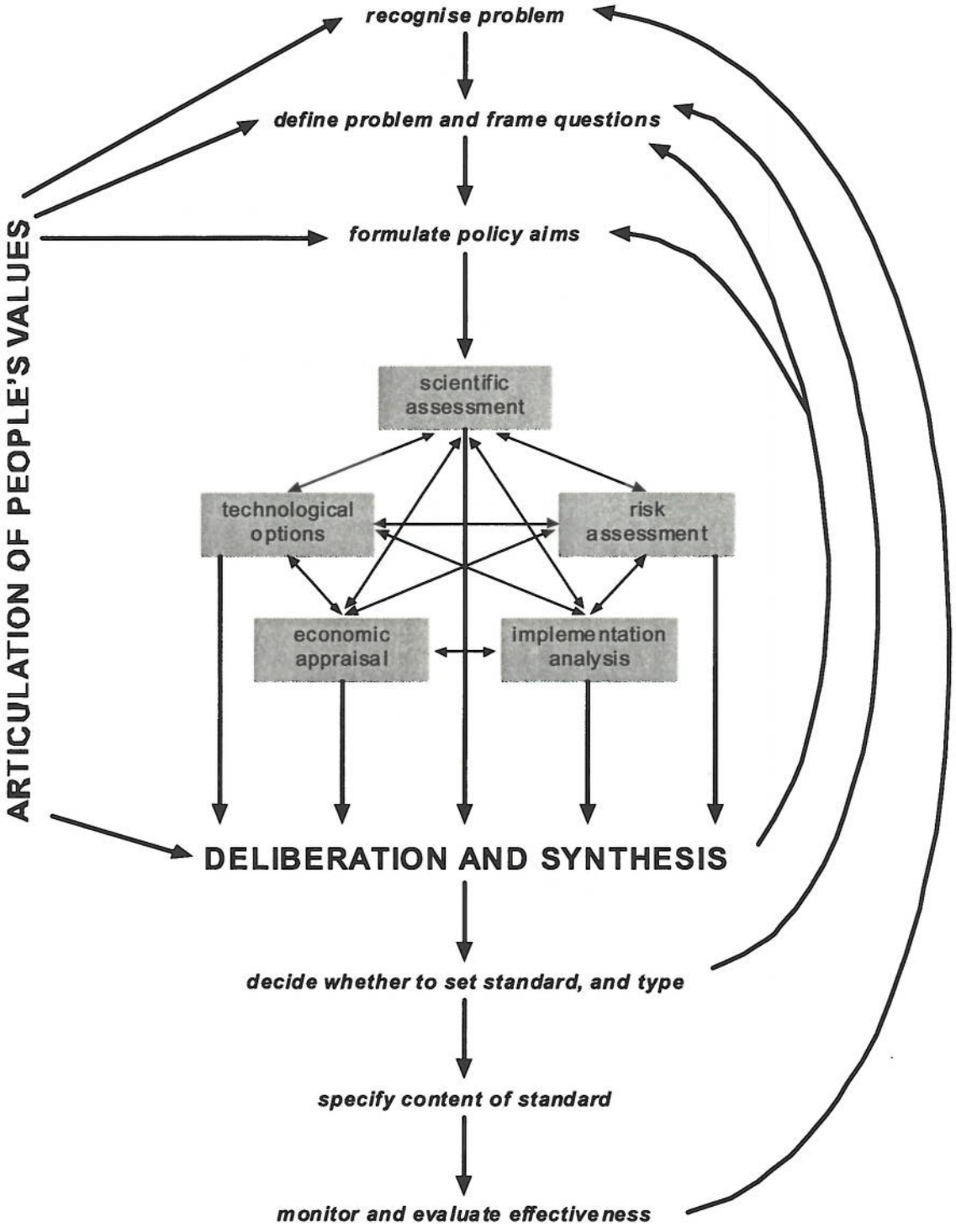


Figure 2.2 Environmental Policy Process (from RCEP, 1998)



The above discussion illustrates the tensions that have long existed between the interpretation of risk assessment as a technocratic process which feeds results into a risk management decision, and a view that risk assessment is part of the risk management process, itself subject to social, political and economic influences that affect the management decision (Gerrard and Petts, 1998). Regarding risk assessment as a component of risk management acknowledges that the objectives of the latter influence the former.

It is important to note that the DETR's revised guidance (if not explicitly the Figure – 2.1) gives considerable prominence to the need for engagement of the public in risk decisions and for participation in risk assessment, something which the first edition (DOE, 1995) had not done. This theme, echoing that of the Royal Commission, is returned to in Section 4. In the context of this review, the two Figures serve to raise an important issue: i.e that participation cannot be limited to the 'technical' risk assessment, defined as including the four-step process of hazard identification through to risk evaluation. Equally, if not more so, participation is important in the problem formulation stage that precedes these.

Risk assessment is often thought of as either being primarily quantitative (i.e involving the production of a quantified estimate of risk) or primarily qualitative. The latter is often used to refer to assessments which are prioritising options: such as in the identification of contaminated sites which may warrant further attention based on the qualitative ranking of the hazards of a large number of sites. It is true that both assessments produce a judgement about risk which will be relevant to the decision context and which warrant public participation. It is not necessarily true that quantitative risk assessments present greater problems in terms of public participation than qualitative assessments.

Despite the variable definitions of risk assessment there is common agreement as to its benefits, e.g.:

- Providing a structured approach to the understanding of risk.
- Establishing a rational basis for risk management.
- Promoting direct recognition of the uncertainty inherent in any decision.
- Providing for a transparent record of the basis of decisions made.
- Allowing site-specific or context-specific decisions to be made which reflect local circumstances and priorities.

2.2 Agency risk assessment

There is a wide range of risk issues that the Environment Agency is required to deal with. These have been outlined in a recent Environment Agency risk portfolio (Environment Agency, 2000b; Pollard, 2001; Pollard *et al.,* 2002; Table 2.1.

The Environment Agency recognises that, in general, it deals with two types of assessment:

(i) **regulatory risk assessment**, where the Agency *per se* undertakes the risk assessment;
(ii) **applicant risk assessment**, where the Agency is involved in critically reviewing risk assessments that operators, dischargers, developers or abstractors are required to undertake to support applications to discharge, operate or develop facilities (Environment Agency, 2000b)..

Table 2.1 Environment Agency and Risk Assessment

Directorate Agency function	**Context/ application**	**Approach/ decision support tool**
Environmental protection		
Process industry regulation	Authorization of permits with reference to local and transboundary issues; safety cases for COMAH sites with reference to EC Seveso II Directive; IPPC; inspection frequencies; notification of new and existing substances.	Quantitative distribution modelling of predicted environmental concentrations in air at ground level; fault- and event-trees for safety cases, risk ranking schemes for pollution hazard and operator performance (OPRA) and for Operator Monitoring Assessment (OMA; under development); generic, quantitative exposure models for the notification of new substances (NONS). Quantitative risk assessment within performance assessment of disposal sites.
Radioactive substances regulation	Safety cases for radioactive waste disposal; radioactively contaminated land (not yet implemented)	Quantitative deterministic and/or probabilistic risk assessment within performance assessment of disposal sites.
Land quality	Designation of statutory contaminated land	Qualitative risk assessment and quantitative exposure assessment with reference to soil assessment criteria. Local authority responsibility as lead regulator. Agency may check, offer guidance, etc.
Water quality	Groundwater protection with reference to EC Groundwater Directive; discharge consent setting; prioritisation of pollution prevention visits; prioritisation of anti-pollution works	Qualitative and quantitative risk assessment with reference to groundwater protection policy; vulnerability maps and water quality criteria; quantitative distribution modelling of predicted environmental concentrations in surface waters; ranking tools for pollution prevention visits
Waste management and regulation	Protection of groundwater with reference to EC Groundwater Directive; licensing of installations; inspection frequencies	Qualitative and quantitative risk assessment of waste management installations; quantitative assessment of leachate leakage; risk-ranking schemes for pollution hazard and operator performance.
Water Management		
Flood defence	Project risk appraisal for strategic plans and individual flood defence schemes; inspection of flood defence assets	Hazard identification brainstorming techniques for project lifecycle risks; probabilistic modelling; fault- and event-trees for engineering risk; ranking schemes for asset management.

Table 2.1 – cont'd

Water resources	Assessments of critical flow levels for the granting of water abstraction licenses; licence conditions may provide for river support to be provided by abstractor.	Low flow hydroecological modelling, objective setting; tiered approach varying from look-up tables to detailed biological response modelling for river assessment; environmental forecasting of climate change impacts.
Conservation	Impact of regulated activities on designated habitats with reference to EC Habitats Directive	Sensitivity mapping and 'environmental footprints' of regulated sites. Risk assessment by virtue of Habitats Directive and review of authorisations / permits in proximity to SSSIs.
Fisheries	Health and safety risk management of activities undertaken by staff	Qualitative assessments and checklists. Risk assessments associated with introduction of non-native species and fish disease.
Navigation	Pilotage of craft within ports and harbour areas operated by Agency	Comprehensive hazard identification and semi-quantitative risk-ranking on basis of expert knowledge
Environmental Policy		
Environmental Strategy	Strategic analysis of future issues and directions for Agency work	Analysis of uncertainty using scenarios (under development). State of the environment reporting and prioritisation of diverse risk issues across environmental media.
Environmental monitoring and assessment	Risk-based compliance and surveillance monitoring (ongoing)	under development
Research and Development	Prioritisation of R&D implementation	Qualitative/ semi-qualitative risk ranking based on delivery and business need
Operations		
Areas and regions	Prioritisation of regional and local Agency plans; Y2K risks to Agency and externally; as support to environmental impact assessments for which the Agency is a statutory consultee; flood risk mapping and development control	Range of tools: most risk ranking approaches. Under development – risk-based approaches to development (planning) control.
Finance		
Corporate planning/ internal audit	Identification of business risks over three year horizon	Business risk management - qualitative 'boston box' approach of importance and ability to influence
Personnel		
Health and safety	Health and safety risk assessment at work	Qualitative assessments and checklists

The majority of Agency involvement in risk assessment is in the latter category; the regulatory and technical review of the risk assessments of others.

Agency risk assessments may apply at specific stages of the development, operation and decommissioning of specific facilities, or may be parallel to other decision processes. This can be illustrated by reference to the development of waste management installations. Risk assessment could be applied at the following stages (Environment Agency, 2000a):

- Strategic planning, pre planning and planning stages as part of the environmental impact assessment - Agency only a consultee
- Licensing – Agency regulatory assessment (Regulation 15 in particular) and also applicant assessment
- Site supervision and regulation – through use of the Operator Pollution Risk Appraisal (OPRA) techniques
- Prior to modification or amendment of a licence – regulatory assessment and also applicant assessment
- Prior to site completion and closure – applicant assessment (Pollard and Guy, 2001)

The assessments produced within this example 'decision chain' should be linked if risk management is to be effective. Arguably, risk assessment at the strategic planning stage is the most important in preventing unsuitable development or in ensuring that appropriate mitigation and risk reduction is designed-in at an early project design stage. Yet at this stage, the Agency is not the primary decision-maker. The implications of the different roles of the Agency at different decision points, and also of the nature of the assessment being undertaken, for the design and conduct of participatory risk assessment processes are examined in Sections 5 and 8.

2.3 Risk management decision context

Table 2.1 and the waste management example above serve to illustrate the different contexts in which risk management decisions are made and the different nature of the assessments carried out. The National Research Council (NRC) in the US (Stern and Fineberg, 1996) identifies five categories of decision context:

(i) Unique and wide-impact decisions – i.e. that of national or wider importance where significant resources will need to be allocated to the process.
(ii) Routine and narrow impact decisions – i.e. those where little resources would be required – e.g. well-characterised wastewater discharges.
(iii) Repeated, wide-impact decisions – i.e. those decisions that may gain widespread attention because of their possible effects but are sufficiently similar in nature that the same process could be used each time – e.g. siting of hazardous facilities.
(iv) Generic hazard characterisations – i.e. assessments which serve as a class of input to a decision, such as the assessment of the health risks of dioxins. In these it may be difficult to identify interested and affected parties.
(v) Decisions about policies for risk assessment – i.e. methodological or procedural decisions, e.g. about which dose-response model should be used.

While arguably not entirely appropriate as a basis for characterising decisions, this categorisation does reinforce that risk management decisions vary significantly in their context, data requirements, the extent to which it might be necessary to undertake a

quantitative as opposed to qualitative assessment, the formal demands of the legislation, the likely degree of public interest, and, in the Agency's context, the extent to which it is the sole decision-maker or assessor.

Table 2.2 provides some examples of the Agency's risk assessment contexts and attempts to illustrate the decision context variability based on the NRC's categorisation which addresses the uniqueness of the process (Column 3) and the scale of potential impact of the decision/activity (Column 4). In addition, Column 2 refers to the frequency with which the assessment may need to be undertaken (and hence is an indicator of the frequency that participation activity may be required). The degree of stakeholder and lay public interest (Columns 5 & 6) in the issue/decision and the extent to which the lay public may be able to impact on the decision (Column 7) are important indicators of the expectations there may be of participation. The definitions of public and stakeholder are addressed further in Section 3.

Public is taken to mean the lay or general public. Stakeholder refers to organised or official interests. Column 8 classifies the different risk assessment decision contexts using the Agency's 'regulatory' and 'applicant' classification. Finally, Column 9 considers whether the Agency is the sole or primary decision-maker. This is important because the degree to which any participatory process will be able to be managed by the Agency, and will be able to limit its consideration to risk issues which are the responsibility of the Agency, will be affected by whether the Agency is the sole decision-maker. In fact this situation is relative rare, and therefore, any participatory process instigated by the Agency needs to be cognisant of, or even to be integrated with, other participatory activities instigated by other authorities/agencies; an issue examined in Environment Agency R & D Project E2-030 – *Evaluating Methods for Public Participation* – see Petts and Leach, 2000).

Development of participatory risk assessment processes will require a careful consideration of the requirements that different decision contexts create, not least the different objectives of participation, the different potential participants and exactly what they should participate in and when. The degree of stakeholder and/or lay public interest will be an indicator of the volatility that may be inherent in the decision process.

One aspect not included in Table 2.2 but which also needs to be considered is the extent to which the risk assessment *per se* is important within the decision. This may be dictated by the statute or by the general requirements of the regulator and is a primary constraint on the opportunity for stakeholder and/or public involvement. Thus, for example, in relation to historically contaminated sites, the risk assessment is part of the regulatory basis of the control of sites which may present a significant risk to the environment or humans, under the Contaminated Land (England) Regulations, 2000 (DETR, 2000). However, in relation to a PPC application the risk assessment may be just one element of the assessment and could be linked to a broader and more extensive environmental assessment under the land-use planning or environmental permitting processes.

Table 2.2 Decision Context Variability of Risk Assessment

1. Decision Context Example	2. Frequency of RA	3. Uniqueness of Process*	4. Scale of Impact	5. Degree of Stakeholder Interest in Decision	6. Degree of Lay Public Interest in Decision	7. Degree of Public Impact of Decision	8. Agency RA Purpose	9. Agency as Sole Decision-Maker
Development of water quality criteria	Rare	Common	Regional/ National	Med**	Low	Low	Regulatory	Joint
Design and approval of flood defence schemes	Common	Common	Local/ Regional	Med/High	Med/High	High	Regulatory	Primary/sole
Identification of statutory contaminated Land	Common	Common	Local	High	High	Med/High	Applicant	Sole
Assessment of PPC applications	Common	Common	Local	Med/High	Low – High	Med/High	Applicant	Joint
Assessment of sludge disposal to land	Rare	Common	Local/ Regional	Med/High	Low	Low/Med	Regulatory	Sole
Assessment of radioactive waste facilities	Rare	Common	Local-National	Med/High	Low – High	Low - High	Regulatory/ Applicant	Joint

* i.e. would the same process of risk assessment be applied across different but similar decisions, or is it a 'once off' process (this is different to how frequently the process would need to be applied). Thus, setting of national water quality criteria would be a rare event but the process used on the different occasions would be common

** the qualitative scaling of 'low', 'medium' and 'high' is used merely as a relative indicator. Particularly where a range is presented it is used to indicate that the degree of interest could vary on a case-by-case basis.

The Royal Commission's process diagram (Figure 2.2) provides some key decision elements in the assessment process – namely, recognition of the problem, definition of the problem and framing of the appropriate questions and formulation of policy aims (in this case environmental standard setting). The NRC in the US in its discussion of analytic-deliberative processes (see Section 4) identifies a number of "diagnostic" steps in decision-making which mirror these early steps in the Royal Commission's process, specifically:

(i) Diagnose the kind of risk and state of knowledge.
(ii) Describe the legal mandate.
(iii) Describe the purpose of the risk decision.
(iv) Describe the affected parties and likely public reactions.
(v) Estimate resource needs and timetable.
(vi) Plan for organisational needs.
(vii) Develop a preliminary process (decision) design.
(viii) Summarise and discuss diagnosis within organisation.

This starts to identify the decision process requirements of which public participation in the process might be one element. Importantly, it serves to emphasise the accepted fact that risk assessment does not sit as an isolated component of decision-making, but rather is integral to it.

The public/stakeholders may have as important a role to play in the early stages of problem definition and problem framing (as identified in Figure 2.2) as in the risk assessment or technical element of the process itself (DETR, 2000). Most importantly, stakeholders and lay public may have different roles to play in these different elements – e.g. both could be interested and relevant to the problem definition stage and the hazard identification stage of the risk assessment. Key stakeholders, however, may be more important in the assessment of the magnitude and probability of the consequences (i.e. the hazard assessment and risk estimation stages). Both the lay public and stakeholders could be relevant to the risk evaluation stage. This key consideration is returned to in Section 4.

2.4 Uncertainty

Risk assessment is characterised by uncertainty (although this is not unique to risk assessment). Two simple categories of uncertainty are normally defined – data uncertainty and decision uncertainty – although the two are closely linked.

Data uncertainty includes:

- Incomplete or irrelevant problem definition.
- Model errors.
- Parameter variability.
- Incomplete baseline or background information against which to compare the estimated risks.
- Problems in defining dose-response relationships, particularly where dose-response curves have not been reliably established.
- Incomplete understanding of synergistic and antagonistic chemical effects.
- Inaccurate collection of data – e.g. poor or inappropriate soil sampling during site investigations of contaminated sites.

Decision uncertainty includes:

- Data manipulation to meet different interests.
- Pressure to use worst-case scenarios to deal with data uncertainty.
- Optimism about ability of control systems.
- Optimism about reliability of expert systems to deal with complex problems.
- Biases in expert judgements and overconfidence.

Where uncertainty is recognisable and quantifiable, it can be represented statistically and therefore incorporated into risk estimates. Sensitivity analysis is a technique for identifying the parameter or variable within a model which is the most sensitive to change, enabling the contribution of specific parameters to the uncertainty in the risk output to be understood. Monte Carlo analysis is a simulation approach that can be used where there is large uncertainty in input data and when a model involves non-linear relationships. Probabilistic risk assessments are subject to such statistical manipulation. Inherent to many nuclear risk assessments, this approach has found relatively limited application to date in UK regulatory risk assessments. However, the DETR/Environment Agency's new CLEA (Contaminated Land Exposure Assessment) model for deriving soil assessment criteria, and the Agency's CONSIM (Contaminated Land Simulation) model for estimating risks to groundwater from contaminated sites are two examples of a new breed of regulatory models that use such statistical approaches for dealing with uncertainty. They differ from 'deterministic' models based upon the choice of worst-case scenarios.

Thus, objective or frequency-based probability measures are used to describe uncertainties associated with randomness, and subjective probability measures those associated with lack of knowledge. However, it is misleading to confuse the latter with probabilities estimated on the basis of the empirical data. This is because uncertainty in expert knowledge encompasses two important elements of ignorance and indeterminacy. Wynne (1992) in developing this argument has identified four types of uncertainty in expert knowledge:

(i) Risk – where we know the odds.
(ii) Uncertainty – where we do not know the odds though we may know the main parameters. Uncertainty may be reduced but commonly at the expense of increasing ignorance.
(iii) Ignorance – where we do not know what we do not know.
(iv) Indeterminacy – where we do not know how a system will function because its operation depends in part on (unchecked) social behaviour.

Dealing with ignorance and indeterminacy as well as most of the decision (as opposed to data) uncertainties necessitates approaches to clarify and understand different perceptions, values and concerns. This serves to focus attention on participation in the risk assessment process by non-experts, or rather, people who are not part of the expert risk assessment process (Green Alliance, 2000; ESRC, 2000).

Funtowitz and Ravetz (1991) attempted to develop a framework for discussing the grounds and prospects for lay participation in scientific analysis and modelling. They presented two dimensions to any decision – the degree of uncertainty and the scale of the decision stakes. When uncertainty and decision stakes are low they argued that applied science is relevant. When uncertainty and decision stakes are high they argued the normal quality assurance mechanisms of science are insufficient and participation becomes important – what they

termed the realm of 'post-normal science'. This typology has attracted criticism for its simplistic definition of uncertainty, in particular its failure to recognise ignorance and indeterminacy. Nevertheless their argument that post-normal science is important in dealing with uncertainty provides a strong basis for the argument in favour of participatory risk assessment (Sections 4 and 5).

2.5 Comparing risk assessment and environmental assessment

Risk assessment is often presented as distinctive because it has to deal explicitly with uncertainty in estimating adverse outcomes. However, other forms of assessment of environmental impacts (e.g. odour, noise, traffic generation, air quality, etc) are arguably equally subject to uncertainty, ignorance and indeterminacy though these assessments rarely attempt to deal explicitly with this uncertainty. What is distinctive about the handling of uncertainty in risk assessment is that:

(i) the decision stakes may be very high – e.g. controlling the potential for catastrophic impacts which could cause death or serious injury to many people;
(ii) the presentation of probabilistic output can be complex and for non-experts may involve concepts with which they are not familiar;
(iii) the credibility of risk assessment has already been called into question, and in the US for example, risk assessment has been seen to be tainted by its failure to deal effectively with uncertainty (Silbergeld, 1997);
(iv) for the expert, set against this background of credibility and also of data complexity (and sometimes confidentiality), there may be a culture which deters openness and honesty, and
(v) the science that underpins the uncertainty may be difficult to unpack.

3. PRESSURES FOR PARTICIPATION - GENERAL

3.1 Definitions

Having defined risk and discussed the context of environment risk assessment, we now consider some other key definitions before moving to review the pressure for participation. Five key terms require definition: the lay public; stakeholders; participation; deliberative processes, and consensus building.

There is no single group or interest that can be defined as '*the public*'. Rather, the term provides a convenient catch-all to describe those with an interest in a decision other than a proponent, operator or responsible authority. Those interests may be organised or disorganised, explicit or implicit, simply by the fact that an individual is a member of the public. The 'public' are often viewed and approached as an homogenous entity - an object or audience which in being so large encourages focusing upon definable or specialist interests. Minorities (social, ethnic etc) may inadvertently be ignored, or an assumption incorrectly made that their views will be adequately represented by others. A clear understanding of who "the public" are, and what their interests are is essential to a recognition of the benefits of participation and the design of specific activities (Petts, 1999). The term '*lay public*' is often used to draw a divide between members of the general public and those who have a defined interest in, and knowledge about an issue.

The term '*stakeholder*' has become popular in the UK and is frequently used to refer to those with a defined stake or interest in an issue, which may include government agencies, industry, non-governmental organisations (NGOs) and individuals. Often it has been used in relation to consultation with definable and organised stakeholder groups. Stakeholders must be considered in their broadest sense, remembering that even if people choose not to declare their 'stake', they still have a 'right-to-know' if their interests may be affected.

The concept of stakeholders has been defined by English (2000) in terms of the different perspectives that people may have. For example, *risk losers* may be those who stand to be adversely affected by an environmental risk decision in terms of their health, economic or social well-being, contrasting with *risk gainers* who may be favourably affected usually through economic gains. *Risk perpetrators* may be those who create the risk, and they may also be a if they stand to gain financially (such as a developer). Finally *risk managers* have responsibilities for preventing or minimising risks, typically regulators but also, of course, the risk perpetrators. These categories although significantly overlapping, remind us that stakeholders bring different perspectives, interests, and abilities to participate in any participatory process.

There are also degrees of *participation* in decision-making according to the amount of power that is transferred from the responsible authority to the public. At one extreme, the responsible authority can provide raw, unprocessed information to the public. At the other, the responsible authority can delegate power to a group of individuals to make decisions on its behalf. This review is not concerned with the latter, as this is not a situation relevant to environmental decision-making in the UK. Rather, we are concerned with approaches that fall between the two extremes, in which the public are asked to directly and actively take part, but the responsibility for the decision remains with a public body. Following the earlier review (Petts and Leach, 2000), and reflecting Arnstein's (1969) ladder of citizen participation (adapted by Wilcox,1994), these approaches can be categorised as:

1. Education and information provision.
2. Information feedback.
3. Involvement and consultation.
4. Extended involvement.

Related particularly to elements 3 and 4, two other terms are part of the current participation language: *consensus building* and *deliberative processes*.

Consensus building is defined by the Environment Council (1998) as "agreement by consent", with the end result of such agreements being commitment both to the agreement and to its purpose. Consensus does not imply full agreement. How the consensus is achieved is paramount - the concept of building consensus implies participative processes which allow for discussion, for disagreements to be aired, for questioning of facts and expertise. Consensus building implies a bottom-up approach where stakeholders are enlisted into the drawing-up of initial proposals as well as the consideration of the preferred proposals and solutions.

Deliberative processes are particularly favoured in current research council (e.g. Economic and Social Research Council) and also Office of Science and Technology (OST) activities (OST, 1999). Deliberative processes (such as community advisory groups and citizens' juries) engage relevant interests in debate, discussion and negotiation and are presented as needing to be integrated with assessment methods. The Environment Agency's use of multi-criteria decision analysis in the LEAP for the New Forest (Clark *et al.*, 1998) provides an example (Section 6). Deliberative processes imply a new relationship between decision-maker and stakeholders and go beyond traditional participation methods. The concept of the deliberative process is at the heart of the US National Research Council's commitment to participatory risk assessment (Section 4; Stern and Fineberg, 1996).

3.2 Official pressures

Consideration of participatory risk assessment is inherent in the pressures for extended participation by stakeholders and lay public in decision-making (Petts and Leach, 2000). Participation is considered to be 'a necessary condition for a cohesive society and a route to reducing social exclusion' (Barnes, 1999, p. 61). One of the principal foci of current discussion of participation is the concept of democracy, with reference to participation in a 'democratic society'. However, the notion of democracy is open to interpretation and the extent of participation that is implicated is subject to qualification. For example, Leach and Wingfield (1999) identify representative democracy and participatory democracy. The former indicates the notion that in governmental circles there is no need for participation as the elected representation is enough; the latter supports the notion of community politics and hearing the 'voice' of the citizen.

Petts and Leach (2000) have summarised the national and international pressures for enhanced public participation in decision-making. In the legislative context, most UK requirements have been limited to consultation to gain people's opinions on already drafted plans and proposals. The concept of representative democracy has underpinned these requirements. Legislative change could be precipitated by the Aarhus Convention (and draft EU Directive giving effect to the Convention – Anon 2002) which stresses the need for early public participation "when all of the options are open".

National advice of relevance includes:

- *The Environment Agency*. The Agency, in its *Environmental Strategy for the Millennium and Beyond*, has expressed the need to 'operate openly and consult widely' and to 'resolve conflicts' by 'building consensus'.
- *Local Authorities and Local Agenda 21*. The Local Government Management Board in its 1995 guidance on Local Agenda 21 recommends increasing levels of public consultation and developing partnerships with stakeholders. The 1998 White Paper *Modern Local Government: In Touch with the People* (DETR, 1998) indicates that one of the four pillars of democratic renewal is the creation of opportunity for citizen participation in government. Public consultation is one of the important features of the Best Value regime itself part of the modernisation agenda.
- *Central Government*. Service First seeks an improvement of formal consultation processes by Government departments and agencies, on the basis that this will lead to "more realistic and robust policy" (Cabinet Office, 2000). The *Modernising Government* 1999 White Paper stresses improvement in the way risk is managed and the need to follow good practice in policy-making in terms of assessment, management and communication of risks.

Of particular relevance are the reports of the Royal Commission on Environmental Pollution (1998) and the House of Lords Select Committee on Science and Technology (2000). Both stressed the need for direct methods to ensure that people's values, lay knowledge and understanding are articulated and taken into account alongside technical arguments. Participation is no longer presented as an optional add-on to policy making, but an integral and normal part of the process. Both reports present their conclusions in the context of a declining public trust in decision-making and decision-makers and a crisis of confidence. A research report commissioned by Government departments on the role of scientific advice in policy making recommends:

> "the full inclusion of stakeholders in....problem identification; defining policy issues and possible options; framing of scientific questions; selecting the advisory mechanism and adviser(s), and assessing the findings. It is vital that stakeholders are encouraged to participate in these stages of the process if the overall success of the process is to improve. In addition all stages should be transparent, to avoid stakeholders being excluded through lack of information" (OXERA, 2000)

This returns us to consideration of the risk management decision process discussed in Section 2 and to the issue of the need for participation in the key problem definition phases.

3.3 Methods and objectives

Participation can vary according to:

- whose participation is being sought;
- the type of knowledge to be accessed through the process of participation;
- the location within which participation is being sought;
- the objectives of participation;
- the degree of power-sharing implied through opening up opportunities for public participation; and
- the scope of participation and the level at which change may be achieved (Barnes, 1999).

Each of these dimensions influences the way in which the participatory process is conducted and is likely to influence the degree of public confidence and trust in the process. In particular, participation necessarily involves a shift in the balance of power from decision-maker to the public. This requires that decisions are open to influence and change as a result of participation. If a decision has already been taken, participation is likely, at best, to be viewed as a waste of time; at worst, to adversely affect the degree of trust in an organisation.

Different levels of participation require different methods of involvement. The conventional information provision tools include leaflets, newsletters, and the use of adverts placed in newspapers. Public meetings and staffed displays, as well potentially more novel techniques such as the Internet and teleconferencing, provide for consultation but rarely allow for discussion. It is the more innovative methods of involvement that provide for two-way discussion, not merely consultation on existing proposals, and for public input to the decision process. These methods include citizens' juries, 'Planning for Real', and consensus conferences (Petts and Leach, 2000). Extensive processes clearly have their place in participation, although to over-rely on them could reduce the validity of the information obtained. Importantly, most forms of participation demand the use of multiple methods to meet different objectives.

4. PARTICIPATORY RISK ASSESSMENT

4.1 Concept

Recent literature (e.g. Renn, 1992; Fischer, 1993; Irwin, 1995; Stern and Fineberg, 1996; Presidential/ Congressional Commission on Risk Assessment and Risk Management, 1997; Charnley, 2000; OXERA, 2000; Petts, 2001a) has reflected the general drive to public participation and identified that participation is an essential aspect of risk assessment. In particular it has been acknowledged that the process should be open, accountable, credible and inclusive (Parliamentary Office of Science and Technology, 1996, 2001).

Underlying the recent changes in approaches towards participation generally, and risk assessment specifically, is the need to view the process in a more holistic way. In particular, is the need for wide-ranging engagement of stakeholders in as much of the decision process as possible. Figure 4.1 illustrates this, taken from the report of the US Presidential/ Congressional Commission on Risk Assessment and Risk Management (1997).

Figure 4.1 The role of stakeholders in risk decisions

This need for a wide-ranging process is reinforced by Renn (1992: p. 494-5), who maintains that within the risk context, the need to "find a process that facilitates the involvement of all affected parties and at the same time produces a prudent and informed judgement based on expertise and knowledge" is one of the major challenges of a modern democratic society. The success of such a process depends on a number of different factors including time; openness of result; equal position of all parties; willingness to learn; resolution of allegedly irrational responses, and demoralisation of positions and parties (Renn, 1992).

As introduced in Section 2, risk has a number of characteristics that distinguish it from other decision-making and communicative processes. In particular, it has been suggested that it

operates over three distinct levels: a 'factual' level (the expert/ analytical processes); a 'clinical' mode (involving the practical arrangements and infrastructure established to deal with risk); and a 'world-view' perspective (the values and lifestyles associated with interpretation and perception of risk) (Funtowicz and Ravetz, 1985; Rayner and Cantor, 1987; Renn, 1992). Each of these is potentially imbued with complexity and it is the role of participatory risk assessment to try to harness the positive attributes within each, to combine and include them in an holistic way to produce a meaningful outcome.

There are increasing numbers of potential methods by which such participation could be achieved and facilitated. These approaches are generic in that they are not specific to risk assessment *per se*. However, they could be effective providing that context is taken into account in their implementation. It is always crucial in any participatory project to fit method to purpose. As such, the following way of proceeding with participatory risk assessment – i.e. by means of an analytic-deliberative process - is not so much a method as a context within which existing participatory processes might be used. However, if accepted as a relevant way forward, it assists in the identification of relevant participatory methods.

4.2 Analytic-deliberative processes

The concept of analytic-deliberative processes has gained increasing importance in the literature, being identified as one of the key ways to move forward with regard to participatory risk assessment (Stern and Fineberg, 1996; Petts, 1997; McDaniels *et al.*, 1999; Renn, 1999; Petts, 2001b). This means of proceeding with environmental decision-making suggests that the best way to achieve an inclusive process that is both transparent and more prone to trust is one that involves all parties from the outset: i.e. that both experts and lay people are involved in defining and reflecting upon the pertinent issues throughout the risk assessment. This means that both analysis (the specific and more specialized processes associated with risk assessment) and deliberation (a more interactive means by which ideas are deliberated upon by wider stakeholders) are not seen as mutually exclusive but instead inextricably linked and influential.

In this analytic-deliberative process, **analysis** refers to:

> 'ways of building understanding by systematically applying specific theories and methods that have been developed within communities of expertise' (Stern and Fineberg, 1996, p. 97).

Analysis has traditionally remained the preserve of the expert elite. It provides the theoretical and empirical evidence for the risk assessment and therefore is an important input into the risk evaluation. Indeed, not only does it help in defining the risk *per se* but it can also help in providing the options by which this risk can be managed and reduced. According to Stern and Fineberg (1996) there are a number of criteria that the analytic process should meet:

- It should be relevant.
- The questions addressed must be appropriate for the available analytical techniques.
- It should detail the limits of current knowledge.
- It should respond to the needs of the interested and affected parties.
- It should address issues that need to be resolved for the decision.
- It should be independently reviewed as to its assumptions, calculations, logic results and interpretation.

Within the process, analysis should be applied with an awareness of the context (the 'bigger picture'). This is illustrated in Figure 4.2, which indicates the ways in which stakeholders (defined by Stern and Fineberg to include members of the public) and wider issues of concern, such as economics and legislation, could guide the technical aspects of the risk decision process. The 'stakeholders' are involved in identifying potential issues of interest and the consequent use of this information in terms of compiling the questions that need to be answered through the analysis. The risk assessment is then performed and the results interpreted and communicated, although the Figure does not identify who is involved in this process. Furthermore, the means by which stakeholders could be involved are not addressed and might be fairly limited due to the complexity of the process

Charnley (2000) indicates that the following process has worked well in terms of involving people in a democratised science:

- A group of scientific experts are agreed by stakeholders.
- Collaborative analysis allows a reciprocal relationship to develop between stakeholders and scientists so that the latter can understand the formers' concerns and the former can participate in generating data.
- After scientific information is obtained it is combined with other discussion and considerations to enhance the decision.

This means of proceeding allows for a considerable degree of transparency and power-sharing, potentially building trust amongst the various parties involved and hence leading to a more detailed decision-making process. The analytical process described in Figure 4.2 inherently implies discussion and deliberation.

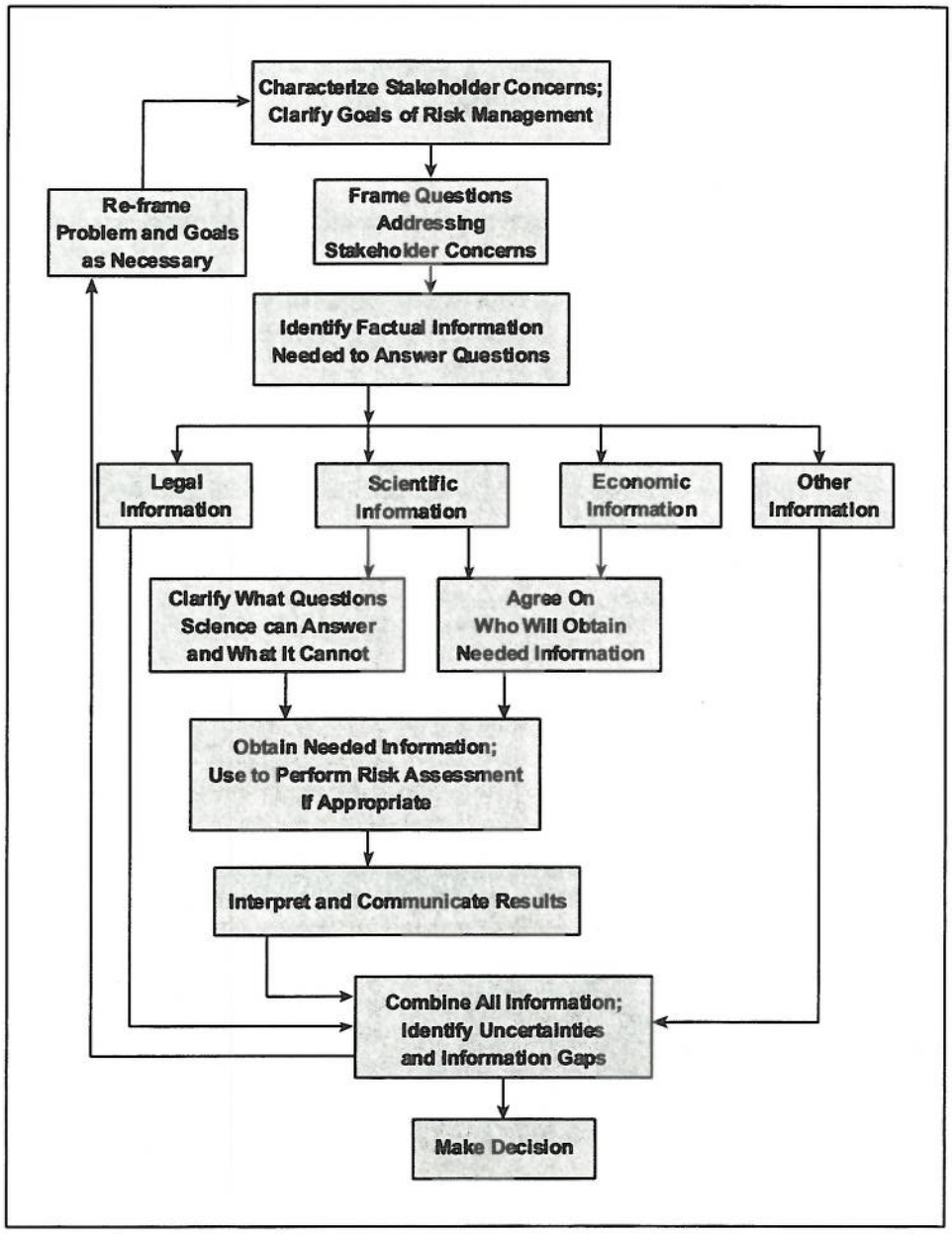
Deliberation implies an iterative process that moves steadily towards a decision/consensus. 'It considers each aspect of an issue and it may revisit earlier discussion on the basis of new knowledge or insights' (Stern and Fineberg, 1996, p. 73).

Broad-based deliberation has the following main purposes (Stern and Fineberg, 1996):

- Improving problem formulation.
- Providing more knowledge.
- Determining appropriate uses for controversial analytic techniques.
- Clarifying views.
- Making decisions more acceptable.
- Promoting dialogue and exchange of information.

Deliberation is the means by which the various stakeholders are brought into the project. Whereas 'analysis uses replicable techniques developed by experts', deliberation uses 'discussion, reflection and persuasion to communicate, raise and collectively consider issues, increase understanding and arrive at substantive decisions' (Stern and Fineberg, 1996). It allows for people to discuss and reflect upon the various issues that are raised by the analysis as well influencing what further analysis is undertaken. In terms of the analytic-deliberative processes therefore, the separation between 'expert' processes and 'lay' discussions becomes an arbitrary one. Risk evaluation is achieved in a 'reflexive' way: 'at its best deliberation becomes an interactive learning process for those involved' (Stern & Fineberg, 1996, p. 74).

Figure 4.2: Framework for democratic science (after Charnley, 2000)



Involving the public can be fundamental to the successful identification of the relevant risks as well as to their effective assessment. This has been demonstrated on a number of occasions where scientists have either produced a delayed or inaccurate risk assessment because of the neglect of local knowledge (e.g. Wynne, 1996; Yearley, 2000). Had local people in these instances had a structured opportunity for input into the processes from the outset then the risk assessment could potentially have been completed sooner (Irwin, 1995). The key seems to be 'involve the public early and often'. In this regard, a number of standards and goals have been identified in terms of deliberation (Stern and Fineberg, 1996):

- Involve the interested and affected parties.
- Define the stakeholders. In particular try to ascertain those people who might not be aware that they are an 'interested and affected' party.
- Identify whether direct participation is needed. It is not always the case that a participatory approach is required although if local knowledge is an element in the decision-making process then poor limited participation will be detrimental.
- Time participation; it should be early in the decision process.
- Listen to the participants.
- Explicitly recognize external constraints, such as legal issues relating to the consulting organizations and, sometimes, the stakeholders.
- Strive for fairness, particularly acknowledging the differential power balances that can exist between the various stakeholders.
- Fit method to purpose.

Figure 4.3 Reciprocal analytic-deliberative processes (Stern and Fineberg, 1996)

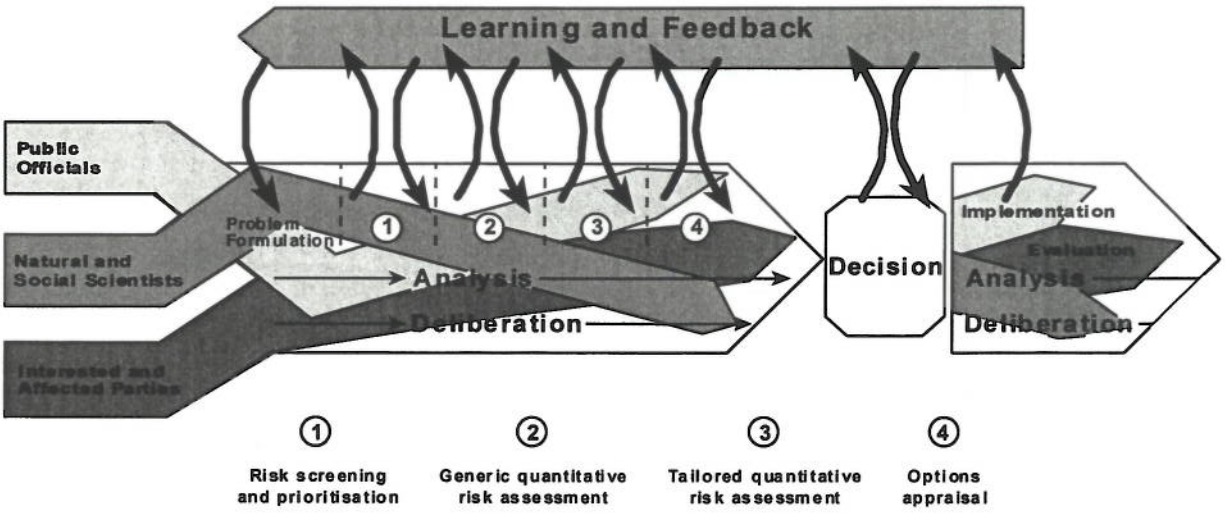


Figure 4.3 shows the processes that are occurring. It illustrates a continual feedback occurring between a number of parties and processes that culminate in the risk decision. However, it is important to note that the analysis and deliberation do not end with the decision. Instead it continues into the implementation and evaluation of the decision. Thus, effective analytic-deliberative processes (Stern and Fineberg, 1996) require:

- Getting the science right.
- Getting the right science.
- Getting the right participation.
- Getting the participation right.
- Developing an accurate, balanced and informative synthesis on the basis of both science and participation.

4.3 Objectives

In the earlier report on public participation (Petts and Leach, 2000) the importance of defining objectives and fitting 'method to purpose' was stressed. Common objectives of public participation (Petts and Leach, 2000) are:

- To satisfy regulatory requirements.
- To resolve conflicting views.
- To increase transparency.
- To increase defensibility (of professional judgements and decisions).
- To change people's views.
- To improve services.
- To determine needs and desires.
- To empower citizens to take action.
- To enable social learning.
- To optimise trust and credibility.
- To elicit values relevant to the decision.

Any or all of these are relevant to participatory risk assessment. However, it is apparent that objectives limited to satisfying regulatory requirements, in isolation, are unlikely to accord with the public's objectives. They are also unlikely to provide for the most effective participatory methods in terms of optimising deliberation and discussion and opening science to public understanding and debate. The additional objectives relevant to participatory risk assessment could include any of the following (Renn, 1992; Funtowicz and Ravetz, 1994; Petts, 1997, 2000):

- To ensure problem scoping is comprehensive and in-line with public and stakeholder concerns.
- To assist in identification of appropriate standards and criteria by which risks will be evaluated – i.e. agreement on what is an acceptable risk.
- To ensure that hazards of concern to the public are scoped into the assessment.
- To provide for public challenge of assumptions and scenarios considered relevant to the hazard assessment and risk estimation.
- To ensure that 'local' information and understanding of environmental conditions, exposure patterns, etc is included.
- To ensure development of stakeholder and public understanding and technical capability.

- To ensure that uncertainty within the assessment is discussed and understood.
- To ensure that alternatives and also risk reduction options are discussed and the interests and concerns of the public incorporated.
- To ensure the public can act as a quality assurance mechanism in the risk assessment process.

The process needs to be continuously evaluated to ensure that progress is being made, that communication is transparent and effective and, practically, that sufficient resource is made available (Yosie and Herbst, 1998). The earlier review (Petts and Leach 2000) defined a set of evaluation criteria that may be relevant to the Agency's participation activities in relation to licensing. These criteria are developed further in Section 7. Thus, evaluation criteria have to be based on the Environment Agency's objectives and those of the participants in any process. People are unlikely to participate if they feel that their needs and objectives are not recognised and the terms of reference for their engagement are unsatisfactory.

4.4 Implications for current Agency practice

Currently, the Agency has not routinely involved people in deliberative processes related to decisions that involve formal risk assessments, although it has engaged people widely in standard consultation and information provision exercises. For the Agency, there are a number of key issues that the analytic-deliberative process raises, relating to the science and procedures of risk assessment and to the institutional and regulatory culture in which assessments are applied. For example:

(i) Is the Agency clear what its objectives are in opening assessments to participation?
(ii) Are the decision processes involved open to public engagement at the early problem-formulation and scoping stage?
(iii) Do regulatory requirements promote public participation, particularly where the assessment is applicant driven?, and if not, is there scope for the Agency to encourage or support applicant-driven participatory assessment?
(iv) Is the Agency willing to engage people in technical discussion where its science, and approach to risk assessment may be challenged?
(v) Do its staff have the ability to explain and discuss complex risk issues and data in lay public fora?
(vi) If a deliberative process leads to a significant challenge to existing risk acceptability criteria is the Agency prepared to consider the need to change these criteria?
(vii) Is it able to integrate any participatory processes with activities by other decision-makers?
(viii) To what extent will the Agency's assessment be viewed as independent? And if not how can independent review be applied?
(ix) Is the Agency willing to be open about limits to current knowledge and able to demonstrate continued attention to the science, data and models which underpin the assessments?
(x) Is the Agency able to support cumulative and comparative risk assessments even where there may be no regulatory requirement?

These issues are now discussed more widely in Section 5.

5 CHALLENGES FOR PARTICIPATORY RISK ASSESSMENT

We now focus on the challenges that the risk assessment process faces, but also presents, when opened up to participation. These difficulties relate to the observation that risk assessment is usually an expert-centred process, where scientific complexity and uncertainties can be understood and managed amongst a group of specialists. In the public domain, complexity and uncertainties have to be explained and opened to challenge. Also, the concept of risk is usually broader than just physical harm, so questions are likely to extend beyond the focus of the risk assessment. Finally, risk assessment is a tool for use within a decision process. The characteristics of the decision process impact on the opportunity for participation and the role of the risk assessment.

5.1 Scientific complexity

One of the main challenges to involving the public in risk assessment is the complexity of the process. Risk management decisions are replete with technical uncertainties and perplexing value tradeoffs. Making and implementing wise policy choices is difficult: 'How could members of the interested lay public hope to understand and play a meaningful role in making such complex, high stakes choices?' (McDaniels *et al.*, 1999, p. 497).

One solution is to engage different people at different stages of the participatory process – informed stakeholders in the more technical elements, the lay public in problem definition and risk evaluation – while not losing sight of the need to inform people in general throughout the process (Section 6, for examples). Whilst acknowledging consultation forms a 'level playing field' it is important that too much is not asked from a group of participants. As has been noted:

> 'The nature, extent and complexity of stakeholder involvement should be appropriate to the scope and impact of a decision and the potential of the decision to generate controversy' (Presidential Commission on Risk Assessment and Risk Management, 1997, p. 16).

Concern has been expressed that in focusing on issues of deliberation and 'smoothing out differences' between stakeholders, technical issues can become increasingly neglected or pushed in the direction of experts alone (Apostolakis and Pickett, 1998). Neither of these outcomes would result in an effective participatory risk assessment as there would be either over- or under-emphasis on the technical aspects of the process. Such issues are part of a wider discussion of scientific literacy and public understanding of science, addressed by the House of Lords Select Committee on Science and Technology (2000). The Committee's report indicates that the need to bolster science and technology is crucial in contemporary society. 'Content-transcending' knowledge is important for the public engaged in socio-scientific issues and for thoughtful and meaningful decision-making (Millar and Wynne, 1988; Driver *et al.*, 1996).

These goals could be achieved through formal and informal means of disseminating science information. For example, the Select Committee acknowledged the role played by museums and science centres. New methods of teaching science for citizenship, particularly through the concept of peer debate, criticism, and evaluation of knowledge claims, are being explored (Klostoe, 2000). These draw directly upon new modes of public engagement in decision-making such as the consensus conference (see www.ukceed.org for discussion of the consensus conference on radioactive waste management held in 1999 and Petts and Leach, 2000).

5.2 Traditional expert approach to risk assessment

Many risk experts appear to use a different language to other stakeholders regarding issues of risk. The concepts of risk vary according to perspective. Three 'types' have been identified: colloquial, technical and insurance (Jardine and Hrudey, 1997). It is suggested that the colloquial view is that of danger, venture and opportunity; the technical one, that of hazard, probability and consequence; and the insurance view, that of chance and uncertainty.

Whilst such distinctions might seem rudimentary, the definition of risk *per se* underlies all expert communication and interaction with the public and can have numerous implications for participatory risk assessment. It has been observed that 'these distinctions [in definition] are not mere nuances which may cause only minor confusion' (Jardine and Hrudey, 1997, p. 490-491). The ability to define risk is imbued with issues of power, as the definition used in risk assessment will ultimately define the risk management actions (Slovic, 1997; Jardine and Hrudey, 1997). There is, therefore, a potential tension between a regulators need for operational procedures for risk assessment in the regulatory context and the desire to engage the public in risk decisions, where the 'technical' language of risk will compete with the colloquial language of the public – hence the initiation of this study.

One example of a way in which expert and lay knowledge differ is in terms of the estimation of severity and judgement about acceptability. This is because risk issues can be emotive for members of the public who see them in terms of fairness: the more unfair they appear (spatially, socially, economically), the more severe and unacceptable they become. Within an expert assessment, risk can become formalised in terms of physical harm. This is not to suggest that experts do not also have concerns about fairness, but that the risk assessment process may not make transparent how such concerns have been addressed.

This differential perception is identified in studies exploring perceived severity and familiarity with risk (Slovic, 1987), indicating divergent assessments between experts and lay people. A 'deficit' model has been described whereby the expert 'elite' tend to see 'the public' as starting from a position of ignorance and the expert from 'the correct position' (e.g. Millar and Wynne, 1988; Wynne, 1991; Locke, 1999). Whilst it is the case that experts and lay people are likely to construct a risk issue differently, this does not mean that one kind of knowledge is more or less valid. Defining and controlling risk is something that has been the preserve of the expert for a considerable period of time, and so public participation might be viewed as challenging expertise and professionalism, resulting in a reluctance to engage in dialogue: a culture of 'we have done this for years – we know what we are doing' (Petts and Leach, 2000).

As noted in much of the research on risk and democracy, the analysis that takes place is conducted by experts in various scientific disciplines each operating within a defined scientific culture (Jasanoff, 1993). This project does not suggest that this should be otherwise. Indeed, it has been observed that the public welcome advice from experts (Millar and Wynne, 1988; Petts, 1997; Petts and Homan, 2000). What needs to be considered is the part that lay knowledge, understandings and perceptions can play in defining the agenda for risk assessment; provision of feedback into the analytical process and in interaction with the experts conducting the analysis.

A further issue is the ways in which experts traditionally share information. Rather than disseminating information in a wide-ranging or 'popular' way, scientists input to

environmental decision-making through peer review processes and reliance on published studies. Whilst such means of presenting information are extremely important, they do not necessarily contribute usefully to open and deliberative stakeholder processes. This can result in a lack of knowledge entering the stakeholder process resulting in a less informed decision-making exercise (Yosie and Herbst, 1998).

Viewing the public as legitimate participants in decisions reflects a changing view of 'expertise', now understood as a learning process resulting from interactions between the public and experts (Limoges, 1993; Petts, 1997). That scientific knowledge is established through a 'critical and consensus-seeking discussion in a community of competent peers' (Driver *et al.,* 1996) has as much relevance to lay understanding and interpretation of science as it does for the process of expertise. Indeed, the world is becoming 'inhospitable' to experts in their traditional role (Bauman, 1987). Whereas the old, archetypal, expert was associated with the notion of social control and governance, the 'new' expert is a more benign actor with a more flexible approach to knowledge (Bauman, 1987, 1988, 1990, 1992).

Linked to the potential for public engagement in the process of expertise is the acknowledgement that people are able to re-skill themselves. This is particularly due to the increased volume of information in the public arena, allowing people to construct their own version of expert knowledge from diverse and divergent sources. The increasing use of the Internet as a resource (approximately 10 million people in the UK have access (NUA Internet Surveys, 2000) means that people are able to gather ideas from millions of web sites. This allows a 'pick-and-mix' version of science to develop from a 'grass roots' perspective that may not be consistent with 'traditional' forms of knowledge, but yet has meaning for the individual concerned

5.3 Difficulties of dealing with uncertainty

Stern and Fineberg (1996) outline uncertainty as a critical dimension in the characterization of risk. However, uncertainty is also one of the most problematic areas with regard to increasing public participation in the risk assessment process. It has become clear that people do not respond well to uncertainty and it frequently increases confusion and anxiety towards a risk issue. Indeed, in a recent study on risk literacy, i.e. trying to ascertain what it is about an issue that either increases or decreases people's propensity to learn about it, it was found that uncertainty can have a negative impact upon knowledge acquisition (Petts & Homan, 2000a). However, there is evidence that when people are faced with issues of uncertainty in participatory processes they are able to recognise and deal it providing they are provided with opportunities to understand the reasons for the uncertainty (Petts, 1997).

Various social, cultural and institutional factors affect how people recognize and use information on uncertainty (Stern and Fineberg, 1996, p. 114). A major problem with regard to managing the concept of uncertainty is whether or not it is acknowledged explicitly in the risk assessment process. It is frequently the case that stakeholders tend to suppress or push aside the information on uncertainty in order to maintain the guise of trust and authority. The sometimes covert nature of uncertainty therefore makes it all the more difficult to deal with, and can increase public alienation (ESRC, 2000).

Many uncertainties associated with risk have a spatial element and need to be presented differently according to location. Those living either close to, or a long way from, a problem tend to acknowledge the greatest uncertainty; although often from a different perspective (i.e.

compare the immediate neighbour with national interest groups). Those 'in between' seem to apply a partial knowledge to the problem and may not concentrate on uncertainties to the same extent (MacKenzie, 1990).

People can have fixed perceptions of the credibility of organisations and the extent to which they can be trusted in terms of providing reliable information. This means that the presentation of a situation as uncertain may be accepted from some sources but not others (e.g. Worcester, 1995; Marris *et al.*, 1996; Petts, 1998; Hunt *et al.*, 1999, MORI, 1999). These studies suggest that the perceived degree of vested interest has a significant impact on trust. Thus, industrial sources of information are less trusted than independent scientists. In a recent project on risk literacy the most trustworthy sources in relation to information on air pollution and health in the UK were found to be the Department of Health, the Environment Agency, the Department of the Environment, TV sources, University scientists and Greenpeace. Least trusted were Government ministers and tabloid newspapers (Petts and Homan, 2000). However, earlier work on waste management information sources called into question the extent to which the Environment Agency might be trusted particularly where it is perceived to be working closely with industry (Petts, 1998). It is clear that it is not an organisation or individual which is trusted *per se*, but that trust in an organisation or individual varies according to the *context* in which their knowledge or opinion or judgement is required and the views and knowledge of the audiences.

The traditional communication risk estimates and evaluations fails to provide for the public testing of expert knowledge and assumptions. Direct accountability and the evidence for the important dimensions of trust –objectivity, competence and empathy are often left untested (Petts, 1997). The conventional approach also fails to acknowledge that risk management requires the locus of control to extend beyond the institutional and political to the personal. People want to make up their own minds and to take personal control over risks that affect them. This desire directly affects their search for information, including their use of media sources. Knowing about the conditions that foster distrust naturally leads to an emphasis on dialogue and deliberation Slovic *et al.*, 1991; Flynn *et al.*, 1993; Renn *et al.*, 1995; Petts, 1995; Stern and Fineberg, 1996; ILGRA, 1998a & b; RCEP, 1998; House of Lords, 2000).

It is important that uncertainty is presented in such a way as to make it appear relevant and worth spending time trying to comprehend. People are more likely to make time to understand something that has practical, personal relevance and that they can do something about (Stern and Fineberg, 1996; Petts and Homan, 2000a). In a leaflet produced by the Environment Agency for individuals new to environmental risk assessment, the following have been suggested as ways of dealing with uncertainty (Environment Agency, 2000c):

- Concentrate on the 'big picture'.
- Concentrate on those parts of the assessment that have the greatest impacts on the outcome.
- Try to communicate where the greatest uncertainties lie.
- Be honest about uncertainties.
- Be sure to review expert judgements and the assumptions recorded.
- If necessary, compare your assessment against similar studies.
- Consider how you will involve those with an interest in your assessment and communicate the issues raised by the output.

5.4 Data availability

A problem linked to uncertainty is that of data availability, both in terms of 'does it exist' and 'can it be made available'. In relation to the former, there are problems where data on specific risks are not available. Most risk controversies in the public domain are distinguished by information scarcity, with some data regarded as essential by at least one stakeholder usually not available (Chociolko and Leiss, 1994). The essential trade-offs necessary in the face of such data unavailability require that these are conducted in as open as manner as possible.

If the public is to participate in an assessment process then data, which are both published and unpublished, may need to be revealed. For some issues, data may be evolving – a problem for example, in relation to international understanding of the health risks of dioxins. If the public are to participate, then they need to have time to become acquainted with technical information and have the opportunity to understand what is still not known and to weigh up alternative views (Petts, 1997). This requires access to the base data not merely summaries or overviews.

Furthermore, participatory processes have revealed that experts can be challenged when the public ask for information on issues which had not been considered to be within the remit of the discussion and/or for which relatively little data exist. In Hampshire, for example, during the Community Advisory Group process relating to the development of the waste strategy, the group members raised questions about the relative risks of the different waste management options. No such data existed at the time, and the County Scientific Officer was charged with undertaking a review of the available literature. This meant that the issue could not be dealt with within the Groups, the report of the Officer's findings only being available towards the end of the process (Petts, 1997).

Confidentiality, or perceived commercial confidentiality, has a significant impact on public involvement by private sector developers/proponents. Legislative requirements for public consultation are relatively limited and certainly have been time-limited in terms of consultation only once proposals are made public. Arguably, this makes it relatively easy for commercial interests and concerns about revealing plans early to dominate. To encourage public participation in assessment processes requires a willingness to engage with people while proposals are developing. At the current time it seems more likely that participatory processes will be able to be used where public sector development or regulatory functions are involved.

5.5 Decision process characterisation

Table 2.2 introduced the different risk decision contexts in which the Agency may wish to engage the public. These contexts raise different decision process characteristics that can present barriers to, or problems for, public participation. These are summarised in Table 5.1 and are based upon known problems in public participation in general (Petts and Leach, 2000; IEMA, 2000). Policy decisions have generally been the most difficult to engage the lay public in, because of the nature of the decision as well as the degree to which people may be interested to participate. Problems arise in selecting a group of people who could be considered to be representative of the general population. It is doubtful whether the complexity of the risk assessment itself is any greater at the policy level compared, for example, with a site-specific decision. It is the nature of the decision process that makes it more difficult to engage people meaningfully.

At the plan or programme level where decisions start to be more local or certainly regional, then the potentially interested public can be easier to identify. However, their participation is still dependent on the issue being of interest to them. Most plan level participation activities (Section 6) have been criticised for not being able to attract the 'ordinary man in the street'. However, such criticisms serve to focus on the objectives of participation. Participation by certain sectors of the population or defined interests may be relevant to the objectives (Section 7).

The site-specific decision process is the most easy to engage people in because often they will consider that they or their interests are directly affected. However, the decision may be contentious increasing the volatility surrounding the process. The timescale for decision-making may be constrained by legislation. As suggested above, the process may also be affected by the extent to which private sector/commercial interests wish to be involved in participation that goes beyond the statutory minimum. There is some experience of reluctance on the part of the private sector to be involved in processes which might require them to engage with the public earlier than they would normally (Kemp, 2000, *personal communication.*).

Where the decision relates to risks that will be localised and relatively short-term then it is plausible to involve a large number of stakeholders from the potential risk losers to the risk managers. However, where decisions relate to long-term risks (such as low level radioactive waste disposal, for example) then stakeholders can only be partially represented, since the future stakeholders who will have to bear and manage the risks have to be represented by the present stakeholders (English, 2000). Where risks are potentially diffuse, then the stakeholders may be numerous and widely scattered, only the 'risk perpetrator' and the 'risk managers' being easily identifiable. The most difficult risk decisions relate to where the risks are diffuse and potentially long-term (e.g. high level radioactive waste disposal). While it may seem possible to involve people in the immediate vicinity of the planned repository these are only partially representative of stakeholders. This situation equates with the difficulty of involvement in policy development. It also requires participants to address not only their own interests or stakes but also the long-term common good.

Table 5.1 Decision process characterisation

Decision Context	Characteristics	Barriers to Participation
Policy	• Often timescale of work is lengthy with different elements of the risk assessment process not definable elements • Process may be iterative involving different agencies & organisations • Likely to be key interested & affected stakeholders • Lay public interest likely to be lower	• Lay public may not be interested • Questions over who is representative of public view • May need to involve people from different parts of the country • Timescale of involvement may be extended • Key stakeholders may have vested interests • Questions over what influence people can have on decision • Point at which decision is taken often difficult to define
Plan/ Programme	• More locally oriented • Likely to be key interested and affected stakeholders • Local public will have interest if issue directly affects them • Timescale of process may be extended • May relate to other plan-making functions: e.g. in local authorities • Likely to require communication/information provision as well as participation • May be volatile situation with already contentious issues in the public domain	• Questions over who is representative of public view • If decision is not open to change (i.e. 'has already been taken') • If definition of the problem is not open to public influence • Overlap with participation activities by other authorities • If public want to discuss other issues relevant to decision which are not part of the assessment • Identifying appropriate roles for stakeholders and lay public • Timescale of involvement may need to be extended
Site-specific	• Often Agency not the only decision-maker • Participation activities may be organised by other parties • Can be highly volatile situation where issue is contentious or of concern to people • Multiple interests can be identified • Likely to require communication /information provision as well as participation	• Questions over who is representative of public view • If decision 'has already been taken' • If definition of the problem is not open to public influence • Overlap with participation activities by other authorities • If public want to discuss other issues which are not part of the risk assessment process • Need to integrate participation with information provision • Timescale restrictions • Private sector may be opposed to extended consultation but their cooperation may be required • Who should pay?

6. EXPERIENCE OF PARTICIPATORY RISK ASSESSMENT

6.1 Problem of definition

Few direct references exist in the open literature to the phrase 'participatory risk assessment', and only a few examples exist in the 'grey' literature. Where the concept is used, it is not always referring to examples of participation in risk assessment *per se*, but often to environmental assessment or technology assessment where risk is a significant issue relating to a controversial decision. A broader literature review relating to participation in environmental decisions provides a richer set of information on public participation in technical and scientific issues surrounding environmental decisions. It reveals that, participation is as, if not more, important in problem formulation, agenda setting and risk evaluation as in the actual hazard assessment and risk estimation elements. It stresses the need to think broadly about the application of participative processes. It is interesting to note that among the case studies cited by the NRC of decisions using stakeholder processes (ecosystem management; incinerator siting; regulatory negotiation for a disinfectant by-products rule; power plant siting; reuse of a former nuclear waste site), none involved members of the public, possibly reflecting the earlier period over which the cases were gathered (Stern and Fineberg, 1996).

Even broadening our definition produces a limited number of practical examples of participatory risk assessment involving members of the public during real decision processes, as opposed to research exercises. Caution is needed in interpreting the value of research studies. Where people are not engaged in *real* decision processes, their commitment to the process, expressed views, problems encountered in handling complex information, questions asked, etc., may not reflect what would happen 'for real', where the issue may directly affect them and/or may be of concern. Who may be prepared to take part may be different in a research exercise as opposed to a real decision process. Certainly, participants are usually not representative of the general population. The following sections identify examples of public participation in both real decision processes and research studies where risk is an issue and/or significant technical discussion is required.

6.2 European experience

6.2.1 Germany – the Three Step Participatory Approach

The research and practice in Germany particularly on energy policy development and waste management planning and siting provides useful insights with regard to participation in environmental decision-making. Particularly the production of a co-operative discourse model, known as the 'three step process' offers a structured way of incorporating the views of a diverse group of stakeholders in environmental decision-making (Renn *et al.*, 1993; *Renn et al.*, 1997; Renn, 1999). The three steps are as follows:

> *Step 1* At this stage the various stakeholder groups identify their values and criteria for judging different options. These include economic, political, social, cultural and religious values. This concerns and criteria list is then appraised and added to by experts, citizens and sponsors of the process and the concerns are transformed into qualitative and quantitative indicators.

Step 2 Identification and measurement of impacts and consequences related to different policy options. The indicators are approved by the participants in the process and are used to evaluate each policy option. The group Delphi method involves experts from a range of disciplines who are asked to judge the performance of each policy option against each indicator, through group interaction and reconciliation of conflicts about the factual evidence.

Step 3 The potential solutions are discussed by a group of randomly selected citizens who evaluate the policy options based on their own knowledge and values with regard to the decision. At this stage the various stakeholder groups, experts and sponsors act as witnesses to the panels. The process facilitator is responsible for the compilation of a citizen report. The final outcome at the end of this stage should be the priority of options and policy recommendations.

The potential of the three-step model lies in its structure and the clarity of the objectives and outcomes arising at each stage. It provides an holistic approach to environmental decision-making including a wide range of people and groups, by involving them in a proactive way (Renn, 1999).

An early, comprehensive use of the three-step process was in relation to energy policy development as part of a research project instigated by the Germany Ministry of Research and Technology (Renn *et al.*, 1985). Box 6.1 outlines the use of the process in real decision-making in the Northern Black Forest Region in relation to waste management planning. As in many of the examples provided risk was not the only issue of relevance but was certainly an aspect of the considerations, for example the relative risks of different waste management options. The three-step process was a primary means of allowing for problem formulation, scoping of issues and ranking of alternatives (i.e. comparative risk analysis) at the strategy or plan level. Arguably, as in all waste management issues, the complexity of strategic planning for waste in terms of demands on expert knowledge, technical complexity as well as information availability of potential risk outcomes does bear close analogy with risk-focused issues. Box 6.2 provides an example of public participation in a site selection process for landfills in Switzerland. Here a similar process of group discussion and a formal means of applying criteria to derive a ranking of preferred sites was used.

Both processes involved:

- multiple meetings over relatively long time periods to ensure that people had an opportunity to understand the issues, to assimilate information, to question experts, to reach a consensus;
- the engagement of stakeholders as well as lay public, and
- recommendations to decision-makers which the latter gave a commitment to considering.

These characteristics are standard to most deliberative processes and are essential. The issue of time is important but the actual optimum length (e.g. compare 3-4 days with 3-4 months) needs to be determined by the objectives to be achieved and the resources available.

Box 6.1: Waste Management Planning in the Northern Black Forest Region (Renn *et al.*, 1999; Schneider *et al.*, 1998)

Context: 1993 three rural counties and the City of Pforzheim formed a cooperative to seek a common solution at the regional level for their waste problems. The process was divided into three decision phrases: (i) waste prediction for the planning period to 2005 and maximum estimates of the treatment capacity required, (ii) selection of the appropriate treatment technologies and definition of site selection criteria, and (iii) site selection.

Format: Three-phase process. In Phases I and II 16 stakeholder groups came together in a series of consensus conferences to develop a prediction of waste arisings and to rank possible technical options for treatment. Experts provided data, explained the methodology and were cross-examined by the groups. Study trips were organised. The groups generated and structured values important to the technical options. A Citizens' report was produced addressing the need for facilities, the value 'trees' generated and the recommendation as to the technical options to be considered. In Phase III a random selection of 200 residents from the potential sites for waste facilities was made and people were assigned randomly to one of 10 parallel working citizen panels. The panels were given the mandate to find the most suitable site from 16. They developed site selection criteria and designed a ranking list considering social, political, economic and ecological impacts Value-tree analysis and a modified Multi-Attribute Analysis (see Section 6.3) were used to reach a consensus as in Phase II.

Comment: The handling of complex, uncertain and ambiguous information required that all relevant information was given to participants in advance – including everything that they requested. The evaluation of alternative sites proved a particularly difficult issue in terms of information and data but also because of its contentious nature. It was important that participants considered proven knowledge rather than allowing prejudices or guesses to intervene. The site selection criteria and preferred options produced by the process were taken forward to the next decision stage, so that the stakeholders' decisions were part of the decision process itself.

Box 6.2: Landfill Siting in Switzerland (Renn *et al.*, 1995)

Context	Need to site one of several landfills in canton of Aargau. The landfill would meet local needs for a period of approximately 40 years. The authority had identified potentially 13 sites
Process	Planning cells formed in each area of the identified sites, to develop criteria for comparing the sites, eliminate unsuitable sites and prioritise remaining sites Four citizens' panels consisted of 2 representatives of local communities round the sites - 104 citizens took part. People were chosen by an oversight committee – random selection not appropriate within the Swiss culture. Panels met 7-9 times over 6 months.
Decision	Each panel reached an unanimous decision and the first ranked site was the same in each panel, but had not been the authority's choice which had reflected geology more than the social and aesthetic issues stressed by the panels. Panel selected site was agreed by the Canton.

6.2.2 Contaminated Site Community Involvement – Germany

Box 6.3 Varresbecker Bach Participatory Process

Context
Need to investigate and assess the risk of a contaminated site in a residential area of Wuppertal. A construction site was found to be contaminated with arsenic, lead, copper, mercury, cyanide and PCBs with stream bed contamination extending 1km from the site. Contamination potentially affected 1000 residents. In terms of public concerns there was evident conflicts between people's long involvement with the local chemical industry and the fact that they may themselves be liable to clean-up and their concerns about health risks. The Environment Agency, recognised that it would be essential to go beyond normal statutory responsibilities to assess the risks and to decide on remediation requirements and to involve the potentially affected public in the decision process.

Method
Three principles underpinned the method chosen, (i) disclosure of all information to the affected parties, (ii) open discussion of all information gaps, (iii) use of an independent mediator to organise the participation process and advise the Agency.

A series of public meetings were held to provide information and to gather information from local residents and property owners. An Interest Group with seven active members was formed by the residents with the stated objective to get answers to questions about the nature of the risks, who would be responsible for remediation and who would pay for clean-up. The Interest Group reviewed the results of the Agency's soil investigation and working with the Agency agreement on information to be sent to residents and on closure of the local playground was achieved. Additional, detailed investigation was necessary and 3 experts were invited to a public meeting to present proposals on how the investigation and risk assessment should proceed. The public present decided upon the manner in which the risk estimates for individual properties should be reported and how information should be made understandable. The residents voted on their preferred approach as presented by the experts.

A Working Group was formed by the residents and stakeholders to ensure that adequate information from the experts would be forthcoming. This Forum had a formalised charter and terms of reference agreed with the Wuppertal Environment Commission. It formed a round table to achieve a consensus on the expert findings and to make recommendation to the responsible bodies. However, a second public interest group also formed which opposed remediation and testing. The independent mediators were able to integrate this group into the overall discussion process by visiting individual members and discussing their concerns.

Outcome
Voting on the assessment process to be undertaken appeared to generate trust amongst residents and led to 98% agreeing to having soil on their properties sampled. The integration of the 'action' group into the process served to help to direct the process towards a consensus decision. A large amount of information was made available to the public.

The Varresbecker Bach participatory process (Claus, 1995: see Box 6.3) is an example of a site-specific process of involving the public potentially affected by land contamination in the risk decision relating to clean-up. It therefore differs from the strategic decisions exemplified in the German and Swiss participatory processes, and did not involve particularly 'innovative'

methods of participation. However, it serves to illustrate the value of focused and structured processes of discussion which are responsive to public concerns and questions and aim to engage a community in a consensus decision on the best way forward. Most importantly it was a process which included and was responsive to public initiatives in the formation of interest groups.

This process was unusual in two respects: firstly, in being instigated by the Wuppertal Environment Agency which like many German agencies had a "tradition of administrative secrecy in public policy" (Claus, 1995), and secondly, the decision was taken to engage an outside mediator to run the process which an agency would not normally consider preferring to maintain strong control as the regulatory body.

6.2.3 ULYSSES Project

The ULYSSES project was an EU-funded project that aimed to incorporate principles of Participatory Integrated Assessment (PIA) into discussions of global environmental issues. The project ran between May 1996 and July 1999 and the principle objectives were:

- To develop and experiment with a participatory methodology for PIA, where the knowledge of stakeholders, the general public and stakeholders is integrated
- To explore the usage and the benefit of Integrated Assessment (IA-) computer models in PIA
- To study and compare the judgements of informed citizens (stakeholders and lay people) (Anon, 2000).

It is important to stress that this project was not related to actual decisions, but was a research exercise.

The focus of the project was climate change and was instigated primarily through the running of focus group sessions. In total more than 50 focus groups were run across Europe and comprised more than 250 sessions. Most of the groups consisted of lay people but others were carried out with regional stakeholders and representatives from regional planning institutions. The groups were run in Barcelona, Stockholm, Zurich/ Basel and Frankfurt/ Darmstadt (Anon, 2000).

The focus groups were recruited randomly and each consisted of between 6 and 10 participants. The five sessions followed a predetermined agenda:

- An unstructured discussion of global environmental issues in session one;
- Presentation and discussion of expert approaches towards the global climate in general and IA models in particular in the second and third sessions
- Identification of acceptable targets and possible courses of action in the fourth and fifth sessions
- The production of a written report on policy recommendations in the fifth session.

These sessions were recorded on audio and videotape. The computer model presentation aimed to give people unrestricted access to expert systems with regard to global climate change. They were presented to the participants in the following way:

- Introduction: people were asked to describe their experience with, and expectations of, experts in the field of climate change. They were then given a presentation, without the use of the computer models, on the expert views on global climate change and the main parameters involved in its assessment.
- Model presentation: three computer-based models were used: IMAGE, TARGETS and PoleStar. The participants were encouraged to interact with these systems in a 'hands-on' way and input their own scenarios to the models to demonstrate their capabilities. The main outcome was to assess how people viewed expert knowledge and decision-making processes but they also had the opportunity to evaluate the trustworthiness and plausibility of the model from their own perspective (Anon, 2000).

A number of points are instructive in terms of presenting information of a scientific, and traditionally 'expert', nature to a lay audience. Firstly, the participants were left to discuss the issues amongst themselves and whilst the facilitator presented the introductory information on the issues of climate change, they did not then intervene in the discussions even if misconceptions arose. Two moderators were used in the focus groups: a moderator for the group discussions *per se* and a model moderator who was present to answer technical questions. A specialist expert in the respective participating countries was available via a 'hotline' should any further questions needed to be answered. Finally, the presentation of the model required a considerable input of time to the process because of the 'dense' nature of the terminology and need for explanation.

The presentation of information using computer models raised a number of key issues:

- Location and atmosphere: the sessions need to be held in an accessible and informal situation.
- Group dynamics and moderation: group dynamics amongst participants and relationship between each of the moderators and the participants are an important part of the process and its outcomes.
- Technology and equipment: there is a need to be aware of the use of technology that participants might not be familiar with. The ULYSSES project introduced the technology relating to the models in small sections a piece at a time so as not to overwhelm those present.
- Expectations of participants about experts and expert knowledge: a clear distinction emerges between people's expectations of experts and their experiences and this is influential in terms of their perceptions of the expert systems that are used. This is common to most participatory processes where experts are required to input technical/scientific information. The public expect open recognition and explanation of uncertainty for example, which may not always be forthcoming.

ULYSSES was one of the first projects to involve the public in an interactive way in terms of assessing expert systems. It has been suggested that a project such as this needs to decide on its approach early on in the process as it can follow one of three suggested paths:

- It can be educational. This tends to be a unidirectional transfer of knowledge from experts to lay people and the process is used as a means to inform people on a particular topic.
- The groups can also be used for consultative objectives whereby the relationship between science, policy and the public is acknowledged in a more complex way.

Consensus and recommendations for policy making are seen to be the principal outcomes.

- The groups can also be used in an analytical way for the exploration of public assessments of global environmental risks or for the development of normatively embedded computer scenarios.

6.2.4 The Swiss Genetic Testing Consensus Conference

Box 6.4 Participatory risk assessment and genetic testing in Switzerland

Context
The principle motivator of the dialogue was a member of the Upper House of the Swiss Federal Parliament who chaired the Support Committee. A Stakeholder Panel was established, comprised of health, insurance, legal, research and religious organizations and companies. A Citizens Panel of 24 men and women was meant to be representative of the 'ordinary' citizen although recruitment proved difficult with only 65 respondents to the two mailings to 6000 addresses. The aim was to engage stakeholders and citizens in a dialogue in the hope of providing a forum for a 'critical, yet constructive, deliberation on genetic testing among various affected social and political actors' (Büchel and Joss, 2000).

Method
The dialogue process began in September 1998 with a meeting of the Citizens Panel. At this initial meeting discussion took place about the issues that were felt to require further exploration with the experts chosen by the participants either from those proposed by the Stakeholder Panel or additional experts considered . The next stage involved discussion with experts after which the Citizens Panel had a chance to revise their concerns and questions for the concluding part of the dialogue, the discussion with the Stakeholder Panel.

Feedback
One month after the process the Citizens Panel met to produce their final statement which was incorporated in the final report. The Stakeholder Panel was also required to produce written answers and comments to the questions established by the Citizens Panel. The final report was sent to institutions, government agencies, members of parliament and the media.

Conclusions
The issue of genetic testing is a controversial one and the dialogue process proved to be an effective way of dealing with this. In particular it provided for the stakeholders to meet and discuss the pertinent issues but also for the public to raise their concerns with these stakeholders and have them recorded. Therefore, the conclusions from the dialogue were that whilst it did not achieve all the objectives that it set out to there was a certain amount of success

A Swiss case study relating to genetic testing indicates the indeterminacy of definition with regard to participatory risk assessment. In many ways it could be seen as a dialogue involving the public and wider stakeholders with regard to risk issues rather than a participatory assessment primarily because the main omission is an involvement from the outset, i.e. at the definition and agenda setting stage. Nonetheless, it raises some interesting observations with regard to including a wider group of people in a complex risk issue at the policy stage (Joss, 1999; Büchel and Joss, 2000) (Box 6.4).

6.3 North American experience

The US regulatory approach to environmental impact assessment and also to remediation of Superfund sites means that the public (or at least major stakeholders) have traditionally participated in environmental decision-making and have open access to information. It is evident from the analytic-deliberative process debate that this does not necessarily mean that participatory processes have always proactively opened risk assessments to public involvement. However, it does mean that there is considerable experience of stakeholder engagement in US Environmental Protection Agency decision processes as well as that of the other Federal agencies. The level of activity provides many examples worthy of mention. The following are merely a small selection illustrating the range of decision contexts.

Worthy of particular mention (largely because the UK has not embarked on such a policy approach) is the involvement of stakeholders in the numerous State-level comparative risk-based priority setting exercises in relation to environmental problems, following the EPA's relative risk study ranking risks to human health and the environment which identified a divergence between public and expert expenditure priorities (USEPA, 1990). The US experience has also led Environment Canada to trial models using comparative risk assessment as a methodology to establish priorities on a systematic basis.

Stakeholder engagement in the comparative risk projects has been significant in a number of States. For example, Vermont appointed a 20-member public advisory committee consisting of people who were representative of key interest groups in the State. The committee had authority over the priority list and the analytical criteria as well as the risk ranking. Technical working groups of State employees conducted the analysis and met several times with the committee, which also commissioned briefings from national experts on health, ecological risks and economics. It was observed that the process helped to align public and expert assessments of risk, enabling officials to shift resources to previously underfunded areas such as indoor air pollution and biodiversity (Minard, 1994; Moffet, 1996). A review of a number of the State-based initiatives observed that the some had redirected money from 'lower' to 'higher' risk priorities and that the most effective projects were those that were the most democratic (Minard, 1994). The review noted a number of criteria of effectiveness in this regard, including:

Participants learning a significant amount about a comprehensive list of environmental problems.
The exposure of weak arguments, poor data and fuzzy thinking.
(iii) Breaking down of individuals' prejudices about other participants.
Consensus being achievable as a result of a process of debate and discussion and learning.
Participants coming to see their views as important and that they should be used to influence policy.

The comparative risk projects of the US have served to highlight the many value judgements which underpin scientific risk assessments, including: determination of which risks to evaluate; the importance assigned to differences in probability versus magnitude of harm; how to account for qualitative differences in possible outcomes; which risk metric to use (e.g. premature deaths, increased morbidity etc); the comparison of ecosystem risks with human health risks, and which risk ranking criteria to use (e.g. cost effectiveness, 'worst first' environmental justice, etc). Most of the risk-based priority setting exercises have developed

social welfare categories that apply a set of criteria related to economic and social well-being to the same issues that are subject to ecological and health risk assessment.

At the US Department of Energy's Hanford Site the public, stakeholders and Tribal governments have been involved in "pre-decisional analysis" for the site remediation. The web-site (http:www.hanford.gov/doe/pubinvolv/pip/pip.htm) provides guidance to remediation managers on the goals of the public involvement policy, not least the concept that "many minds working together can often come up with better solutions for problems". Public involvement is defined as "a process to give officials the best information to make informed decisions while ensuring all concerned people have an opportunity to be heard". Similar concepts and engagement in the Comprehensive Impact Assessment relate to the Columbia River and evaluation of the effects of Hanford-derived materials and contaminants on the river environment. Such engagement projects are supported by considerable public information availability. Independent technical peer reviewers are used to evaluate the assessment with nominations for this role from the public, regulatory agencies, contractors and Indian Tribal representatives. Importantly the definition of the essential work to provide an acceptable comprehensive river impact assessment is provided through stakeholder and public discussion (http://www.hanford.gov/crcia/overview.htm). The Columbia River participatory process has been evaluated as an analytic-deliberative process (Kinney and Leschine, 2002). The lessons learnt include that tribal and other interest group representatives lacked the technical information to challenge claims about the risk assessment process and data produced by the authorities. The authorities found it difficult to deal with suggestions that they were applying the 'wrong science'. However, the evaluation does not see this problem as suggesting that the participatory process failed, rather it reminds us of the importance of language and of authorities recognizing that they may have to change or even drop a particular risk assessment approach.

A Canadian case study illustrates some of the possible means by which citizens can be more democratically involved in a strategic, plan-level risk management process. It was a project instigated by the British Columbia Hydro and Power Authority (BC Hydro), in response to a directive from the British Columbia Water Comptroller, to develop and implement a water management plan with respect to the Alouette River in SW British Columbia (McDaniels *et al.,* 1999) (Box 6.5)

There are also a number of ongoing research projects that are seeking to develop methods of participatory risk assessment. For example, Hrudey and Jardine at the University of Alberta in Canada are currently undertaking a community-based environmental decision-making process that, whilst not in the strictest sense risk assessment, has considered risk issues in that it relates to an accidental release from a waste treatment facility (Swan Hills) in October 1996 due to an incinerator malfunction (Jardine, pers. com.). This process has involved a survey, personal interviews with members of aboriginal communities and a study of what people know, believe and expect from wildlife consumption advice put in place after the release. The use of such methods to understand what individuals are concerned about is important in any communication programme – i.e. it allows for 'user-centred' communication (Petts *et al.*, 2001). However, there is then a need to design a process by which individuals can engage in debate and discussion about a decision that responds to this understanding of concerns, particularly in the agenda setting process.

Box 6.5 The Alouette River stakeholder involvement process (McDaniels *et al.*, 1999)

Aims: to address ecological risks; power generation and flood control issues and options through stakeholder participation.

Stakeholder Selection
In this case stakeholders were selected for both their interest in the project *per se* but also for methodological reasons. The Alouette Stakeholder Committee (ASC) was thus comprised of key local groups and agencies identified as important by the Water Comptroller; invited individuals (including local citizens, municipal staff, governmental agencies, BC Hydro) who were considered to have an interest; and individuals who were considered to be good candidates for a participatory process.

Method
This comprised approximately 15 official meetings, approximately three hours each, over a six month period. The meetings followed the following format:
1. A status report by the consultants
2. Discussions of member concerns
3. Presentations by consultants or invited experts to address the knowledge gaps.

Towards the end of the consultation process minutes of meetings were replaced by report-style documents for consideration. The final report was submitted by the consultants to all ASC members and to BC Hydro. The process was intended to be as open as possible. The final decision on the management plan lay with BC Hydro. However, it was maintained that any unanimous decisions arrived at by ASC would be taken seriously. In order to keep the process as transparent as possible the consultants decided on the following:

1. All information should be shared
2. To keep the process as flexible as possible
3. Respond to ASC's information requests through modelling and computer simulations
4. Bring in speakers to provide further information when requested
5. To involve ASC members in decisions regarding evaluation strategies
6. Maintain close ties with other relevant processes taking place within the community and province
7. Acknowledge that some of the issues would provoke emotional responses.

It was also acknowledged that the wider community (i.e. other than that represented on the ASC) would want to be involved in the process. Examples of the way this was done was the holding of an open house and reporting by the ASC to key decision makers that were not on the committee.

Reaching Agreement
It was clear that processes such as trade-offs were going to be a part of the decision-making process. In addition, when working with a group of people comprised of diverse interests it is clear that reaching consensus is unlikely. In this particular case study, when agreement was not possible participants were asked to designate their favoured component of a plan from among a small set of alternatives and to give their reasons for doing so. After 15 meetings the ASC reached complete consensus on all the major issues it was asked to address. Indeed, following the success of the Alouette project, BC Hydro and the Province of British Columbia announced the intent to carry out a similar process for all hydroelectric systems in the region.

The Canadian "Risk Management: Guideline for Decision-Makers" (CSA, 1997) was used to evaluate the safety of transporting waste to Swan Hills including an extensive program of risk communication. Although the word 'communication' is used, in essence a participation process is involved, stressing dialogue in the initial problem framing and issues identification.

6.4 National experience

Box 6.6 Participation in Local Air Pollution Assessment (Bailey *et al.*, 2000; Yearley, 2000)

Decision Context
Research project rather than testing of method to involve the public in specific decision process. However, did involve model being used by Sheffield City Council to monitor and assess air pollution and routinely being used for public policy purposes. Purpose of research to identify lay values and public understanding of air pollution measurements and computer modelling.

Method
Citizens' groups run like focus groups. People selected on basis that they might have specific knowledge of, and interest in, air pollution in Sheffield. Included were environmentalists and conservationists and members of the City Environment Forum; community groups; representatives of local environmentalists associated with traffic campaigning; public sector workers including health specialists, and a business group. Facilitated discussion around three themes of understanding of air pollution, measurements of pollution used by the City and computer modelling.

Findings
People had important comments on validity of assumptions used in the computer modelling system and how they would like to have the output communicated to them. Had suggestions on how air pollution monitoring could be improved in terms of pollutants, locations, and related to sources of pollutants (particularly traffic).

Involvement of health professionals found to be useful as although they were involved in the City Council's discussions this provided an additional means for them to comment. Suggests that stakeholders should not be privileged over lay public in such involvement approaches.

There has been considerable research interest in the UK in identifying public understanding of science and the potential to involve people in technical, scientific and environmental assessments. Box 6.6 summarises such a research project undertaken in Sheffield to identify people's understanding of air pollution and their views on the air monitoring and computer assessment model being used by the City Council. Although the focus groups run were part of a research exercise and had no direct decision-making capacity, the computer model which they discussed was being used routinely by the City Council. The groups did provide an opportunity to bring together lay and scientifically-based knowledge. They confirmed that people were interested in, and able to deal with, technical issues as has been observed in other projects (e.g. Petts, 1997).

Environmental assessments for site-specific development offer considerable opportunity for lay involvement in the assessment process. The traditional legislative focus on consultation

post-submission of a planning application with an environmental statement has meant that in the past commercial issues have tended to militate against private sector developers in particular seeing any value in more proactive involvement of the public in the assessment process. However, experience of public opposition to certain major developments has resulted in some developers seeing the benefit of much earlier public engagement. Box 6.7 outlines such an approach by Hampshire Waste Services in relation to the preparation of the environmental assessments for three new energy-from-waste incinerators. Although the Contact Groups formed were designed primarily as an opportunity for the company to listen to local concerns and to ensure that information about the proposals was made available to local people, the timing of the Groups' meetings (i.e. whilst the environmental statements were in the process of preparation) meant that Group members were involved in technical discussions and had input to the developing assessments, including for example identifying deficiencies in the proposed baseline traffic study.

Box 6.7 Public Involvement in Environmental Assessments for 3 Energy-from-Waste Incinerators

Decision Context
The preparation of the planning applications for 3 energy-from-waste incinerators in Hampshire (at Chineham, Basingstoke, Portsmouth and Marchwood), over the period 1997-1999, by Hampshire Waste Services (HWS). HWS saw groups as a formal means of gathering the views of local people and learning about local concerns.

Method
Formation of three 'Contact Groups' comprising 8-12 members of the three local communities. People were selected to be representative of local interests and to be opinion formers in the local communities. Included members of activist environmental groups known to be opposed to the developments. Each Group was chaired by a local person.

Groups met at regular intervals for between 6 and 10 meetings. Meetings were held in the evening and lasted 2-2.5 hours. Purpose was to explain the development proposed and to go through elements of the environmental assessment being undertaken concentrating on issues known to be of concern to local people – e.g. traffic, air pollution and health risks, ecology, visual impact and design of the plant, site selection process. People had opportunity to question the consultants undertaking the assessments, and to identify issues which they considered were not being addressed adequately. They commented on the draft designs for the facilities. They did identify elements to be added to the draft assessments. In addition the members of the groups were provided with background technical information and were also taken in a site visit to an operating energy-from-waste incinerator (SELCHP).

Findings
People were able to take part in technical discussions although they had relatively limited time in each meeting to look at the developing assessments in detail. They did identify some issues which were not being assessed and which were subsequently added to the environmental assessment. They brought local knowledge to the assessment process. A deficiency of the process was that the environmental assessment had not being scoped by each group in advance. In addition to the groups HWS ran a more traditional public consultation process both prior to and after submission of the planning applications.

The process run by Hampshire Waste Services was the last element of participation in a whole series of activities that had commenced with public discussion of the waste management strategy required for Hampshire. This process had used Community Advisory Groups/Fora to provide for public discussion of the Best Practicable Environmental Options for managing waste in Hampshire (discussed in Petts and Leach, 2000). The process of discussion has been replicated in Essex and West Sussex and Merseyside and in Lancashire a shorter method of discussion in the form of a 5-day citizens' jury has been used (Petts, 2001a). Although not referred to as participatory assessments all of these processes have aimed to provide for public identification of key issues ('framing' of the problem), structured discussion of the 'pros' and 'cons' of different waste options and identification of key information needs.

Box 6.8 UK CEED with the Science Museum: an example of the use of the consensus conference

UK CEED, in conjunction with the Science Museum, held the UK's second national consensus conference, in May 1999. The conference was funded by the Office of Science and Technology (OST) the Natural Environment Research Council (NERC), and UK Nirex and was on the subject of radioactive waste management (www.ukceed.org).The citizens' panel for this consensus conference comprised fifteen members of the public who were selected at random. The panel were able to meet and prepare for the conference over two weekends when they decided on the questions they wanted answered as well as the experts they wished to hear from. The experts were chosen from industry, government and environmental groups and were cross-examined by the panel who then wrote a report on their findings. The overall conclusions were as follows:

- Radioactive waste should be stored underground as opposed to on the surface but must be monitorable and retrievable. Options should be left open for future solutions.
- A neutral body should be appointed to oversee the process. The criteria for site selection should be open and publicised.
- High standards should be applied that are consistent between companies dealing with radioactive waste. These should be open to random checks.
- Research and development should be carried out on a large scale and there should be international co-operation.
- Privatization of the nuclear industry could proceed as long as adequate safeguards were in place.
- Public awareness of the issues must be raised and decision-making should be open and transparent.
- Nuclear power in itself is unproblematic but should not be expanded until the issue of waste disposal is resolved effectively.
- There is need for an international waste classification that clearly communicates information about waste to the public as well as to industry.
- Existing reprocessing contracts should be honoured but no new ones should be taken on.
- The panel noted a new shift in culture amongst industry which includes a greater degree of openness.

A consensus conference is a policy –level method providing for dialogue between the public and experts. It allows a democratic process to develop whereby people are involved in the decision-making process and are able to respond to recommendations and potential solutions to the problem. Consensus conferences have been widely used internationally in policy

development (see Petts and Leach, 2000 and example in Box 6.4). Box 6.8 summarises the recent conference relating to radioactive waste disposal. Here participation is designed to provide for public framing of the problem and through debate and questioning of experts identification of technical questions and information needs.

6.5 Multi-criteria analysis or mapping

Multi-criteria analysis (MCA) (variations on the term include multi-criteria evaluation, multi-criteria decision-analysis and multi-criteria mapping (MCM)) is a process regarded as potentially increasing participation in the risk assessment process (e.g. Apostolakis and Pickett, 1998; Stirling and Mayer, 1999; DETR, 2001). MCA has a 30 year history, but has mainly been used in planning fields and technological decision-making, less frequently in the context of the environment.

MCA is essentially a means by which a series of criteria relating to a particular issue are scored, weighted and then ranked according to their importance. The basic MCA approach involves constructing a matrix which combines issues of policy or project options with a range of criteria or attributes which represent the decision criteria in a way that relates to the specifics of the plan, policy or project in question (Clark, *et al.*, 1998). Appropriate measures are established/agreed/elicited for each attribute and information is collected on the performance of each option against each criterion (the score). This information can be qualitative or quantitative.

Most techniques require the weighting of each criterion according to its perceived relative importance. Such methods can be used in a narrow and 'analytical fix' way but they also lend themselves to more deliberative processes. Clark et al (1998) tested the use of a MCA method for prioritising issues in the New Forest LEAP. Apart from the benefits of participation derived from an inclusive and deliberative small group process, they reported that the development of criteria encompassed a fuller range of evaluative dimensions than would normally be the case and that the application of the criteria systematically to each issue on the same terms which were agreed by the participants ensured transparency.

Apostolakis and Pickett (1998 – see Box 6.9) used an MCA approach in order to guide deliberation as opposed to producing a decision, and found that it contributed to the following:

- focusing on the interests of the stakeholders;
- prioritizing the most important risks, as perceived/ valued by the stakeholders; and
- providing a starting point for the generation of creative alternatives.

The interesting aspect of the process is that it allows the ascription of relative values to important criteria to the risk assessment. Therefore a context is given in that options are being weighed against one another as opposed to deciding whether a single option is safe or not. The potential of MCA approaches could be particularly realized at the outset of a risk assessment whereby stakeholders could use the method to prioritise the issues of greatest relevance and concern. These might then become the focal points for analysis and deliberation and could be a valid means of facilitating stakeholder involvement in setting an agenda for a participatory risk assessment process. As Clark *et al.* (1998) point out the method does not have to be costly nor involve complex models, simple spreadsheets can be used.

Box 6.9: Stakeholder Engagement in Remediation Option Selection (Apostolakis and Pickett, 1998)

Context: Stakeholder engagement in environmental restoration decisions relating to a hazardous waste site at a US National Laboratory contaminated with chromium and TCE

Stakeholders: Six people representing the public, the site owner and regulatory agencies were engaged in the whole process, while a larger number took part in the initial meetings. Many did not wish to continue given the time involved, the fact that this was the development of a prototype participatory process and lack of interest in the site.

Method: Series of workshops lasting 1-2 days over 7 months. The latter was dictated by the time needed by the risk assessors to carry out their work as well as the availability of the stakeholders to attend. During these workshops the stakeholders contributed to every part of the process to reach a consensus view on each remediation option from six alternatives. A ranking of the alternatives was produced using methods of multi-attribute utility analysis, with influence diagrams constructed to calculate the impact of each alternative on 19 performance measures derived by the stakeholders. The final output was an agreed list of reasons for and against each alternative with a view about the least preferred and most strongly preferred options.

Comment: The process was interesting to people and they were able to deal with the technicalities. However, they preferred not to be asked to agree or vote on the 'best option' They wanted to be able to influence the decision-makers' choice.

Stirling (1997) argued that evaluation is fundamentally subjective and questioned the drive to objectivity in MCA. He suggested a mapping technique which produces diagrams of the sensitivity of the analysis to different sets of perceptions concerning the relative significance of various issues. The Stirling and Mayer (1999) (see also Stirling and Mayer 2001) case study (Box 6.10) is useful in terms of presenting MCM as a method of involving people in a risk assessment. However, it is important to note that while the participants were knowledgeable to greater or lesser degrees about the debate they had some background knowledge: arguably they were 'expert stakeholders'. The participants were drawn from regulators, academic scientists, representatives of the biotechnology industry and the food supply chain and a variety of religious and public interest groups.

What was revealed by the method was that cultural, social and ethical issues are clearly bound up with risk and to consider them separately to, or even after, the risk assessment is unlikely to produce a meaningful outcome. Instead, Stirling and Mayer (1999: p7) suggest:

'An MCM approach may therefore assist in the crucial business of 'risk characterization', prior to – and subsuming – the conduct of other risk assessment techniques'.

Variations of the MCA approach thus have considerable potential in terms of enabling inclusion of a range of perspectives in the risk assessment process. It also facilitates stakeholder involvement in the early part of the risk assessment process when participation is more difficult to organize.

Box 6.10: Case study of a pilot project exploring a GM crop in agricultural systems in the UK (from Stirling and Mayer, 1999)

The participants were presented with a set of policy options regarding the use of GM crops in agricultural systems:

- no GM crop, organic agricultural system;
- no GM crop, integrated pest management system;
- no GM crop, conventional agricultural system;
- GM crop with segregation and labelling;
- GM crop with post-release monitoring; and
- GM crop with voluntary controls on areas of cultivation.

These options were presented to the participants in a 2-3 hour interview. They were also able to add their own options for consideration.

The criteria used to evaluate these options were defined by the participants therefore allowing for a process unconstrained by the method. Ultimately they were grouped into five categories: environment, health, agriculture, social and economic. Each of the options was given a score according to the criteria being used to evaluate it and thus a multi- as opposed to a one-dimensional picture emerges.

The method was found to successfully incorporate a wide spectrum of interests as well as adopting a wide range of criteria (117 criteria were identified by the different participants) that covered ethical and institutional issues as much as more technical factors such as gene flow and toxicity. In particular, because of its openness to include a range of perspectives it did not try and enforce consensus, an important aspect of an iterative and flexible consultation process.

The final rankings obtained by the different participants produced some significant contrasts but also some points of similarity, for example the organic option was popular and conventional intensive agriculture came out poorly.

Whilst this particular case study worked with participants that had some prior knowledge of the issues concerned, Stirling and Mayer (1999) indicate that it might also be a possible technique for involving wider sections of the general public. MCA(M) approaches could thus be particularly valuable in:

- establishing perceived priorities in particularly controversial or emotive situations, i.e. most risk assessment situations;
- exploring more complex issues that may have a wide range of criteria associated with them to evaluate;
- involving a wide range of stakeholders as it offers a means by which a variety of views can be compared and some reconciliation might be found.

7. CRITERIA OF EFFECTIVE PARTICIPATORY RISK ASSESSMENT

7.1 Criteria of effective public participation

The previous review included an extensive discussion of what is meant by effective public participation and presented key criteria for judging the Environment Agency's engagement of the public in the selected licence application process (Petts and Leach, 2000). Key elements of this discussion are summarised here, because it is evident that what is effective participatory risk assessment will be largely determined by consideration of what is effective public participation *per se*. The key principles of effective participation, are usually presented as practical or working principles for adoption which should guide the selection of methods. The principles include:

(i) set clear objectives for participation;
(ii) identify and target all the relevant stakeholders;
(iii) tailor the participation process to the objectives and the needs of the stakeholders;
(iv) set out the process in an honest and understandable way;
(v) ensure that participation is timely and allow sufficient time;
(vi) ensure that the process is credible;
(vii) ensure that the process is interactive;
(viii) ensure that the process generates a response, and
(ix) only make commitments that you will be able to keep.

Often effectiveness has been defined in terms of the outcome – particularly the legitimation of the decision. However, constructs of 'discursive' and 'deliberative' democracy, demand a broader set of effective criteria concerned with the process itself. The focus shifts to a working definition of effectiveness which rather than hoping that everyone will be happy with the outcome (unrealistic), concentrates on getting the 'right science' and the 'right participation' (Stern and Fineberg, 1996, pp 152).

'Fairness' and 'competency' criteria (Webler, 1995; Petts, 2001a) have underpinned many international evaluations of participatory processes. *Fairness* relates to the terms of access to the participative process; providing opportunities for participants to shape the agenda, choose the moderator and the rules of deliberation, and the provision of an equal chance to every participant to put forward their views. *Competence* relates to the ability of the process to provide participants with (i) access to knowledge, explanation of terms and access to interpretations of understanding and (ii) the best procedures for resolving disputes about knowledge and interpretations and for checking the authenticity and sincerity of claims.

What is evident is a move from instrumental to pluralistic evaluations that include ethical and value-based dimensions (Environment Agency, 1998) including the extent to which a process is:

- honest;
- equitable;
- impartial; and
- respectful

Renn *et al.* (1995) compared the application of the various innovative participation methods against the fairness and competency criteria. In terms of access to the process Community

Advisory Committees were considered to be the most restricted with citizen juries somewhere between this and the complete openness provided by study groups.

Evaluation of the two methods as used by British local authorities in relation to the development of waste management strategies (Petts, 2001a) identifies juries as scoring more highly in terms of the representativeness of participants of the general public but lower in terms of opportunities for participants to influence the agenda and rules of procedure. Both processes score reasonably well in terms of the quality of the discussion, learning, and gaining of knowledge although Community Advisory Committees are more successful primarily because of the longer time-frame over which they operate. Juries are relatively poor in allowing for the claims of experts to be tested and verified.

Most of the above discussion addresses the evaluation of specific, individual methods of participation usually operated in line with the traditional form of the method. However, in practice, multiple methods of information provision, consultation and also deliberation may be appropriate if the overall effectiveness of a programme of participation is to be considered. Mixing methods to match overall objectives, and adaptation of methods to meet local conditions or to enable a less costly method to be used is likely to improve effectiveness. For example, a citizens' jury process might be adapted to deal with the deficiencies identified above by running it over a slightly longer period to allow for participants to take a break during the process, to read and look at information from multiple sources and to have an opportunity to formulate questions. During the jury itself there could be opportunities provided for multiple experts to be questioned together in a form of debate as opposed to individual witness cross-examination.

Furthermore, as discussed in Section 6.5, the use of more structured processes such as multi-criteria decision processes needs to be considered to allow for the public to be involved in the actual choice of assessment assumptions, scenarios to be considered, criteria of acceptability, rather than merely being provided with an opportunity to question choices already made by experts. This will start to provide for participation *in* decision-making itself.

7.2 Participatory risk assessment – are different criteria relevant?

The discussion in Sections 2-5, particularly the objectives discussed in 4.3, suggests that participatory risk assessment must provide for:

- Stakeholder and public engagement in the problem definition and framing stage, including the identification of hazards, identification of information needs, and definition of criteria relevant to the risk evaluation.
- Stakeholder, at least, (and possibly the public where local issues are important) engagement in the hazard assessment and risk estimation stage to allow for questioning of technical assumptions, model use, and uncertainty management and to ensure that all relevant information is available to the assessment process or commissioned where missing.
- Stakeholder and public engagement in the risk evaluation stage.
- Open access to information relevant to the risk assessment process.
- Participation to act as a quality assurance mechanism in the risk assessment process.
- Integration of the risk assessment with other assessments and with the decision process (i.e. not just participatory risk assessment but a participatory decision process).

Distinction is made here between stakeholders who may represent particular interests (industrial, regulatory, conservation, etc) and the public who may be representative of particular interests within a community, but who would not take part in a participatory process as a representative of these interests, but as individuals. The distinction is drawn to ensure that the right people are asked to participate to meet the objectives. The stress is placed on the importance of early engagement, in the problem definition stage. Given the objectives of participatory risk assessment it is not evident that radically different criteria of effective participation are appropriate, rather it is necessary to consider whether any additional criteria need to be included to ensure that the staged process of participation suggested is effectively managed.

7.3 Potential Environment Agency participatory risk assessment criteria

It is not the purpose of this review within the context of the overall project, to define specific criteria for a specific participation activity. The objective is to identify evaluation criteria that may be used for the choice and conduct of participatory risk assessment processes. These will be tested against the application of up to two such processes with an evaluation based on the views of both the public participants and also the Agency and other key participating stakeholders. The preferred criteria of these participants will be combined with the generic criteria that are presented here. Inevitably the choice of decision context (e.g. site–specific land contamination decision compared with a strategic flood defence plan) will influence the nature of the methods which can be used and their actual implementation and conduct.

Given the earlier (Sections 2.2, 5.4) observations about the difficulties which applicant-driven, commercially confidential assessments could present in terms of participatory processes, it is evident that the Agency will have to focus its efforts on those risk assessments which it initiates (i.e. the regulatory assessments identified in Table 2.1). It may be in a position to influence applicant-driven processes where these relate to major developments that are known to be contentious and where the full process may benefit from a more deliberative process. However, any such activity will still be outside of regulatory requirements and therefore dependent on applicant support.

It is considered appropriate for the generic criteria presented in Table 7.1 to form the basis of the selection and operation of participatory risk assessment processes These will need to be adapted according to the decision context.

Throughout, the term 'process' is used to refer to the whole participation exercise, which should include appropriate methods of information provision, consultation, and deliberation integrated together. The term 'participant' is used to refer to any person - member of the public, people from the industry/company concerned, Agency staff, members of organised interests (governmental and non-governmental) who may be affected. However, the criteria are presented from a public participation viewpoint as opposed to the institutional/organisational issues which may be relevant only to the Agency. The criteria stress the effective conduct of the process itself as much as the outcome of the process.

Table 7.1 is based upon the criteria presented in the earlier report (Petts & Leach, 2000). Where criteria have been added relevant to the risk assessment process these are highlighted in bold.

Table 7.1: Potential Agency participatory risk assessment effectiveness criteria

Clarity of objectives:

- Are the objectives of the overall participation activity clear both to active and non-active participants, including the limitations of what can be achieved - i.e is the connection made between purpose, process and outcome?

Clarity of legal process:

- Are the legal process and linked processes (e.g. planning) which will influence the decision made clear to all participants, including the limitations but also the responsibilities of these other processes?

Potential decision responsiveness:

- Is the decision open to amendment if agreed to be appropriate by participants (i.e. the decision has not already been taken)?

Clarity of linked processes:

- Are all participants provided with information about other linked participatory and information processes that have been, or will be, undertaken by other responsible authorities and by the Agency?
- Is the process designed to integrate with rather than duplicate or conflict with any other participation activities organised by other authorities?

Consensus on agenda and procedures:

- Is there sufficient opportunity for participants to have input to the agenda for discussion and decisions on the procedures to be used including the choice of facilitator/chairman/moderator?
- If there is no opportunity for participant input prior to commencement of the process, are their opinions sought at the start?
- **Is there opportunity for participants to engage in the problem scoping – including agreement on the definition of the problem and the issues that will need to be addressed?**
- **Is there opportunity for participants to discuss likely data and information deficiencies in the assessment process and to agree how these will be rectified?**

Consensus on effectiveness:

- Is there opportunity for participants to input their own views on what will make the participation process effective and for these criteria to be included in the evaluation?

Representativeness:

- Are the participants in any participatory process representative of the full range of people and interests potentially affected?
- Is the process of identification and selection of any specific participants objective and open?
- Is opportunity provided for new or additional participants to take part in the process if identified by others and it is agreed that their participation would be beneficial?

Inclusivity:

- Are the barriers to participation - physical, social, economic - removed or at least minimised as far as is possible?
- Is the choice of location, times, venues, etc undertaken with due regard to local circumstances and participant preferences?
- Is adequate notice given to participants of the dates and times of any event, and are their views sought on the latter as new events are arranged?
- Are appropriate methods used to ensure that those who do not participate directly are made fully aware of the issue, the consultation being undertaken, where information can be

obtained and a variety of appropriate opportunities provided by which they may make known their views if they wish to?

Transparency:

- Is the participation process transparent and open from inception, through operation, to communication of its outcome?
- Are the views, both for and against, of the majority and minority acknowledged in the outcome?
- Are Agency staff and also officers in other authorities and in the applicant company, who are not directly involved made aware of the participation process?

Deliberation- General:

- Are adequate opportunities provided for participants to engage in dialogue, discussion and group interaction?
- Are adequate opportunities provided to everyone to put forward their personal opinion if they wish?
- Is sufficient time allocated throughout the process to allow effective deliberation to take place and do participants feel that they have had sufficient time to take part to the extent that they want?
- Is disagreement acknowledged and dealt with openly, but also managed to ensure that it does not impact adversely on discussion?
- Does the process enable participants to improve their own anecdotal and intuitive knowledge by being exposed to relevant experiences (e.g. visits to sites, discussion with people who live close to similar facilities, etc)

Technical Deliberation

- Is information provided to ensure that all terms, definitions, technical details, are available to everyone in advance and are clear so enabling people to participate in discussion fully and critically?
- **Is a formal process involved which allows for the concerns and values of participants to be captured and recorded such that the criteria which will be relevant to the risk evaluation are agreed?**
- Is the technical assessment process sufficiently transparent and open to challenge and to input of alternative assumptions if agreed to be appropriate by participants?
- Are adequate opportunities provided for the uncertainty inherent in factual information to be acknowledged, explained and discussed?
- Are knowledge deficiencies openly acknowledged by the official contributors?
- Are opportunities provided for expert knowledge and information to be challenged and claims to be tested through discussion?
- Are opportunities provided for other expert knowledge agreed by participants to be relevant to the discussion to be made available to the process and to be considered directly – i.e. peer review?
- Where questions cannot be answered immediately are adequate arrangements made to ensure that participants receive the information as soon as it is available?
- Where it becomes apparent that information or knowledge is missing or insufficient are resources made available for further work or assessment to be undertaken?

Capability:

- Are all technical experts, organisers and other officials providing input to the process sufficiently skilled as communicators and have received appropriate training?
- **Are all technical experts able to communicate and explain complex science and risk data?**

- **Are all technical experts willing to be open about limitations in current knowledge?**
- Are sufficient financial resources allocated to the process?
- Does the process have sufficient time allocated within the overall timetable to allow for any unforeseen issues and needs to be dealt with and responded to?

Social learning:

- Does the process make a difference to participants in terms of their understanding of the issue and knowledge gained, **in particular their understanding of the risk assessment process and its role in decisions?**
- Does the process lead to an improvement in the public availability of information?
- Does the process promote understanding of different viewpoints?
- Do people enjoy taking part?

Actual decision responsiveness:

- Does the process add value to the decision?
- Are recommendations which represent a consensus of participants' and respondents' views taken on-board in the decision?
- **If the process leads to challenge to existing Agency risk assessment methods and/or decision criteria is the Agency prepared to revisit these?**
- Is the decision communicated to all participants, non-participants and to Agency staff?
- Is an evaluation (preferably independent) of the process completed and the results made known to participants and recorded for input to the design of future processes?

Enhancement of trust:

- Does the process lead to an enhancement of the Agency's credibility as an environmental regulator and promote trust in its **risk** decisions?

8 EVIDENCE FROM AGENCY STAFF INTERVIEWS

8.1 Background to interviews

We have felt it essential in this research to scope the views of Agency staff about public participation and the potential for participatory risk assessment. Seven structured interviews were conducted with senior staff in the Agency, including Head Office staff involved in public participation, team leaders for licensing, process industry regulation and enforcement, and area environmental planning staff.

The interviews were conducted by telephone and lasted up to one hour. They followed a set of questions related to the following: what is perceived by the term participatory risk assessment; the objectives and outcomes of increasing participation in risk assessment; experience of participatory projects; perceptions of public participation in practice; the perceived barriers within the Agency to increasing participation in risk assessment; the types of decision about risk where public participation would be particularly useful, and views about what would make effective participation.

The primary objective was to gain an initial understanding of internal views about participatory risk assessment. It was recognised that Agency experience to-date has been primarily of consultative processes related to regulatory responsibilities but that many staff within the Agency understand the importance of extending participation and some have been involved in broader activities, as indicated in an Agency Workshop on risk perception and communication and a Workshop related to Agency Project E2-030, 'Evaluating Methods of Public Participation' (Environment Agency 2002a).

8.2 Summary of interview findings

The following is a summary of the key points made by the interviewees derived from an analysis of the interview transcripts.

The overall message was that people had a positive view of public participation and felt that the Agency could do more. However, this needs to be considered alongside the fact that the majority of risk assessments are 'owned' by operators and developers who submit them to the Agency for review. There was no reluctance within the Agency to consider in the concept of broadening participation to open up risk assessments to public discussion and challenge. Indeed, a number of beneficial potential outcomes were noted:

- building of local knowledge into the risk assessment;
- the possibility of a more robust decision being taken which is less likely to be challenged;
- the provision of education about risk issues and risk behaviour;
- promotion of "social auditing" of the Agency; and
- the potential to increase trust in the Agency and decisions.

For example, the discussion of risk output at a public meeting, where the Agency had revised proposed monitoring activities related to the management of hazardous waste from the Channel Tunnel Rail Link, noted that "once they'd [the public] seen we'd taken notice of their concerns [...] the process went unchallenged". Another interviewee considered that effective participation would be "if there was understanding that the Agency is acting in the best interests of the environment".

The bulk of respondents' experience was of traditional public participation activities including of public meetings relating to authorisation/licensing issues. Two interviewees articulated concerns about public meetings being attended by people who are experienced in arguing cases and speaking, to the detriment of input by others. One noted that the "vociferous voice" can determine the way that a participation process progresses and that there is a need to be aware of this in the types of event organised. One respondent, describing experience of local liaison group meetings, commented on the "more productive format" offered by small group meetings.

One respondent considered the Agency already engaged in participatory risk assessment but the experience described was of traditional consultation methods with the technical assessment not open to public influence as such but subject to public comment. Few people within the Agency have reason to be familiar with the literature on analytic-deliberative processes as presented in this report. Therefore it was not surprising that the concept of participatory risk assessment was limited to that of discussion of risk assessment output. Importantly, throughout the interviews, there was evidence of a tension between what can practicably be achieved by the Agency and the more extended processes that are discussed in previous sections of this report.

The regulatory framework was seen as a potential barrier to extending participation, not least because the Agency is not always the sole regulator (Section 2) and because there are often time constraints due to regulatory stipulation of response times (e.g. relating to determining licence and environmental permit applications). Where local discussion was already underway (perhaps related to a planning application) then the Agency's involvement in the issue might commence when views may be already polarised. Respondents did express concern that industry may not favour any extended participation as this would be outside of regulatory requirements, yet as one noted, the involvement of the industry was "essential".

All of the respondents had either direct experience of risk assessment and/or understood the difficulties that the Agency has faced in communicating risk information. There was extensive discussion of the perceived technical barriers to participation and the difficulties that the Agency faces in presenting risk information in public.

The interviews suggested different, but not necessarily conflicting, views about the extent to which the public is interested in the technical aspects of risk assessments. The point was made that people can, to an extent, find technical issues difficult but that is because "we're bringing the issues that *we* are expert on...if they are involved in defining the problem or raising an issue that might be different". One respondent suggested that public interest is lower when complex issues such as probability and uncertainty are raised, another that "some things are too complex for the public". However, others noted that it is wrong to generalise about 'the public'.

Many members of 'the public' are themselves experts in technical, scientific and engineering issues. Caution was expressed about generalising about public interests and skills with the view that there was a need to understand different potential audiences and also their potentially different roles in a participatory risk assessment process. There was also concern expressed about the need to communicate technical issues more effectively – for example, using lay language. One person explained how his office had presented a 60-page public document in plain English to explain their decision about an incinerator authorisation. They

wanted to make the information more accessible and to show how issues raised during public consultation had been addressed.

Risk was viewed as a difficult concept to discuss. One person gave the example of where a flood defence system had been built to withstand a 1 in 50 year event but people had been flooded three times in a short period – "the concept of risk can be difficult for them to get their head around – not surprisingly". Another person described how he and colleagues had faced "difficulties" in presenting levels of risk in relation to BSE and the terminology used, citing 'none' acceptably low' and 'negligible' as examples.

Interviewees involved in process industry regulation noted that Pollution Prevention and Control (PPC) applications do not relate to cumulative risks in a local area and yet this is often a concern for the public. In other words, in public debate the risk assessment that the Agency produces or evaluates may not deal with all of the issues of concern to the public. This could impact negatively on any participatory risk assessment process either because the terms of reference would need to be limited, or if these could be extended and the process could involve other parties and authorities responsible for considering other risk issues then there would be implications for resourcing and timing.

Health risks were identified as a difficult area for discussion as the Agency is not always able to deal with the detailed "scientific questions", often needing other technical support or expert advice from other competent authorities. All of the respondents noted health risks as a key current issue for the public. One raised the evidence of increasing public awareness of limitations of current scientific knowledge about some risks – such as health – and the difficulty of responding to questions about future risks. Such comments should direct us to identify appropriate methods that can engage people in more extended discussion of uncertainties and also provide opportunities for people to listen to different scientific views (as demonstrated in a number of the case studies in Section 6).

In two interviews, people noted that specialist Agency staff may not necessarily always be confident about presenting technical issues in non-technical fora and that they may lack confidence which can then impact negatively on public perceptions of Agency performance. One person suggested that some staff might view extended participation as challenging their technical competence or authority. There was also concern "from an operations point of view that it is another skill that you are asking officers to have. It was argued that people who are best at dealing with the technical issues are not necessarily the right people to deal with this type of thing".

Such comments are important in understanding the need to increase confidence in those who have to organise and/or take part in extended participation activities. This is partly about communication skills but also about increasing understanding about what extended participation methods can achieve in practice. As one interviewee concluded:

"Involving the public in risk assessments is going to be a long process. Most Agency staff see public participation as a formal exercise rather than people being able to make a real contribution to a decision. When we get on to participatory risk assessment there could be problems with the acceptance of people's contributions".

9 EVIDENCE FROM SPECIALIST AND NON-SPECIALIST STAKEHOLDER INTERVIEWS

9.1 Background to the interviews

Having collected some initial views of Agency staff, a further aspect of this study was to collect views from specialist and non-specialist stakeholders who might be involved in any participatory processes. Structured telephone interviews were conducted with 23 individuals, in the role of stakeholders:- twelve non-specialists and eleven 'specialists'.

The non-specialist interviewees were, on the whole, 'members of the public' who had had varying experiences of participation/ involvement in environmental decisions in the past. Two of the interviewees had formed action groups as a result of their experience, however, and therefore had more experience than could be expected of most non-specialists. When asked about their familiarity with the Agency, the majority said some, but often only in relation to a specific local issue. The specialist stakeholders included people in NGO/ pressure groups, local authorities and those representing industry.

The interviews were conducted over the telephone. An initial interview, lasting approximately 10 minutes, generated background information about the participant's prior experience of risk and participatory processes, was used to engage them in the research. The participants were then provided with brief reading material (a six-sided summary of some key information from the draft of this literature review) in order to familiarise them with the project prior to the longer, second interview, lasting about an hour. The second interview was recorded and transcribed. The interview questions are included in Appendix 1.

The interviews explored three main areas of interest:

- the perceived effectiveness of the Environment Agency as a regulator, as representing the public interest and as a communicator;
- information sources - including perceived trustworthiness of government, NGO and industry information; and
- their experience of public participation – in particular the current methods being used such as the public meeting and criteria for effective involvement.

It was important to consider that 'risk assessment' may not be defined or recognised by interviewees. Therefore, the interviews focussed on decisions relating to risks in a broader sense. As far as possible in the following discussion of the results, direct quotes are used. A number of questions asked people to grade the effectiveness of the Agency, however, the sample size was too small to warrant presentation of any statistics and often people did not give a clear view, using the prompt more as a means of opening up a discussion. The following classifications are used to identify the type of stakeholder expressing a view:

- N/S member of the public;
- S/LA specialist stakeholder from local authority;
- S/NGO specialist stakeholder from NGO or pressure group;
- S/IND specialist stakeholder representing an industry perspective; and
- S/O other stakeholders who might work in consultancy/ expert roles.

9.2 Perception of the effectiveness of the Environment Agency

In order to understand stakeholder responses to participation organised by the Agency it was deemed necessary to ascertain people's views of the Agency as a regulator. There was a degree of agreement from our interviews between specialist and non-specialist stakeholders, with the greatest differences of view between those representing industry's interests and those who did not.

9.2.1 Perceptions of the Agency as an environmental regulator

The comments below are organised as illustrative quotes from the interviews and represent a sample of the perspectives from both specialist and non-specialist stakeholders. In general there was a view that the Agency is partly an effective regulator and partly not. The common theme underlying the points made is essentially one of power – many people did not feel that the Agency has enough power to regulate the environment effectively:

- 'Not very effective at the moment - not enough teeth, not enough backing. They are more of a monitor at the moment than an enforcer' (N/S)
- 'I don't know how many people there are on the ground checking things but the perception is that there are not enough doing that' (N/S)
- 'Sometimes very good and sometimes very poor' (S/NGO)
- 'In terms of their statutory, regulatory function I would say extremely [effective] but I don't think that they play their part as they should in terms of championing their corner in things that are more discretionary' (S/NGO)
- 'There are some huge failings....partly through unwillingness, partly, sometimes, through incompetence and partly, possibly, because of political pressures' (S/O)
- 'Looked at from an industry point of view...it has been a 'jobsworth' kind of approach - very detailed and regulatory....' (S/IND)
- 'In terms of protecting the environment, yes they are effective; in terms of getting the balance right between over-protective and acceptably protective it's very variable...you often get the impression that the intention is to have a development with zero risk rather than a development with an acceptable and realistic level of risk' (S/IND).

Several respondents and particularly the members of the public commented that is difficult to get information from the Agency and that is not always clear what the Agency has actually achieved. People who were members of NGOs tended to a view that the Agency was not really protecting the environment because it did not "intervene" enough. However, two people did note that the Agency is new and still developing its roles. The following two summary quotes, the first from an interested member of the public who has been involved in a local incineration application, the second from a specialist in an NGO, sum-up quite well the overall opinions:

- 'They are doing a grand job in very difficult circumstances most of the time.'
- 'They should start looking more to do the job that the public thought they were set up to do, safeguard the communities' health and the health of future generations'

9.2.2 *Effectiveness in representing the public interest*

The comments below are indicative of a notion that participation is only done effectively when it is process-led (i.e. part of a regulatory requirement to consult). There were a variety of perceptions about the way public interest is represented by the Agency. Interestingly, there was a difference between industry people who thought that the Agency was on the public's side, and the public and NGOs who thought that the Agency was on industry's side:

- 'They do not represent the public interest, they represent industry interest' (N/S)
- 'I don't think they always know how people think....such a big establishment' (N/S)
- 'They don't involve the community in any stakeholder dialogue - they don't see the community as stakeholders' (N/S)
- 'They....erm...take a rather technocratic approach to it [public interest]' (S/NGO)
- 'Tends to be better if it has a process to follow rather than something more generic' (S/NGO)
- 'Although they purport these days to do that they don't have any interest in it whatsoever' (S/LA)
- 'They are very effective in representing the public interest - sometimes, particularly on contentious issues, they go beyond what is necessary in terms of risk assessment to provide additional justification to the public' (S/IND).

9.2.3 *Effectiveness in communicating issues to the public*

As with effectiveness in terms of representing the public interest, views on the communication of issues were also inconsistent depending on both issue and communicator. Beyond the confines of a process-led approach communication was seen as being "hit and miss". However, this was not necessarily interpreted as a lack of willingness to communicate but due to a lack of resources or a culture that was not supportive of communication and participation:

- 'If they follow the script they are brilliant but as soon as you deviate from the script they are floundering' (N/S)
- 'The information doesn't get to the public effectively' (N/S)
- 'I don't think they really know where to get the information, how to get it to people, where to put it where people would think to consult it' (N/S)
- 'I have had to give them information sometimes and I wouldn't consider myself to be an expert - I was giving them information I would have expected them to give me!' (S/NGO)
- 'If I hadn't been involved thought Friends of the Earth and Green Party contacts I would have known next to nothing about the public enquiry that was going on and the role of the Agency' (S/NGO)
- 'They try very hard but they often seem to miss the mark' (S/LA)
- 'In terms of having a one on one discussion about a particular issue of concern to our business then I think they're quite good; in terms of their wider ability to express the nature and extent of environmental risks to a 'lay' or 'public' audience, I think it's absolutely woeful' (S/IND).

9.3 Information sources

Interviewees were asked about their experience of different information sources - Government, NGOs and pressure groups. Within these categories they were asked about their perceived role in supplying information on risk, the credibility of the source and also the importance of independence.

9.3.1 Government information sources: role and perceptions

People accessed a range of government sources including DEFRA, the Agency, the Department of Health, and the Health and Safety Executive. However, this was easier for the specialist stakeholders. Members of the public usually either had no experience of government information or tended to use local government information sources. Context was seen as being very important - if approaching an election, for example, issues were perceived to have been dealt with differently. Non-specialists stressed the importance of independence, however, specialists tended to be more sceptical – 'expert' services are 'always paid for by someone.'

In the pre-interviews the discussion of trust and different sources of information produced familiar responses amongst the non-specialist stakeholders. People were asked to allocate a score of 1-5, where 1 is high trust and 5 is low trust. Government departments were ranked 3-5 (i.e. medium to low trust). NGOs were ranked 2 by everyone (i.e. medium to high trust). Industry was accorded the same rankings as government departments to a large extent but with a slightly larger score at 5. Academics received a spread of rankings depending on whether people considered that they were paid by government departments to provide advice, the majority of these being 2.

9.3.2 Non-governmental and pressure group information sources

NGOs and pressure groups were regarded as important information sources by both specialists and non-specialists particularly for providing the 'alternative viewpoint' and raising the profile of an issue. However, it was recognised that NGOs and pressure groups had the potential to be "emotional" and "single-minded", although possibly more at a local rather than national level. The reliability of information from these groups was considered to therefore vary enormously. Therefore as with all information it was considered important to read it critically. Most people were aware that NGOs would put their own slant on an issue. The comment of one member of the public sums up the views: "In the main I think that it is always wise to have a pressure group, but treat it at arms length"

9.3.3 Information from industry: perception and role

Most non-specialists had not used information from industry; most specialists had but had struggled to obtain it. Industry was perceived to have an important role as they have the fullest data sets and the best understanding of complex industrial processes. They were seen as having an important communication role in gaining the trust of the public, and there were several comments on the lines of "they should be producing something, they have a responsibility". However, some industries or industry associations were regarded as more responsible than others.

Non-specialists, almost without exception, said that independent experts would be more credible in producing information on behalf of industry. Specialists were more sceptical – "if anyone commissions research to prove a point and the research doesn't say what they want it to say then they are unlikely to publish it" (S/NGO). All research is funded - if commissioned from industry it is considered likely that it would put forward a particular point of view.

9.4 Public and the risk assessment process

This section of the interviews explored potential barriers to participation; the potential stages at which the public could become involved in the decision-making relating to risk; the issues surrounding public meetings (as the traditional approach) and the importance of various criteria of effectiveness in a participatory process.

Public meetings were selected because these have to-date been the most common form of participation that either people or the Agency have been involved in. It is likely that some form of public meeting will be required in any participatory process. Indeed, Agency Project E2-030 "Evaluating Methods of Public Participation" identified that members of the public favoured some form of public meeting because these are genuinely open to anyone to attend. However, the project also identified that traditional forms of public meeting should usefully be adapted to provide for more discussion and to provide for some form of pre-meeting at which public concerns and questions could be identified.

9.4.1 Barriers to participation in risk assessment

Non-specialists saw more barriers than specialists to wider involvement in the risk assessment process. Specialists felt that there was no avoiding science and technical issues and that people have to take these on board if they want to participate. In many ways the problem was not seen as being the scientific and technical language *per se* but the overtly jargonistic manner in which this can be expressed: "mindboggling"; "gobbledegook" were two descriptions used. One member of the public questioned why, if NGOs can turn science into lay language, cannot official bodies do likewise?

A typical comment from specialist stakeholders was that,'[We] shouldn't underestimate the public in terms of understanding complex issues' Accessibility was seen by the majority as being a key issue – "it is sometimes very difficult to find exactly what you need and have to know where to look".

9.4.2 Stage of involvement in the process

The Royal Commission on Environment and Pollution's diagram relating to the building of public values into decision making (see Figure 2.2) was used as a focus for discussion of when the public might participate. For the purposes of the interview this diagram was discussed as including four possible stages when participation could be important:

1. At the stage where the problem or issue is first being discussed
2. At the stage where you or your organization may be asked to identify the criteria/ key elements that will be used to help specify the risk
3. During the risk assessment process when technical experts are actually working on the data
4. When you will be asked to evaluate before a decision is taken.

Overall, the majority of respondents (specialist and non-specialist) wanted to have input at all stages of the risk assessment and decision process. Amongst non-specialists the least popular stage was during the risk assessment itself (Stage 3 above) although this was only a minority view. In relation to Stage 1 – concepts of the "earlier the better" and "people must be involved in actually understanding that there is a problem in the first place" were expressed by two members of the public.

In relation to Stage 2 the following was comment from a member of a local NGO (not a specialist) who had been involved in a locally contentious incineration application and who stressed the importance of local knowledge in the scoping of issues:

- 'Framing the questions – obviously the person viewing the proposal is viewing it on a technical basis and may be blinkered a little by this. What they are not aware of is the local conditions which may influence the decisions that are made'

The larger NGOs stressed the importance of involvement at the strategic level when issues of need were open to consideration.

Involving the public in a process early and often was seen as 'the best way of avoiding difficult situations'. Non-specialists tended to discussion indicating a feeling of disempowerment by the way the system of decision-making is currently organised.

Most people felt that the Agency would gain the most relevant input at the outset of the process (problem definition) and/or at the end (decision-making). Arguably the public are involved only at stage 4 at the current time. The main reasons for involving people earlier than this were:

- 'Should go in at the very beginning with the public and listen to what the public's concerns are and answer truthfully' (N/S)
- 'Many different sectors of the public, with different perspectives, could be brought to bear on an issue' (S/NGO)

It was also observed, however, that close involvement throughout a process should be provided for if there is scope for the decision to be influenced:

- "The worst possible thing to do is to consult and then not to be able to respond to the consultation" (S/IND)

Practical considerations did come into play:

- 'We are all part of a community. As individuals they can't all go to all of the meetings. But as a community what I think that people would like is that between us we could cover all of the stages' (N/S)

9.4.3 Views of public meetings

The interviews then explored the value of public meetings. The information is presented in two graphs divided according to responses from non-specialist (Figure 9.1) and specialist stakeholders (Figure 9.2). Some respondents did not feel able to comment on these statements.

Figure 9.1 – Views of non-specialist stakeholders about public meetings

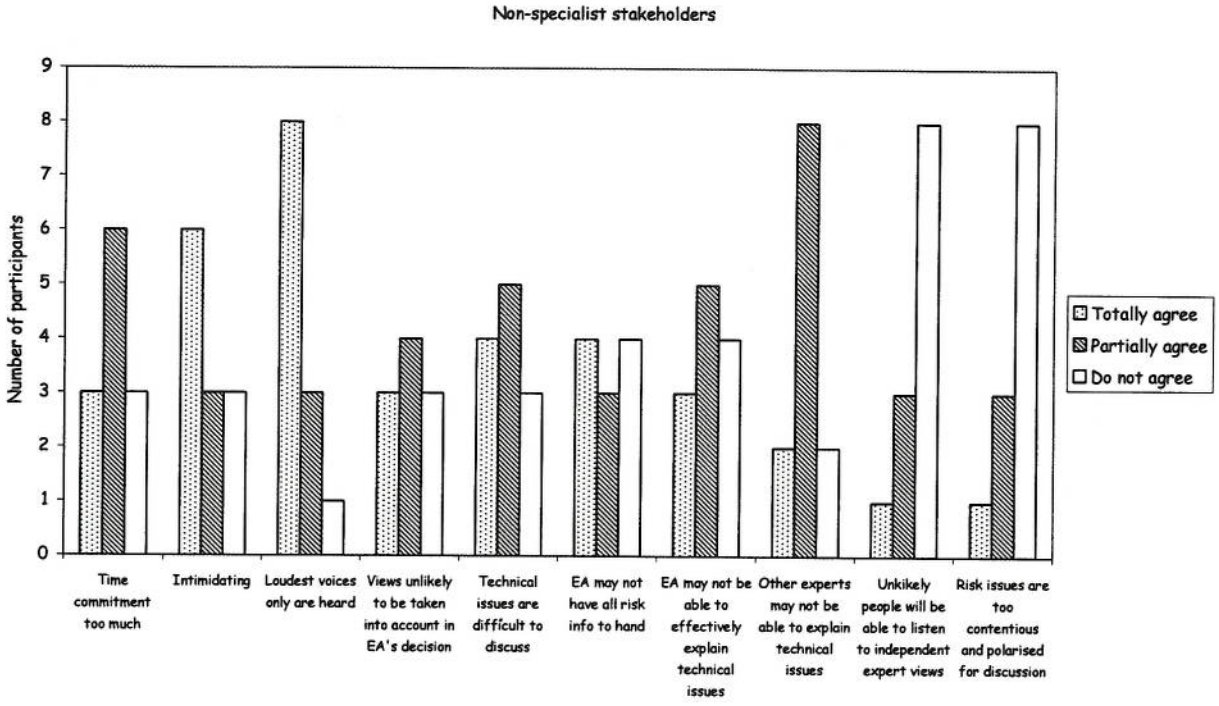
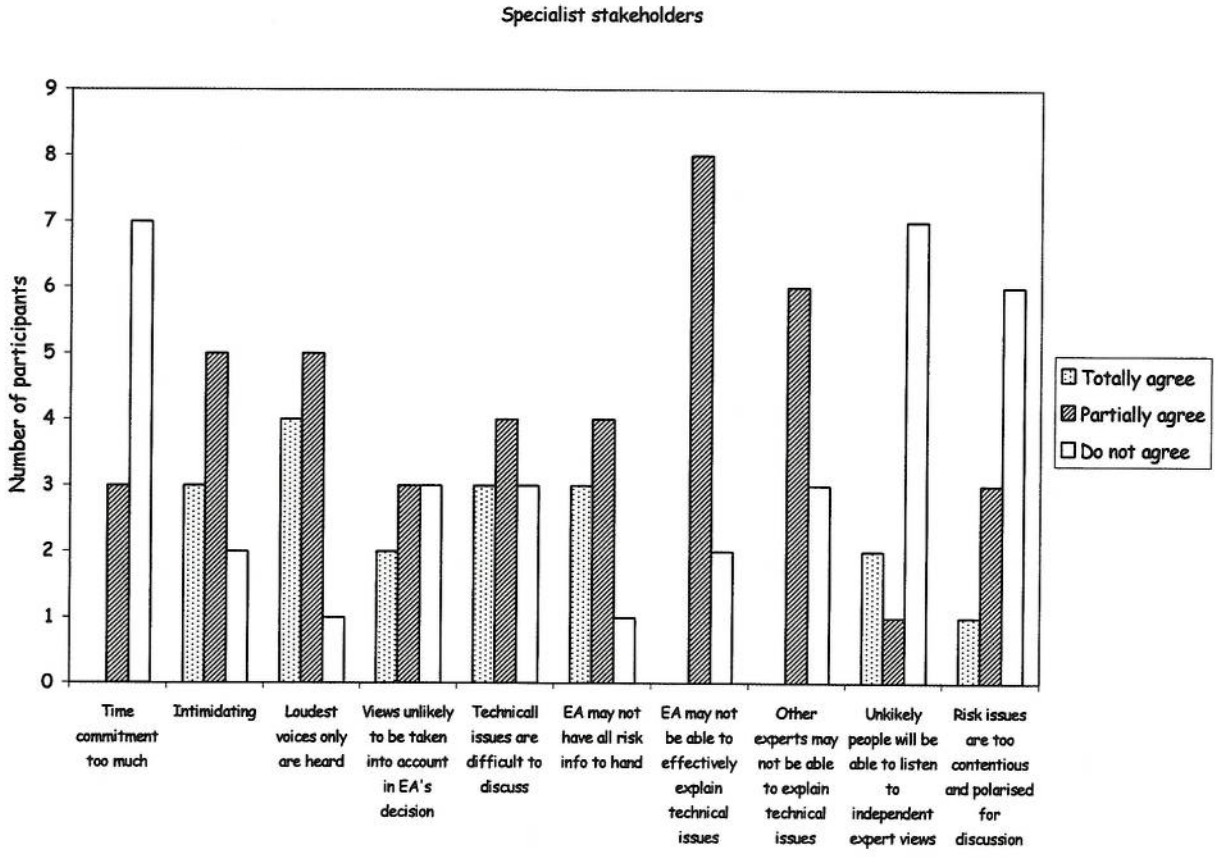


Figure 9.2 – Views of specialist stakeholders about public meetings



The Figures mainly differ in terms of the more logistical issues, for example, that the time commitment for individuals may be too much. The specialists' perspective was that people should make time if the issue is important, non-specialists saw more potential problems. Similarly, non-specialists were more likely to find public meetings intimidating - perhaps indicative of the fact that amongst the specialists many had been involved at meetings from a different perspective and therefore remain unaware of the difficulties for some people in contributing.

Interestingly, a main point of departure between specialists and non-specialists was in terms of the Agency and their ability to explain technical issues to the public. Many of the specialists were quick to note that this depended on the particular individual present. However, whilst their impressions in many cases were formed from being required to attend numerous meetings, non-specialists might only have been able to gauge an impression from one or two meetings and thus were less aware of variation.

There was agreement amongst respondents that risk issues are not too contentious and polarised to allow for discussion. This is not to say that risk issues do not generate contention but that public meetings should be able to deal with this, indeed:

- "there is no point having a public meeting if you only discuss the things that everyone agrees on" (N/S).

There was also optimism that public meetings do provide for people to listen to independent views.

9.4.4 Criteria of effectiveness

Seven criteria of effectiveness were adapted from those presented in Section 7: consensus on agenda; representativeness; inclusivity; opportunities for discussion; transparency; clarity of the linked decision processes; adequate time, and a decision which is responsive to the findings of the public participation. Interviewees were asked how important they thought each of these were and how likely it was that they would be able to be implemented.
Perhaps not surprisingly most of the respondents felt that all of these criteria were very important. In terms of the twelve non-specialists all of the criteria were graded as very important by all of the respondents except for two people who graded opportunities for discussion as 'not very important' A number of people noted with regard to time that whilst this was very important it is also the case that decisions do eventually have to be made and cannot be indefinitely deferred. A number of specialists also felt that the notion of consensus should be approached with some caution. They expressed the hope that the Agency is not looking at the whole process as a way of getting the public to 'rubber stamp' their decisions.

9.5 Conclusions

The interviews revealed a perceived, varied success to-date of communication and participation by the Agency with stakeholders. In particular, there seems to be a lack of a consistent approach, which means that people gain different impressions of the effectiveness of the Agency according to region, issue and individual. The interviews revealed a considerable enthusiasm for much earlier involvement in risk decision-making including most importantly in the framing of the problem but they also emphasised the importance of being able to affect the outcome. For the industry respondents (a very small sample) there was not

any evidence of an adverse response to the need to broaden participation *per se*, but there was also not a view that this was definitely something that they should be initiating. Further work with industry representatives is necessary to explore their role.

10 CONCLUSIONS

10.1 Risk assessment is increasingly being viewed in participatory terms, in response to the 'risk society' debate, evidence from the risk communication literature, the environmental justice agenda, and a growing understanding of scientific values. There are official calls for increased stakeholder involvement from 'problem definition' or 'framing' through to the evaluation of risk estimates. The transition to a 'right-to-know' society is requiring greater public access to these assessments.

10.2 Mechanisms for stakeholder involvement in risk decisions, however, while understood have to-date not been adopted widely and still require evaluation in practice. Even at the international level experience is limited, although there are increasing attempts to apply participative processes to policy, plan and project-level decisions. These more participatory processes have been demonstrated to be effective in reaching decisions, as discussed in Section 6, although it would be naive to assume that a more inclusive and deliberative process automatically results in lack of contention in relation to the decision. Indeed, as was raised in the interviews with the stakeholders, involving the public may result in more diverse opinions as opposed to consensus.

10.3 There is evident difficulty in defining risk decisions, and in practice caution is needed in viewing public participation as being limited to the risk assessment. It is rare that risk issues can be separated from the broader environmental, social and economic elements of decisions. Furthermore, as examination of the decision contexts in which the Agency is involved has revealed it is rare that the Agency is the sole decision-maker or is itself using risk assessment as the only decision tool.

10.4 We need to establish at what stages, and in what ways involvement can be incorporated meaningfully (Pollard *et al.*, 1999). The current debates on deliberative and inclusionary processes and on 'analytic-deliberative processes' informs this development. The challenge is to develop *informed* processes that enable decisions involving science to be debated widely in a social context. This report has reviewed the Agency's different decision responsibilities and has developed criteria for effective participatory decision processes where risk is an important issue within the decision. The criteria were tested in the interviews with stakeholders, and the majority agreed that they were very important.

10.5 At present the public tend to become involved in the later stages of decision processes, i.e. at the point of evaluating risk assessment output before the final decision is taken. Even then it may not be possible for the public to influence the decision that is made. This review has indicated strongly that involvement of the public needs to be much earlier in the decision-making process: i.e. at policy and strategy level rather than just at the local, licensing and decision level. Indeed, the interviews with stakeholders have revealed a desire to have input above the level of the risk assessment itself: i.e. involvement at a more strategic level to evaluate options that may consequently rule out a risk assessment altogether and in the actual definition of the problem and identification of the issues and information that need to be considered. There are considerable opportunities for involvement of the public in the government's waste strategy development, and in regional waste strategies for example, as opposed to the current situation where it is primarily official, organised and representative interest groups that are involved.

10.6 A key aspect of the decision-making process is to ascertain the role that stakeholders can realistically have. If there is no potential to influence a decision then participation can create false hopes. In some cases it is clear that consultation, as opposed to participation, is required. It is important to establish, therefore, the risk decisions that can be made using more deliberative techniques. This will form the basis of the next part of the project.

10.7 The interviews both with Agency staff and with stakeholders reveal enthusiasm for greater participation but also pragmatic understanding of the difficulties and barriers. There is little doubt that within the Agency there will be a need to increase the confidence of staff to engage in these processes and to show that extended participation in risk decisions will bring benefits. Indeed the Agency is responding to these opportunities (Boxes 10.1 and 10.2), but, in general is not entirely surprising that stakeholders suggested that they had met with Agency reluctance to engage with, and assimilate, ideas from third parties beyond the regulatory requirements for consultation because practice as yet is not well-developed.

10.8 What is clear, therefore, is the need for the Environment Agency to develop more deliberative techniques for involving the public in the decision-making process. This would benefit the Agency in terms of quality of decisions reached and the trust it would gain with the public, it would also have the potential to increase scientific literacy amongst the public and enable them to have greater ownership of decisions made. Whilst doubt is frequently expressed about the ability of the public to participate in technical debate, interviews clearly demonstrated that this is a misconception - it is the presentation of this material that causes the problems rather than the material *per se*.

Box 10.1 Folkestone to Rye Coastal defence Strategy Study Consultation and Roadshow

The Folkestone to Rye Coastal Defence Strategy Study was conducted to reduce the risks to people and the environment from flooding and coastal erosion. Commissioned jointly by Shepway District Council and the Environment Agency in partnership with consultants HR Wallingford, the Strategy recommends the provision of sustainable coastal defence measures.

In finalising the Strategy, a series of meetings and road shows provided opportunities for stakeholders to participate in shaping the future management of the coastline. Information was also made available thorough the internet at www.folkestone-rye.net. At each road show the key findings of the study were on display and members of the project team available to discuss issues. The road shows were widely advertised and designed to achieve maximum attendance levels by a careful selection of venues and dates, including weekends in high tourism areas so as to capture input from recreation interests. The road shows proved a popular and accessible means for inviting comment and over 1000 visitors were recorded, representing a diverse spectrum of stakeholders from MPs to local residents.

In the region of thirty or so concerns or aspirations expressed at the road shows, reflecting both common and site-specific issues, are considered in the final Strategy Study. For example, the predicted impact of changes in geomorphology on the capabilities of local fisherman to launch their vessels will now be studied in greater detail. In so far as these concerns related to coastal defence issues, the Strategy incorporated the information provided by consultees and offered solutions and feedback where feasible.

Box 10.2 Magnox Consultation

The Magnox consultation process provides a good example of extended consultation and greater openness in practice. In January 1998, British Nuclear Fuels Limited (BNFL) applied to the Environment Agency for authorisations to dispose of radioactive wastes for each of its eight ageing Magnox power stations. The Agency approached the consultation offering a more open and accessible consultation process. Members of the public were invited to discuss the proposals for each site at public meetings. Local surgeries (one-to-one meetings with Agency staff) were held before and after each public meeting, providing opportunities for a more informal exploration of the issues of concern. The package of consultation documents was made available on the Agency's website and as a CD-ROM, in addition to the conventional paper format. Where additional concerns were expressed – for example, over a proposal for a small incinerator – the Agency organised further meetings for local people, and extended the submission deadline for comments.

While the consultation generated interest around specific local issues such as the incinerator, no national campaigns developed and, in general, polarised positions were avoided. The opportunities to discuss concerns individually with inspectors, and the willingness of the Agency to hold additional public meetings were appreciated by local people. Some of the lessons from the Magnox consultation – such as the need for technical information to be presented in a way that is more accessible for lay people - have been taken on board in subsequent consultations on nuclear sites, specifically in the recent Sellafield consultation.

10.9 The review has established the following requirements for participatory risk assessment:

(vii) the integration of information provision, consultation and participation methods for all risk-based decision purposes if the key criteria of representativeness, inclusivity, potential decision responsiveness and enhancement of trust, are to be achieved;

(viii) use of methods which optimise opportunities for deliberation and multi-criteria assessment must be included;

(ix) a staged process which optimises stakeholder and public participation at key stages within the assessment process – i.e. problem definition and framing; assessment; evaluation;

(x) adaptation of methods and process to meet the different decision contexts and timescales over which regulatory assessments have to be conducted;

(xi) achievement of a careful balance between consultation overload where multiple participation activities might be organised, - for example, by the Agency, the local authority and a developer/applicant, - and

(xii) meaningful participation in the public's mind which will require evaluation of participation activities.

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APPENDIX 1: INTERVIEW SCHEDULES

Participatory Risk Assessment – E2-043
Questions to (non-) specialist stakeholders

Initial Phone Call to (Non-) Specialist Stakeholders

I am ringing to ask you if you would be willing to be interviewed for a project we are working on with the Environment Agency, called Participatory Risk Assessment.
The objective of the project is to develop risk assessment guidelines for third parties to enable the Agency to guide wider stakeholder involvement in risk assessments for the benefit of better uptake of regulatory decisions.

The purpose of the interviews is gain a (non-) specialist stakeholder perspective of how risk issues are viewed, their information requirements and how they would like to be involved. This will then contribute to the formulation of guidance to involving wider stakeholders in risk assessments.

The interview will last about 40 minutes, we will pay for the call. You will be provided with a small amount of background information in advance so that you have time to think about what we will be asking. The interviews will need to be tape recorded, because I cannot write that fast! However the tapes are purely for the purpose of producing an accurate record of the interview and will be destroyed when this has being done.

1. **Are you interested in participating in this project?**

If no:
Thank you for your time. Goodbye.
If yes:
Can I ask you a few questions now to enable us gain a better understanding of your previous involvement in local consultation and participation processes?

You may find it helpful to have a pen and paper handy to make some notes

2. **Have you / I know you have been involved in expressing concern about a local project/s (or national issue). Could you tell me a bit more about your involvement?**
   - **2a** What were you involved in/what was the topic you were looking at?
   - **2b** Whereabouts was this?
   - **2c** How long ago was it?
   - **2d** Why did you want to be involved?

Keep in mind the project you have been involved with as I ask you the following questions.

3. **In our experience there are often a number of reasons why people become concerned about a project (that is proposed in their community). There are some concerns which are more common than others, five of the most common are:**

1) Concern with the health risks that the project may pose to the **health and safety** of people (living in the community);
2) Concern with the potential impact (of the project) on **natural systems and the environment**;
3) Concern that **enough may not be known about the potential risks** to the environment / health;
4) Concern with the **nuisance impact of the project** on the neighbourhood such areas as traffic, congestion, visual impact, attracting additional industry, property values, quality of life; and
5) **Concern with the kind of facility** that is being proposed and **mistrust** of how it will be operated.

You may find it useful to record the key points.

3a Which of the five issues I have told you about would you say were of concern to you?
3b Which of the five issues would you say were of concern to your local community? (rephrase where necessary)
3c Were there any other areas of concern which were not covered in the list which you think may related to risk in some way?

4. **In general if you wanted to know more about the health, environmental, nuisance or mistrust risks of a project, or a new policy, Who would you turn to, or where would you go for information?**

5. **On a scale of 1-5 (1 being trust completely, 2 being trust somewhat, 3 being neither trust nor distrust, 4 being distrust somewhat, and 5 being distrust completely) how would you rate the following as being a source of information:**

   5a Government Departments
   5b NGO's, national bodies who are often statutory consultees, national environment groups.
   5c Academics associated with colleges and universities.
   5d Industry, specialists based with industry or consultants
   5e Independent organisations, not for profit organisations, and royal societies.

Thank you for answering those questions. The next steps will be that we will send you some material to read as background and then call you two weeks from now. If when you have read the written material you have any questions or concerns then please call me and I will hopefully be able to help you.
What would be a good day to call you for the next part of this exercise, what time?

Participatory Risk Assessment – Project Ref. E2-043
Questions to specialist and non-specialist stakeholders

Follow up - Phone Call Two

Did you receive the written material we sent you?

As you know from our first conversation and from the material we sent you, this project is sponsored by the Environment Agency and is designed to put in place processes that will ultimately help people to be better able to assess the risks associated with a specific project

The questions are divided into three sections: the first looks at the Agency itself; the second looks at information sources; and the third looks at the involvement of the public in risk assessment processes.

Section One
I would like to start the questions by knowing something about your own knowledge/experience with the Environment Agency:

1. **I would like to start by asking you some questions about your knowledge of the Environment Agency.**
   Would you say that you have:
   i. A lot of knowledge about the Agency;
   ii. Some familiarity with the Agency; or
   iii. Little or know nothing about the Agency.
   If iii who do you think the Agency is?

The background information, which was sent out to you, went into some detail about the Environment Agency's role in risk assessment processes. The EA are a Government Agency set up to protect the natural environment and regulate processes within the environment.

2. **With regard to your knowledge of the Environment Agency, would you consider that the *EA is an effective regulator in protecting the environment*?**
   Would you say that the Agency were:
   i. Very effective;
   ii. Reasonably effective; or
   iii. Not very effective.

Why?.....

3. **With regard to your knowledge of the Environment Agency, how effective would you see them being *in their role as representing the public interest in deciding* whether a new facility should receive an operating licence?**
   Would you say that the Agency is:
   i. Very effective;
   ii. Reasonably effective; or
   iii. Not very effective.

Why?.....

4. **With regard to your knowledge of the Environment Agency, how effective would you see it as being *in communicating information about the specific risk* that a project or development poses to the health of the community or the environment?**
   Would you say that the Agency is:
   i. Very effective;
   ii. Reasonably effective; or
   iii. Not very effective.
   Why?.....

5. **When you were thinking about how effective the Agency were in any of these areas we have just talked about, what did you see as the main role/s for the Agency?**

6. **As we indicated this project is entitled 'Participatory Risk Assessment', what do the *words Risk Assessment mean to you?***

Section Two

Now I would like to ask some questions that link risk assessment to your own background in having some concerns regarding a project proposed for your community/a project that concerned your group

7. **In our initial interview with you, you indicated that the most important concern(s) you had with the related to the potential risk a project might pose to health/ the environment/ nuisance/ lack of trust of the proponent). In the original interview these were:**

1) Concern with the health risks that the project may pose to the **health and safety** of people (living in the community);
2) Concern with the potential impact (of the project) on **natural systems and the environment**;
3) Concern that **enough may not be known about the potential risks** to the environment / health;
4) Concern with the **nuisance impact of the project** on the neighbourhood such areas as traffic, congestion, visual impact, attracting additional industry, property values, quality of life; and
5) **Concern with the kind of facility** that is being proposed and **mistrust** of how it will be operated.

Have you thought of any other concerns since the initial interview or as a result of reading the background information that we sent through to you?

Now looking at your specific area of concern what kind of information would have helped you to assess how much of a risk:
the environment was being exposed to;
the community was being exposed to,
the track record of the proponent.

When/ if receiving or accessing any information relating to risk that was provided by a government department (local or national)

Can you tell me anything you remember about the information?
Did you find it helpful?
What was it about the information that you found helpful?

In general what do you see as the kind of role or responsibility that Government sources might play in producing information about risk?

On a scale of 1-5 how would you rate Government in terms of its effectiveness in providing credible sources of information about risk? (1 being completely effective, 5 being completely ineffective).

Earlier we discussed the EA. They are required to provide to the public the information that they receive from the operator as part of an application.
Would you give the material which is assembled by Environment Agency the same score or a different score?

Would you find the information about risk:

- More credible if it was produced by the government department itself.
- More credible if the government department contracted out the risk assessment to external experts in that field.

8. **Now thinking about the same question but this time applying it to non-Government sources/pressure groups can you remember receiving, accessing any information they might have provided about risk**
   Can you tell me anything you remember about the information?
   Did you find it helpful?
   What was it about the information that you found helpful?

   In general what do you see as the kind of role or responsibility that NGO/Pressure groups play in producing information about risk?

   On a scale of 1-5 how would you rate NGOs pressure groups in terms of their effectiveness in providing credible sources of information about risk? (1 being completely effective, 5 being completely ineffective).

   Would you find the information about risk to be:
   - More credible if it was produced by the NGO/pressure group itself?
   - More credible if the risk assessment was commissioned to independent experts?

9. **Now thinking about the same question but this time applying it to companies, who may be operators of plants which require a risk assessment to be carried out, or industry associations which represent industries. Can you remember receiving, accessing any information they might have provided about risk**
   Can you tell me anything you remember about the information?
   Did you find it helpful?
   What was it about the information that you found helpful?

In general what do you see as the kind of role or responsibility that companies or industry associations have in producing information about risk?

On a scale of 1-5 how would you rate companies or industry associations in terms of their effectiveness in providing credible sources of information about risk? (1 being completely effective, 5 being completely ineffective).

Would you find the information about risk to be:

- More credible if it was produced by internal experts in the company or industry association?
- More credible if the risk assessment was commissioned from independent experts?

Section Three

10. **What do you see as the difficulty that people experience in reading/understanding information about risk assessment?**

11. **Can you tell me if there are any issues you see as relevant around the following points?**
    - Are there any aspects relating to the complexity of the science which you see as relevant?
      Yes No
      Which aspect?
    - Are there any aspects relating to the technical terms and language which are used by experts which you saw as relevant?
      Yes No
      Which aspect?
    - Are there any aspects relating to the availability of written information which you see as relevant?
      Yes No
      Which aspect?
    - Are there any aspects relating to any gaps or uncertainties that you feel exist in experts opinions which you see as relevant?
      Yes No
      Which aspect?

12. **We sent you a diagram taken from the Royal Commission on Environmental Pollution's 21st Report on Setting Environmental Standards. Considering the following stages would you like the opportunity to express your views if an issue/project came forward which was of concern to you:**
    Step One At the stage when the problem or issue is first being discussed
    Yes ! No ! Other: !
    Comment:

Step Two At the stage when you or your organisation may be asked to identify the criteria/key elements that will be used to help specify the risk;
Yes ! No ! Other: !
Comment:

Step Three During the risk assessment process when technical experts are actually working on the data;
Yes ! No ! Other: !
Comment:

Step Four When you will be asked to evaluate before a decision is taken.
Yes ! No ! Other: !
Comment:

13. **As we look at those four steps involved in assessing the risks posed by developments, how would you prioritise *where your involvement would be most effective*. Why?**

14. **If you were looking *at where the Agency would gain the most relevant input* from the community, where would you say that was? Is it the same as where you would gain the most information or different? Why?**

Finally I would like to ask some questions regarding various forms of events that are typically held to inform the community:

15. **What would you expect to hear at a typical public meeting held after the risk assessment work had been done, but before a decision had been made?**
    What kind of information would you expect to receive?
    Who would you expect to attend?
    What information do you feel is typically missing at meetings of this kind?

16. **I would like to read to you some statements that people make regarding the difficulties people experience in participating at public events about developments where risk issues are discussed. I would ask you to indicate if you 'totally agree' with the statement, 'partially agree' or 'do not agree'.**

a) The time commitment required in attending a public meeting is too much for most people
b) A Public Meeting is an intimidating forum for members of the public
c) A Public Meeting only ensures that those with the loudest voices are heard
d) Views expressed at a Public Meeting are unlikely to be taken into account in the Environment Agency's decisions
e) Technical issues are difficult to discuss in a Public Meeting
f) The Agency may not have to hand all the risk information that is required at the meeting
g) The Agency may not be able to explain effectively technical issues to the public
h) Experts may be required to offer technical information and sometimes they are not able to explain effectively technical issues to the public
i) It is unlikely that a Public meeting will allow people to listen to independent expert views
j) Risk issues are too contentious for a public meeting and view too polarised to allow for discussion.

17. Bearing in mind the issues you felt were attached to public events, the following are a number of criteria, which could be relevant in ensuring that risk discussion is easier. How important do you consider the following:

a) Consensus on Agenda (all participants have opportunity to raise issues for discussion)
Very important Not very important Not relevant

b) Representativeness (participants are representative of the full range of people & interests potentially affected)
Very important Not very important Not relevant

c) Inclusivity (barriers to participation – e.g. location, cost, time etc – are minimised, and those who cannot participate directly are informed of issues)
Very important Not very important Not relevant

d) Discussion (adequate opportunities provided for discussion and dialogue)
Very important Not very important Not relevant

e) Transparency (process is transparent and open)
Very important Not very important Not relevant

f) Clarity of linked processes (people are made aware of other linked participation and decision processes)
Very important Not very important Not relevant

g) Time (adequate time is allowed for people to understand technical issues)
Very important Not very important Not relevant

h) Decision response (consensus views of the public are taken on board in the decision)
Very important Not very important Not relevant

Now I'd just like you to review those issues again and indicate to me on a scale of 1-5, how likely that you feel it would be possible to implement.
Finally, anything I have not covered or anything else that you would want to mention to me / or a message to pass on to the Agency.

CONSIDERING 'ENVIRONMENTAL HARM': QUALITATIVE AND SEMI-QUANTITATIVE TREATMENTS FOR STRATEGIC RISK ASSESSMENT

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Abstract

A central problem for risk assessors and managers is the *characterisation* of risk, and more specifically, the expression of risk significance. Conventionally, environmental risk has been characterised by reference to environmental quality standards that act as surrogates for presumed 'harm'. Such standards focus on the magnitude of impact and do not easily capture harm attributes such as irreversibility, or latency of onset. At a strategic level, comparisons of harm from hazards of wide ranging characteristics becomes complex, but is nevertheless essential for prioritising regulatory effort. We present for discussion, some recent research and development work undertaken for the benefit of informing our own strategic risk assessments. Semi-quantitative and qualitative methodologies under development are presented and their applications discussed.

Introduction

The conventional approach to considering detriment to the environment (from chemical releases, for example) has been through the comparison of environmental concentrations with an environmental quality standard. In general, the adoption of standards has served regulators well at the site specific level, in so far as they provides clear objectives for industry and other regulated groups as to what environmental levels are considered acceptable for various uses in different environmental media. A recent review, conducted by the Royal Commission on Environmental Pollution[1], has commented on how standards are used and derived. At the strategic level, however, where data are often either sparse, or conversely, too voluminous, 'coarser' assessments are more often required to inform strategic decisions and prioritise regulatory effort. These strategic studies often rely on an informed view of the broader characteristics of harm (or potential harm) posed by the hazard(s) under study and usually centre on a consideration of observable impacts.

The Environment Agency of England and Wales (hereafter, the Agency) is one of Europe's largest regulatory bodies with regulatory and supervisory powers across the areas of environmental protection, water resources and flood defence, recreation, navigation and conservation. Beyond its 'front-line' regulatory work, the Agency is involved in setting environmental priorities at the area, regional and national level and in developing long-term strategies for its activities, by reference to the goal of sustainable development. This type of strategic work needs ways by which observable or potential impacts from a variety of existing or future hazards can be compared alongside one another in order to inform corporate planning and resource decisions. This is a complex activity and tools in use are often 'broad brush' and focus on a 'Boston Box'[2] approach or versions of it, sometimes formalised into ranking systems. Two strategic risk assessment (SRA) tools currently being developed by the Agency to consider environmental harm are briefly presented below.

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Developments on structured approaches to considering 'environmental harm'

Semi-quantitative tool. Initial work has been focussed on providing a ranking tool for environmental impacts from different sources that could then be tested on data derived at local, regional and national levels[3]. The objective was to bring the tool to a proof of concept stage. In broad terms, development of this tool has focussed on:

- assessing whether it was possible to identify key relationships that could be used to map different environmental impacts from a range of human and natural activities by reference to the *characteristics* of environmental harm; and
- evaluating whether these relationships could be *normalised* to allow a comparison of environmental impact through the use of a simple ranking system.

Following an initial feasibility study, a model was structured using 'look up' tables, populated with elicited criteria for what were regarded as the key attributes of harm:

(a) the potential scale of the effect (H); ranging, for chemical contamination, from 'presence without overt effect' (low) to effects at the community level with 'long-term irreversible effects' (severe);
(b) the potential status of the receptor (R); sensitivity in terms of local, national or international designation; and
(c) the persistence of the hazard (acute to chronic relative to receptor life-time; T1) and reversibility of impact with respect to each receptor and/or media (readily to irreversible; T2) and

The indices are ranked and scored using the above criteria and the scores shown in Table 1 with the shaded areas indicating areas of unacceptable harm. A spreadsheet was then used to compute a normalised 'harm index' for each hazard-receptor combination, by estimating 'harm' as: $\sqrt{[H^2 + R^2 + (T1 + T2)^2]}$.

Table 1: Severity matrix for the semi-quantitative ranking of environmental harm

Criteria	Severity rank (and scores)			
Scale of Effect (H)	Low (1)	Medium (2)	High (4)	Severe (8)
Status of Receptor (R)	Low (1)	Medium (2)	High (3)	Severe (4)
Persistence in Media (T1)	Acute (1)	Short-term (2)	Medium-term (3)	Chronic (4)
Reversibility (T2)	Readily reversible (1)	Medium-term (2)	Long-term (3)	Irreversible (4)

The tool was piloted for applicability at a local and national scale by using data from the River Teign Local Environment Agency Plan (LEAPs are catchment-based local environmental strategies) and from the Agency's "State of the Freshwater Environment Report" (which provides a national, strategic overview). These pilot studies showed that the issues identified by the SRA tool were generally similar to those identified by other approaches. The tool also provided a scaled ranking of the issues and allowed meaningful comparisons and the prioritisation across a range of geographical scales (e.g. between and within regions). A structured approach offers the prospect of a framework for improved objective setting, prioritisation and monitoring, although as with all such ranking schemes, it is important to ensure that the numerical scores are not overrated.

A qualitative approach to considering socioeconomic aspects. Ranking tools such as those discussed above inevitably raise issues of weighting and the values ascribed to the various attributes. Formalisation of these issues is always a complex matter. The level of information available on the social and economic impacts of environmental damage is often sparse and its collation and presentation can be contentious. As a consequence, a qualitative (rather than semi-quantitative) approach is now being considered to integrate these aspects.

In concept, the approach involves capturing the key characteristics of environmental harm (magnitude, reversibility, spatial and temporal extent, latency etc.), using key words, or

'attributes' with meaning in a technical and socioeconomic context. In the first instance, a number of candidate interpretations from the literature were reviewed[4-6] with the objective of developing a view on the value of the different approaches considered. An initial set of attributes were developed and tested on a local case study for initial applicability. This information was presented and discussed at a workshop[7] to obtain feedback from a wider audience of Agency colleagues and external experts actively involved in this field. In considering the attributes of harm, it was assumed for simplicity that the "source-pathway-receptor" relationship was already established and that realisation of the hazard results in some degree of damage. Without prioritisation, a total of 22 potential attributes of harm were initially identified. For each attribute a description, a qualitative scale and examples were provided. Examples of these attributes, together with the proposed scales are presented in Table 2.

Table 2: Examples of attributes of harm identified in the initial framework

Attribute	**Scale**				
	Low	**Intermediate**			**High**
Spatial	Point source	Local	Regional	National	Global
Reversibility	Reversible in short period	Reversible in weeks	Reversible in years	Reversible in decades	Irreversible
Dread	None	Specific individuals affected		Groups of individuals affected	Widespread
Mitigation potential	Not required	Controllable by simple management procedures		Controllable by complex and active management	Cannot be controlled

The workshop concluded the following:

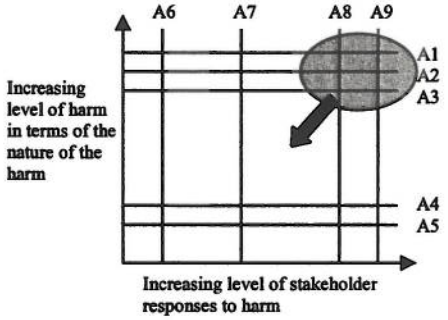
(a) The complexity of the task can be overwhelming, but the need was for a straightforward framework that could be easily applied by non-experts in environmental risk, albeit with some expert assistance;
(b) The issue of agreed definitions is recurrent. There is considerable potential for conflicting and overlapping meanings especially when incorporating multidisciplinary inputs;
(c) A central challenge is the context-specific nature of individual impacts, which makes the selection of a 'core set' of attributes, and meaningful comparison between impacts difficult – case studies can assist;
(d) In general, the approach was thought to be useful within a regulatory context, but needs refining and requires testing on a number of "real" case studies. Often, statute has specific definitions of what constitutes environmental harm that may over-ride a general treatment;
(e) Further consideration needs to be given on how to handle uncertainty;
(f) It may not be helpful to force distinct technical, social and economic interpretations on the various attributes. For example, the *magnitude* of an environmental impact can be described in technical, social *and* economic terms – a more holistic treatment is sought, but can very difficult in practice to operationalise;

With reference to the latter point, two sub-lists can be recognised -

(a) those attributes that describe the nature of the harm, i.e. which may be used to indicate the extent to which an activity, event or process is harmful; and
(b) those attributes that describe the values we place on the nature of the harm.

One way of integrating and thus, operationalising the various attributes may be to consider them graphically, by plotting the attributes that describe the nature of the harm on the vertical axis and the attributes describing stakeholder reactions to 'harm' (i.e. how we feel) on the horizontal axis (Figure 1). Figure 1 also provides examples of individual attributes that might fall under these categories. Each of the attributes is scored on a qualitative scale (as shown in Table 2) so that attributes that have been plotted it the shaded area of Figure 1 will cause the highest overall impact in terms of the nature of the harm or the perception of that harm. This sort of approach can be used in decision-making to target the impacts that are causing the greatest concern.

Figure 1: Graphical representation and examples of attributes



Examples of attributes that describe the	
nature of the harm	human responses to harm
• Temporal extent • Spatial extent • Stock at risk • Severity • Likelihood	• Mobilisation potential • Uniqueness • Tolerability • Dread • Imposition

Conclusions

The approaches developed have value as coarse screening tools allowing the assessment of various issues at a strategic level. They also allow for a common understanding of environmental harm, highlight its multivariate nature and enable comparability across different effects and different sources. There is value in developing a structured approach, but it is recognised that its viability, how to adopt it and when it would be appropriate to use such a framework need to be clarified further.

Acknowledgements

The authors wish to thank the Environment Agency for permission to present this work and colleagues in the National Centre who contributed to its development. They also wish to acknowledge the combined efforts of the expert participants to the Agency's Workshop on Environmental Harm, held at Heythrop Park, Oxfordshire, 29 June-1st July 1999.

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Strategic Risk Assessment: A Decision Tool for Complex Decisions

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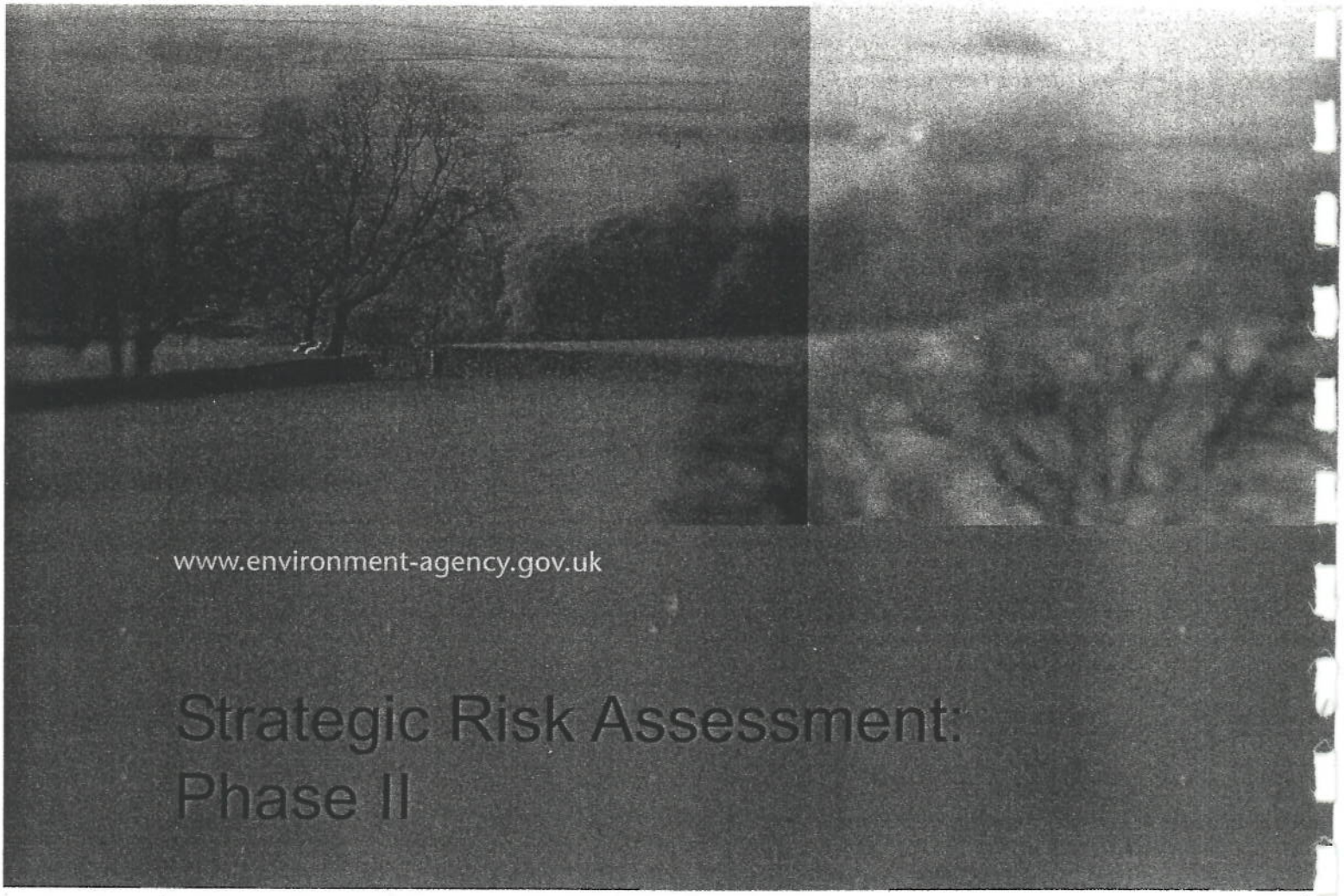
1. Introduction

Reporting on the state of the environment often requires policy makers and regulators to prioritise a range of diverse environmental issues for the purpose of directing future action on environmental protection and improvement. Information on environmental issues to inform this type of analysis can be disparate, it may be too voluminous or even absent. Data on a range of issues are rarely presented in a common format that allows easy comparison. Nevertheless, strategic judgements are required on the significance of impacts from various environmental pressures and on the inherent uncertainties. Prioritising issues forces a discussion among stakeholders of the relative significance of 'environmental harm' [1] from pressures acting on various receptors in the environment. Discussions of this sort rapidly evolve into a discourse on risks and values.

In an attempt to help systematise these discussions and provide practical tools for the analysis of environmental risks at a strategic level, the Environment Agency of England and Wales has initiated developmental research on strategic risk assessment [2-5]. The tools developed under this research use the concept of 'environmental harm' as a common currency, viewed from technical, social and economic perspectives, to analyse impacts from a range of environmental pressures. Critical to an informed debate is an understanding and analysis both of the various characteristics of harm (spatial and temporal extent, reversibility, latency, etc.) and of the social response to the actual or potential environmental harm [4, 6]. Recent developments in this approach [5] allow a presentation of the analysis in a structured fashion so as to better inform risk management decisions.

Here, we present recent developments in the strategic risk assessment research tool, as tested by case studies from state of the environment reporting and the analysis of a regional environmental plan [5]. We discuss its relative advantages and limitations and its wider potential role among a range of strategic appraisal tools for environmental assessment.



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Strategic Risk Assessment: Phase II

R&D Technical Report E2-041/TR

ENVIRONMENT AGENCY

Strategic Risk Assessment: Phase II

Environment Agency R&D Project E2-041

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Statement of Use
This report describes the development of a tool to compare strategic risk issues according to their potential for environmental harm. The comparison is based on non-weighted attributes of environmental harm. The tool is intended as one tool for Agency personnel to assist in risk prioritisation, options appraisal, and risk management.

Key Words
Strategic risk assessment, environmental harm, social response, options appraisal, risk management, uncertainty.

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FOREWORD

The Environment Agency of England and Wales invited me to undertake a peer review of this document in November 2001. My review and that of Professor Ortwin Renn are included as Appendices below. This document aims to present a framework and set of tools that can be employed to compare a wide set of often diverse environmental risks, to assist the screening and prioritising of risks, and to provide useful information and analysis valuable for selecting management approaches. This is no small task and the issues involved are complex and difficult. The approach presented in this document has a number of important advantages or assets, particularly:

- the method explicitly addresses both technical and social considerations that must be included for any broad-based and effective assessment tool that will be useful for management;
- the framework and method are systematic and comparative;
- both qualitative and quantitative modes of assessment are captured in the procedures;
- a high degree of transparency and replicability is achieved; and
- the tools strike a good balance between sophistication and simplification so that the approach is accessible to decision makers and public alike.

The intention as I understand it, is for the method to develop through application and testing. At this point, having reviewed the method, I anticipate that the following areas for potential improvement may need to be considered as experience is gained:

- the potential for catastrophic events, we know, is a major driver of "knock-on" events, public concerns, and management attention - a more explicit treatment of the expected level of harm and the potential catastrophic nature of worse cases may be required;
- uncertainty may best be considered as a separate key variable - even several dimensions of uncertainty could perhaps be depicted;
- deliberative processes and how they may be embedded in such a scheme; and
- a number of more detailed questions on issues such as procedural equity, social blame, implicit an explicit weighting of variables and cost effectiveness of risk reduction may require clarification and resolution as experience in applying the scheme is obtained.

While any approach can always be added to and improved upon, the reach of this approach into relevant social issues of risk is admirable and a major advance over other available schemes. This is a thoughtful and sophisticated addition to existing methods which should provide valuable information and analysis to risk decision makers.

Professor Roger Kasperson
Executive Director, Stockholm Environment Institute

EXECUTIVE SUMMARY

Prioritising disparate environmental risk issues forces a discussion both within an organisation and among stakeholders of the relative significance of "environmental harm" from pressures acting on various receptors in the environment. Discussions of this kind rapidly evolve into a discourse on risks and values. Harm to the environment is conventionally assessed by reference to the magnitude of the impact. However, this does not account for other important characteristics of the harm, such as delayed onset, irreversibility and spatial and temporal extent. Neither does the magnitude of the harm necessarily reflect economic or social values that society places on different components of the environment. These broader aspects are critical to strategic decision-making, and become particularly important when prioritising issues at the regional, national and international scale.

Strategic judgements are increasingly required on the significance of impacts from various pressures on the environment and on the inherent uncertainties that accompany them. This is a challenge that has confronted senior managers within government and across a range of industrial sectors in recent years – how to manage resources in a sustainable manner that is both justifiable and accountable to an organisation's key stakeholders. Strategic risk management tools have been developed, "championed" and applied in the nuclear, oil and gas, and pharmaceutical sectors – to name just a few. This report presents the development of a strategic risk assessment (SRA) tool by the National Centre for Risk Analysis and Options Appraisal (NCRAOA). The tool is now at the stage of needing testing in real decision-making situations so that the potential benefits of the approach to the Agency can be realised.

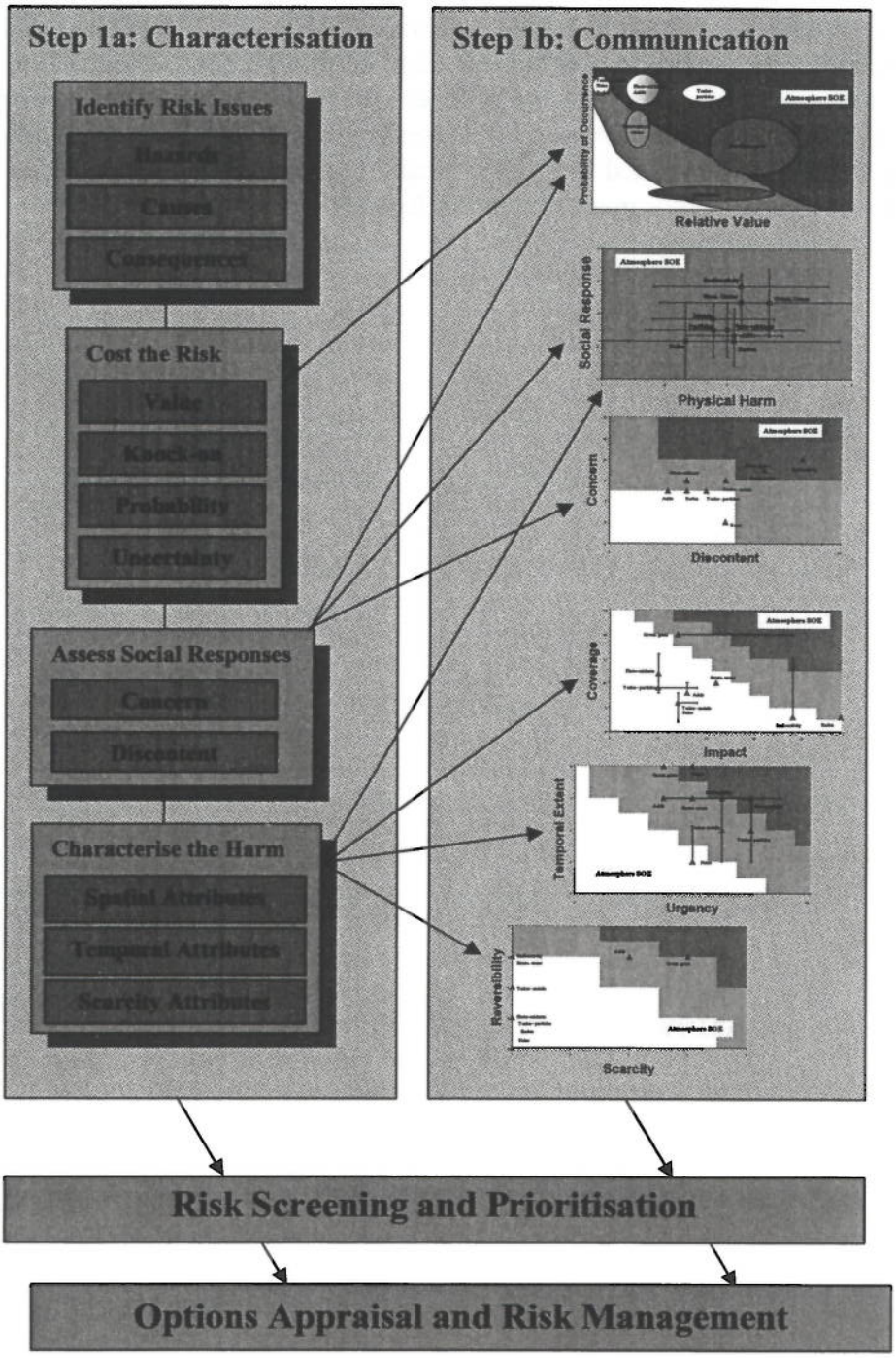
The SRA tool presented in this report compares environmental risk issues using the concept of the environmental harm related to the issues as a common currency, viewed from technical, social and economic perspectives. A set of generic attributes are scored on a qualitative common scale for each issue to capture the physical, social, and economic characteristics of the environmental harm associated with the issue. Of particular note is the tool's explicit focus on drawing together technical information relating to the chief characteristics of a potential environmental risk issue with a consideration of the societal responses or impact associated with the realisation of the risk.

The SRA tool encourages a systematic, traceable, and transparent analysis of different environmental risks. The output is a documented characterisation of the risks, in terms of common attributes and scores, and a series of presentational schematics showing the characterisation. The intention is that the tool be used, where appropriate, by Agency to inform:

- Risk screening and prioritisation: the attribute scores can be examined in isolation and in summary schematics to help identify and prioritise key risk issues from various standpoints. Different presentational styles can be adopted to help present and justify decisions for different audiences (e.g., senior managers, the public, technical groups).

- Options appraisal and risk management: different presentational styles can be adopted to identify which aspects of each risk issue are of most potential concern and/or present particular problems. These aspects can then form an input to an options appraisal concerned with identifying which actions might be most effective and appropriate in managing risk issues.

The application of the SRA tool is illustrated below.



The SRA tool has been developed over a period of time through expert review, peer review, workshop application and case studies. Importantly, it is intended to provide an additional aid to strategic decision making on environmental issues – and not the sole or necessarily preferred method.

Phase II of the Agency's work represents a significant step forward in the development of SRA tools. First and foremost, the SRA tool seeks to bridge the gap between technical assessments of the characteristics of environmental risk issues on the one hand, and the social

responses to those risk issues on the other. This has particular benefits when moving from risk assessment to the role of helping to consider risk management options. Second, it works at a number of strategic levels by allowing a high-level view of current and potential issues facing society, supported by assessments tied to established empirical data where available. Third, it has the potential to incorporate economic data to compare the "value" of risk issues in economic terms – albeit such data are not yet always available. Finally, it pays particular attention to the issues of transparency in assessment and the communicability of findings. These characteristics are judged to be of critical importance if the tool is to be used as an aid to decision-making by senior managers in the Agency.

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1. INTRODUCTION

1.1 Background

Strategic judgements are increasingly required on the significance of impacts from various pressures on the environment and on the inherent uncertainties that accompany them. This is a challenge that has confronted senior managers in government and across a range of industrial sectors in recent years – how to manage resources in a sustainable manner that is both justifiable and accountable to an organisation's key stakeholders. Strategic risk management tools have been developed, "championed" and applied in the nuclear, oil and gas, and pharmaceutical sectors – to name just a few. It is our view that the advantages of the strategic risk assessment (SRA) tool set out in this report deserve testing in real decision-making situations in order that the potential benefits of the approach can be realised.

Prioritising issues forces a discussion both within an organisation and among stakeholders of the relative significance of "environmental harm" (Environment Agency 2000a) from pressures acting on various receptors in the environment. Discussions of this kind rapidly evolve into a discourse on risks and values (Environment Agency 2000b) – empowering both regulator and stakeholders to make clear the basis for those strategic decisions that affect the environment.

Reporting on the state of the environment often requires policy makers and regulators to prioritise a range of diverse issues for the purpose of directing future action on environmental protection and improvement. Information to inform this type of analysis can be disparate, it may be too voluminous or even absent. Data on a range of issues are rarely presented in a common format that allows easy comparison. Harm to the environment is conventionally assessed by reference to the magnitude of the impact, often through reference to environmental standards in air, water, soil and biota (RCEP 1998). However, the use of standards as surrogates for harm does not account for other important characteristics of the damage, such as delayed onset, irreversibility and spatial and temporal extent. Neither do standards necessarily account for the economic or social values that society places on different components of the environment (RCEP 1998). These broader aspects are critical to strategic decision-making, and become particularly important when prioritising issues at the regional, national and international scale.

The Environment Agency of England and Wales, and its predecessor bodies, have recognised the need for a framework for the multidisciplinary analysis of environmental risks at a strategic level. This is highlighted by various pieces of work undertaken in recent years that have aimed to tackle the issue of environmental harm in a variety of decision-making contexts (see, for example, DETR 1998 and 1999, Environment Agency 1999a). To this end, the Environment Agency's National Centre for Risk Analysis and Options Appraisal (NCRAOA) initiated developmental research on strategic risk assessment tools to help inform the prioritisation of risk issues. The approach is to compare issues using the concept of the environmental harm related to the issues as a common currency, viewed from technical, social and economic perspectives.

Phase I of the Agency's research produced a semi-quantitative tool for SRA that was tested on two case studies (Environment Agency 1999a). However, problems highlighted in the application of the tool were the lack of quantitative data to populate it, and the subjective manner in which the data were normalised. Under Phase II, the NCRAOA has continued to develop the SRA tool based around a more qualitative approach, along the lines of other

international environmental groups (e.g., WGBU 1999, USEPA 1999). Some of the key aspects that Phase II of the work has aimed to accommodate include:

- Inclusion of physical, social and economic values of the environmental harm without contentious weighting.
- Flexibility to allow for the paucity of quantitative data available or suitable to characterise the environmental harm.
- Broadness to allow the consideration and comparison of a diverse range of issues with differing associated environmental harm and differing levels of risk.
- Allowance for uncertainty in, and lack of knowledge about, the nature and extent of the environmental harm.
- Support of decision-making and promotion of traceability and transparency in decisions.
- Communication of findings to different audiences with different needs and familiarity.
- Creation of a balance between over-simplification and over-complication in order to achieve all of the above.

This report presents the development and testing of the SRA tool under Phase II.

1.2 Purpose of a Strategic Risk Assessment Tool

The SRA tool presented here is intended as one tool among many to assist in decision-making, and for review of decision-making, on environmental priorities and risk management strategies in the Environment Agency. It is also intended to facilitate communication and explanation of decisions to different audiences. For example, along with other approaches, it may be considered for use in:

- Helping to develop priorities for resource allocation or consideration of alternative forms of regulatory action on different environmental risk issues.
- Prioritising sets of disparate issues within strategic areas of interest (e.g. agriculture, chemicals).
- Preparing responses to the issues raised by State of the Environment (SOE) Reports.
- The development of Local and Regional Environment Agency Plans (LEAPs and REAPs).
- Providing input to the Environment Agency's response to the strategic plans of Regional Development Agencies, and Unitary and Local Authorities.

Of particular note is the tool's explicit focus on drawing together technical information relating to the chief characteristics of a potential environmental risk issue with a consideration of the societal attitude associated with the realisation of the risk. It must be emphasised that the SRA tool is not intended to be used in isolation; rather, it is intended to complement other appraisal tools and procedures being developed and used by the Environment Agency. In principle, the more information and aspects that can be taken into account in decision-making, the more balanced the decision. Further, the SRA tool is not intended as a substitute for technical assessments at the site-specific level or to replace the use of environmental standards as a means of assessing damage to the environment. Nor is it a substitute for environmental appraisal, focused social research or specific legitimate dialogue with stakeholders into the societal implications of an environmental risk issue.

1.3 Structure

The first phase of development for this work has been reported in Pollard *et al.* (2000). The tool has since been refined and tested on several case studies, both by Agency staff and as part of a research and development project undertaken by Galson Sciences Limited. This report is the main deliverable from the research and development project. It provides an overview of the general approach taken (Section 2) and details the components and application of the SRA tool (Section 3). Section 4 provides an overview of the use of the tool in assisting with risk comparison, and providing input to options appraisal and risk management. The SRA tool has been tested on a series of different case studies, chosen to reflect national and regional strategic assessment (Section 5 and Appendices A to C). Key issues arising from the application of the tool are discussed in Section 6. Finally, conclusions from the work presented and implications for future use are presented in Section 7.

A presentation of Phase 2 of the Agency's work on SRA was given at the VALDOR conference in Stockholm in June 2001. The paper submitted to support the presentation is included in Appendix D. Two peer reviews of this work have been commissioned as part of the research and development project. The first by Professor Ortwin Renn of the Centre for Technology Assessment in Stuttgart was undertaken on an initial draft of this document developed after the first two case studies. This is included as Appendix E. The second peer review was undertaken by Professor Roger Kasperson, Executive Director of the Stockholm Environment Institute. This peer review is included as Appendix F and has also been used to develop the foreword to this document.

2. GENERAL APPROACH

2.1 Definitions

The definitions of some of the key terms used in this report are set out below.

Environmental harm	A deleterious pressure on the physical, social, and/or economic environment.
Hazard	A property or situation that in particular circumstances could lead to harm (here, specifically environmental harm).
Consequences	Adverse effects or harm that cause the quality of the environment (including human health) to be impaired in the short or longer-term.
Receptor	An individual/group or an environment that suffers the consequences of exposure to a hazard, i.e., the harm.
Risk	A combination of the probability, or frequency, of occurrence of a defined hazard, and the magnitude of the consequences of the hazard.
Risk issue	A collective term used here to capture risks that are uncertain to occur (i.e., probability < 1) and hazards whose effects are already being realised (i.e., probability = 1).
Risk assessment	The qualitative and/or quantitative estimation and evaluation of risks, covering *inter alia* physical, social, and economic consequences and perceptions, probabilities, and uncertainties.
Risk management	The process of implementing decisions about accepting or altering risks.

2.2 Development of a Multi-Attribute Approach

There are two particular problems faced by any tool used to compare different issues or features associated with an environmental programme, project or concern. These are the possible exclusion of important information, and the derivation of a "score" that involves the amalgamation of information using a possibly contentious weighting.

The need to present and consider the multiple aspects of environmental harm has been recognised by a large number of national and international bodies concerned with environmental protection (e.g., RCEP 1998, WGBU 1999, DETR 1999, USEPA 1999, Environment Agency 2000b). The work presented here has built on the experience of these other bodies, and has adopted an approach that involves capturing the key characteristics of environmental harm (e.g., magnitude, reversibility, spatial and temporal extent, latency) using key words, or "attributes". The attributes have meaning in both technical and socio-economic contexts, and are applicable to the characterisation of harm resulting from a wide and diverse range of risk issues.

The final list of attributes selected for the SRA tool has developed through a series of steps:

1. Environment Agency Phase I research on strategic risk assessment (Environment Agency 1999a) produced a semi-quantitative tool that, in the first instance, focused on three attributes:
   - the potential scale of the harm (H);
   - the persistence of the hazard (T1);
   - reversibility of impact (T2); and
   - the potential status of the receptor (R).

   The attributes were scored on a scale of 1 to 4 or 1 to 8, and an overall score derived from $\sqrt{[H^2 + R^2 + (T1 + T2)^2]}$. The tool was tested on two case studies. Problems identified in the application of the tool were the lack of quantitative data to populate it, and concerns over the subjective normalisation of the data in the scoring. These are well-recognised challenges associated with these kinds of tool.

2. In progressing this work, NCRAOA reviewed the qualitative approaches to strategic risk assessment adopted by other national and international bodies, including:
   - the German Advisory Council on Global Change (WGBU) strategy for managing global environmental risks (WGBU 1999);
   - the Department of the Environment, Transport and the Region's (DETR's) approach to Management of Unplanned Releases to the Aquatic Environment (DETR 1998);
   - DETR's approach to assessment of harm to the environment following a major accident (DETR 1999); and
   - the United States Environmental Protection Agency Scientific Advisory Board's approach to ranking ecological risks (USEPA 1999).

   The WGBU approach of classifying risks qualitatively in terms of key attributes and uncertainties, and in linking risk management strategies to the different classes of risk, in order to assist in defining management priorities was considered potentially useful (Pollard *et al.* 2000). However, it was unclear how the approach could be adopted in a formal and consistent manner to aid the Agency's decision-making processes. Further, the presentational classification of risk issues by was deemed complex.

3. Building on the approaches of the reviewed schemes, NCRAOA derived an initial set of common attributes to attempt to capture the key characteristics of environmental harm. The initial set of attributes was tested on an operational risk issue - a proposed extension to a domestic landfill that in the future could take special waste, but which was situated above a groundwater source protection zone.

4. Following this initial exploration, NCRAOA hosted a two-day workshop in 1999 with Agency and external participants to obtain feedback on the approach from a wider audience with technical, social and economic expertise. Based on the discussions, the attributes were reassessed and a consensus reached on a core set of attributes, their definitions, and a qualitative scale for each attribute. The attributes were classified by those that describe the characteristics of environmental harm ("A" attributes) and those that describe social responses to the harm ("B" attributes). The revised attributes were tested on the Environment Agency's draft "State of the Environment 2000" report.

5. This Phase II report is concerned with further refinements of the SRA tool. Particular aspects that were considered included:

- *Presentational aspects*, i.e., how to combine the presentation of attributes in a realistic and meaningful manner. It is important not to create a false message when presenting a multi-dimensional problem in two dimensions by oversimplification. Further, different audiences have different presentational requirements and expectations (see Section 3).

- The need to assess *impacts and actions separately*. The SRA tool is intended to compare environmental risk issues, usually at a regional or national level (see Section 3). It can also be used to identify key aspects of risks to feed into options appraisal for risk management actions and strategies (see Section 4). However, to avoid confused messages and comparisons, these two uses of the tool are viewed as distinct.

- The *treatment of uncertainty*. Given a common lack of data, it is important to try to capture the uncertainty both in the probability of various risk issues occurring and in the assessment of the environmental harm (see Section 3). For use of the SRA tool in a regulatory context, it is also important to try to capture the aspects of a precautionary approach in characterising risks with uncertain or insufficient data and with potentially latent and irreversible impacts (see Section 6).

Under Phase II, the SRA tool has been tested on case studies (see Section 5) and developed so that it can be applied by Agency staff, with further modification as necessary to assist in risk prioritisation and inform options appraisal.

2.3 Use of the SRA Tool

The SRA tool is based on qualitatively scoring a set of generic attributes that have been developed to capture the physical, social, and economic characteristics of the environmental harm associated with any risk issue. The identification of the risk issues, the associated harm, and the characterisation or scoring of the harm attributes requires an understanding of the attributes and familiarity with the risk issues. Therefore, the scoring process should involve a group with expertise that covers the physical, social, and economic arenas of the environmental harm being scored, and should be facilitated by an individual who has experience of the tool. The intention is that the SRA tool is used by Agency personnel. Such personnel will have some understanding or perception of the values that might be placed on harm by various stakeholder groups. However, in some applications, it may be necessary to acquire such stakeholder inputs firsthand. In such cases, stakeholder representatives could be included in the scoring group.

Once the scoring is complete and the basis for each score is documented, the SRA tool can be used to assist in two areas on the Agency's risk framework (Figure 2.1):

- Risk Screening and Prioritisation: the attribute scores can be examined in isolation and in summary plots to help identify and prioritise key risk issues from various

standpoints. Different presentational styles can be adopted to help present and justify decisions for different audiences (e.g., senior managers, the public, technical groups).

- Options Appraisal and Risk Management: the attribute scores and summary plots can be used to identify which aspects of each risk issue are of most potential concern. This information can be used as one input to appraisal of the most effective and appropriate options for managing the risk issues.

The use of the SRA tool is illustrated in Figure 2.2. The attributes, the selection of risk issues and the scoring of the attributes, the presentation of results, and the use of the tool in risk screening and in options appraisal are discussed in the following sections[1].

[1] **Note on risk rating systems**
The use of risk ranking systems for informing risk management is well established. Whilst these systems do have their critics, designed well, they can improve regulatory efficiency and offer incentives for better risk management. The selection and grouping of the individual risk factors is conducted according to the needs of the individual scheme. The Environment Agency's Operator Pollution Risk Appraisal (OPRA) system, applied to the resourcing of regulatory inspections within the process sector, has risk factors grouped by the inherent pollution hazard posed by a facility and those dependent on the operator's performance in managing the hazard. The design of risk ranking systems can be contentious because the scale of risk represented by scores is often arbitrary - only the relative risk between facilities has meaning. One benefit of "scoring" over a qualitative descriptor of risk, however, is in distinguishing between probability and consequence contributions to risk. Experience in the US and UK demonstrates that these systems need to be simple, clear, piloted prior to wider use and made reproducible.

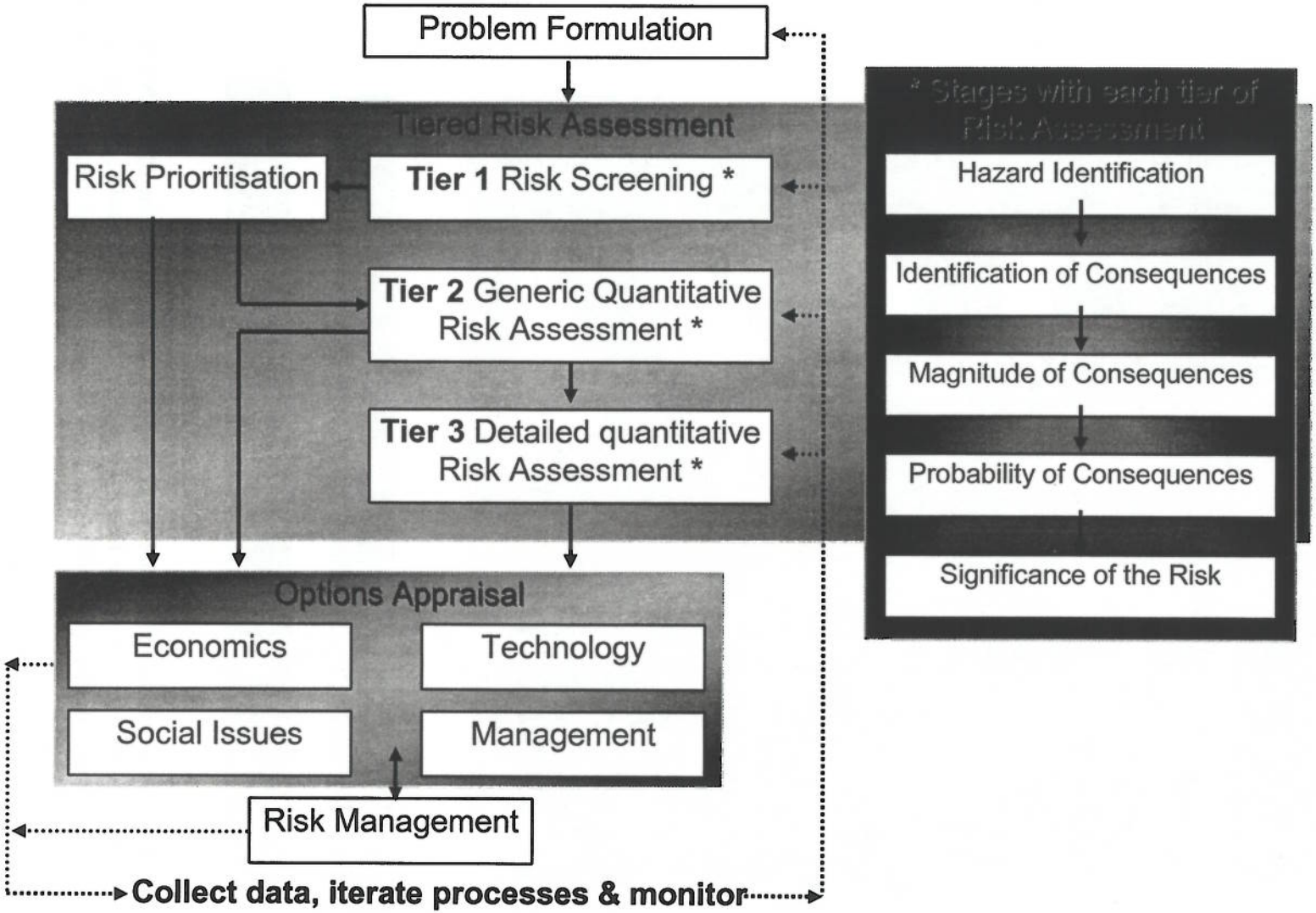


Figure 2.1 The Agency risk assessment framework (from DETR 2000)

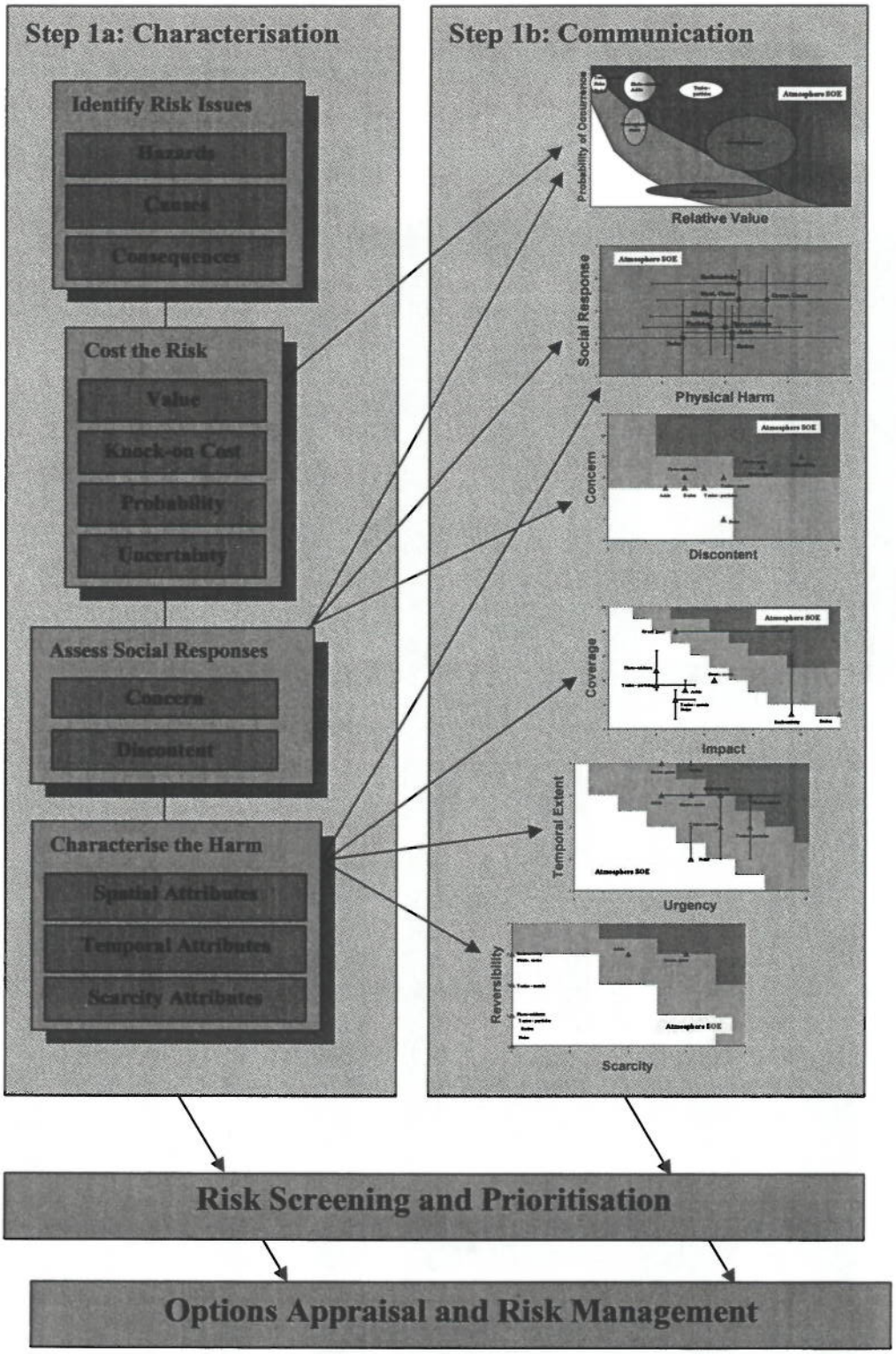


Figure 2.2 **Flow chart illustrating the main steps in the application of the NCRAOA SRA tool to characterise harm, communication of results, and the use of the results in risk prioritisation, and to inform options appraisal and risk management**

3. APPLYING THE SRA TOOL

Figure 2.2 shows that the first stages in the application of the SRA tool involve identifying the risk issues to be evaluated and compared, characterising the risk issues using the tool attributes to capture economic, social and physical aspects of the environmental harm associated with each issue, and then communicating the results. The attributes and scoring scales are presented first below (Section 3.1), followed by discussion of how to identify and characterise risk issues (Section 3.2) and communicate the results (Section 3.3).

3.1 Attributes

The attributes and their scoring scales were first presented in Pollard *et al.* (2000). The attributes have now been refined and grouped as shown in Table 3.1. The main groups are:

- value characteristics;
- impact and coverage characteristics;
- temporal characteristics;
- scarcity characteristics;
- personal concern characteristics; and
- discontent characteristics.

Each attribute represents a characteristic of environmental harm that is distinct, can be scored independently, and is relevant to the overall assessment of the harm. The grouping of the characteristics helps in communication (see Section 3.3) and in the use of the SRA tool to inform risk prioritisation and options appraisal (Section 4). The scoring scales for the attributes are shown in Table 3.2.

3.1.1 Value Characteristics

Environmental harm from different risks may have similar characteristics (e.g. spatial extent, timescales, reversibility), and the principal differentiation between the risk issues will simply be the number of receptors affected by the harm and their associated financial value. Two attributes capture this valuation:

- "Stock at Risk" (A1) represents a valuation of the overall stock of assets affected by the harm. The scoring of this attribute (see Section 3.2) also captures the probability of the harm being realised. Where possible, the valuation should be made in economic terms and may thereby implicitly incorporate an assessment of the net effect of other attributes, such as the sensitivity of the receptors and the severity of the impact. Where economic data are lacking, an alternative scale, such as numbers of receptors, may be used to score this attribute.

- "Knock-on Effects" (A2) reflects the possibility that harm to one receptor affects the wellbeing (physical, social, or economic) of another receptor. Therefore, the value of the harm (i.e., the cost of the potential damage) is escalated.

3.1.2 Impact and Coverage Characteristics

The impact and coverage characteristics reflect the distribution of the hazard causing the environmental harm and the variable responses there may be to the hazard. This is broken down into four attributes:

- "Spatial Extent" (A3) denotes the overall area in which exposures to the hazard that causes the environmental harm are experienced.

- "Heterogeneity" (A4) reflects that within the overall area denoted by the "Spatial Extent", there may be heterogeneity in exposure to the hazard. The use of two attributes to describe coverage allows a distinction to be made between a series of point sources all over the country and a uniform coverage.

- "Sensitivity of Receptor" (A5) reflects the proportion or distribution of receptors within the region that exhibit the harm, as denoted by the "Severity of Effect". This captures the variability of the harm, in that not all individuals in a receptor group will exhibit an impact on exposure to the hazard.

- "Severity of Effect" (A6) defines the general (rather than worst case) effect on an individual sensitive receptor only. Unlike the "Stock at Risk" attribute, it reflects a physical effect, rather than a valuation of the effect.

"Spatial Extent" and "Heterogeneity" combine to reflect the true spatial coverage of the harm, and "Sensitivity of Receptors" and "Severity of Effect" combine to reflect the true impact of the harm. The issue of air pollution from traffic can be used to provide an example of how the attributes work together. Air pollution from traffic is a regional or national issue ("Spatial Extent"), but the harm is focused in urban areas and near to large roads ("Heterogeneity"). The general effect is significant discomfort from respiratory problems ("Severity of Effect"), but only a minority of adults show these problems when exposed to average levels of the pollution ("Sensitivity of Receptors").

3.1.3 Temporal Characteristics

The temporal characteristics are important from a risk management perspective (see Section 4). There are three attributes:

- "Temporal Extent" (A7) reflects the length of time that the environmental harm will be experienced from either the present day, or the point in the future from when the harm is first realised.

- "Latency" (A8) considers that, although the hazard may already be present, there may a period of time before the consequent environmental harm starts to be realised. For example, the impact of eating BSE-infected cattle may only become apparent in human receptors after 10 – 20 years.

- "Accumulation" (A9) reflects that, over the temporal extent of the harm, there may be changes in the rate at which the environmental damage progresses. As exposure to a hazard continues, the harm may accumulate and the effects of the harm may become

more manifest or worsen. For example, at low concentrations, chemical pollution in a lake may only have a small effect on a limited number of receptors. If the pollution accumulates (either slowly or rapidly) in the water/sediments/organisms, it may reach a level where the effects are much more deleterious and widespread.

The "Latency" and "Accumulation" attributes combine to reflect the urgency of the need to address a risk issue. The scoring of both attributes needs to be considered carefully in each application of the SRA tool so as to reflect whether significant latency and effects of accumulation are scored as better or worse than no latency / accumulation (see also Section 3.2).

3.1.4 Scarcity Characteristics

The scarcity characteristics capture how rare the receptors are, and whether the harm or damage is reversible. These characteristics may also be captured implicitly in the value of the harm and in the social perception of the harm.

- "Reversibility" (A10) considers both the extent to which the effects of the harm are reversible and, if so, over what timescale.

- "Scarcity" (A11) reflects the abundance of the receptor, and can be used to consider the loss of social (cultural) resources, as well as physical environments, plants and animals.

3.1.5 Personal Concern Characteristics

The social response to risk issues and the associated environmental harm has been divided into six attributes or characteristics. Other schemes, such as the "Outrage" framework developed by Peter Sandman (1989), have used considerably more factors to represent perceived risk characteristics. However, such detailed approaches are often unwieldy to use and confusing to the non-expert user. Given that there is now a general recognition in the risk perception and communication literature that central issues are individual concern on the one hand and the level of social trust on the other (Kemp 1998; Mays 1999; Petts and Leach 2000). We have reduced the social response attributes to reflect these two dimensions.

The terminology of the social attributes has been adopted such that the scoring scale of all of the attributes works in the same direction.

The "Dread", "Unfamiliarity" and "Notoriety" social attributes are grouped to provide a measure reflecting personal and social concern (see Table 3.1b):

- "Dread" (B1) captures the phenomenon that society may fear an issue to a degree that is not linked to the actual magnitude of the harm. For example, catastrophic events (e.g., a plane crash) are often associated with a higher dread than more continuous hazards (e.g., road traffic). There is a greater fear of cancer relative to other sudden illnesses.

- "Unfamiliarity" (B3) reflects the concern that may be felt about an issue owing to it being uncommon and/or poorly understood.

- "Notoriety/Publicity" (B6) reflects the likelihood of media influence amplifying social concern over an issue.

3.1.6 Discontent Characteristics

The "Unfairness", "Imposition" and "Distrust" social attributes are grouped to provide a measure reflecting social discontent (see Table 3.1b):

- "Unfairness" (B2) captures the discontent that can arise out of an issue being of benefit to a few while causing harm that can affect many.

- "Imposition" (B4) reflects the degree of personal control or choice over being exposed to a potential cause of harm.

- "Distrust" (B5) considers the degree of trust in the sources of information about a hazard, and the trust in the authorities responsible for controlling and/or regulating the harm[2].

[2] **Note on environmental harm**:
We conventionally consider harm to the environment by reference to its magnitude, but clearly the nature of harm has wider dimensions. In terms of the relationship between exposure to a hazard and the harm caused (the dose-response relationship), we recognise attributes such as the amount of harm per unit of exposure (as amount or time of exposure), the lag (if any) between exposure and response and the reversibility of any harm caused. These multidimensional aspects of harm can be equally applied to social and economic impacts (e.g. economic recovery) and are important risk characteristics that inform decisions on how to manage the risk.

Table 3.1a "A" attributes reflecting the physical characteristics of the harm

Attribute	Definition	Examples
Value		
A1 Stock at Risk	Value or size of the population that might be affected and the environment that might be damaged by the harm.	Number of receptors affected or value of the stock in financial terms.
A2 Knock-on Effects	Extent of secondary or indirect effects caused by an initiating effect of the harm.	Harm may be manifest in the ecological arena but have "knock-on" social and economic effects. Loss of income by affected population group may have an impact on other population groups through reduced spending by that group. Loss of resources may restrict ability to deal effectively with the cause of harm, e.g., a major nuclear accident might result in loss of agricultural land and possibly industrial sites, thus restricting the economy of the affected area.
Impact and Coverage Characteristics		
A3 Spatial Extent	Distribution of the harm in geographical space.	Harm may affect a localised area (e.g. siting of an industrial plant, incinerator or landfill site close to housing estate or valuable ecological site) or could have widespread implications (e.g. global harm such as effects from climate change). Refers to the overall distribution of all of the occurrences of the harm.
A4 Heterogeneity	Heterogeneous realisation of the harm in the exposed geographical space.	Although harm may be spread over a wide area, the distribution may be irregular leading to "hot-spots" or localised areas where the deleterious effects are realised. Acid rain deposition occurs over a wide area, but "hot-spots" occur in upland areas with high rainfall. Traffic pollution is widespread, but is more focused in urban areas.
A5 Sensitivity of Receptor	Distribution of the harm manifest.	Some harm may be experienced by a wide population, but only certain communities/receptors are affected or show affects. Large percentage of people show effects from exposure to radiation; only some people are susceptible to traffic pollution; only certain households are affected by the loss of particular amenities.
A6 Severity of Effect	Magnitude of harm or damage to an individual receptor.	Discomfort or irritation are less severe effects than death; this is also reflected in the value given in economic terms as well as by the greater social acceptability of less severe effects of harm.
Temporal Characteristics		
A7 Temporal Extent	The period over which the harm occurs.	The impact of a release may be short if a pollutant is readily degradable but much longer-term for non-degradable (persistent) pollutants. Repetition or continuation of the exposure (e.g., emissions at a set level over the lifetime of a factory) is potentially more serious than exposure from a single or short-term event.
A8 Latency	The possible delay in harmful effects becoming manifest.	Damage which becomes evident only after a period of time (e.g. asbestosis, cancer) can be tackled over a longer timeframe. Therefore, scoring places higher values on urgent problems. However, note that high latency and high uncertainty over possible consequences may indicate a need for precautionary action.
A9 Accumulation	The effects of any accumulation of the harm during the period of exposure.	The extent to which the harm is realised during continued exposure and the severity of the effect may increase with time as the hazard accumulates. Continued exposure to air pollution results in harm becoming more manifest and more severe. If the extent/effects do worsen through accumulation, the rate at which a hazard accumulates influences the ability to manage and control the harm.
Scarcity Characteristics		
A10 Irreversibility	The extent to which the harm can be rectified.	Harm to the natural environment from flooding is reversible over time. Harm is considered irreversible in economic terms where the costs and difficulties of restoring the damage are excessive. This attribute is important when remedial options are being considered.
A11 Scarcity	Availability of resources (living and non-living) to substitute harmed resources.	The extent of harm arising from loss of a site where the only example of a particular species or cultural/heritage resource exists might be considered greater (in both social and economic terms) than loss of a site inhabited by more common species or representative of a more widespread resource. For example, the loss of an area of salt marsh might be environmentally more damaging than loss of an equal area of pine forest.

Table 3.1b "B" attributes reflecting social responses to the harm

Attribute	Definition	Examples
Personal Concern		
B1 Dread	Individual's aversion to, or fear of, a harm.	Dread can be related to a number of influencing factors. There is a greater fear of cancer, relative to other sudden illnesses. There is greater fear of catastrophic events, such as death or severe injury from a chemical plant accident rather than from, say, a severe fall. There is greater fear of the nuclear industry than of conventional chemical process plant, but certain chemicals and sites are also more feared than others.
B3 Unfamiliarity	Degree of knowledge and understanding of the harm.	People are more comfortable with risks of harm that they are familiar with (e.g. drinking alcohol) relative to novel risks, such as the potential harm from exposure to genetically modified foods.
B6 Notoriety / Publicity	The potential for raised awareness of, and concern about, the harm via the media and other channels of information.	If there has been a history of concern and if there is increased publicity, people's concerns may be amplified and require a much greater degree of attention and response.
Discontent		
B2 Unfairness / Inequity	The inequity or unfairness of the harm's distribution.	Harm where some benefit while others suffer the consequences (e.g. because they cannot meet costs) can be seen to be unfair and thereby create discontent. Greenhouse gas emissions result in benefits to the present generation but may result in climate change, which might harm future generations. Scale depends largely on the relative number of those benefiting versus those suffering.
B4 Imposition	Degree of personal control over the harm.	There is greater aversion to harm that is outside our control and externally imposed. Permissions granted without people's knowledge are seen as imposed (this links to unfairness). Voluntary exposure to harm is part of every-day living, however, and this factor is used to adjust treatment of harm from one context (e.g. road accidents, cigarette smoking, knowingly living in a flood plain) to another (e.g. pollution hazards).
B5 Distrust	Lack of trust in the characterisation of the harm.	Lack of trust will relate to the compliance history of a particular site or process and whether there has been a degree of culpability, the level of transparency and accountability associated with previous and current activities, and whether independent and trusted sources of information are available.

Table 3.2a Attribute scaling for the "A" attributes

Attribute	Scale				
A1 Stock at Risk	Any quantified scale that can be used to compare the value of harms relative to each other, or a qualitative scale of high (3), medium (2) or low (1) Plus: an assessment of the probability of the harm being realised (high, medium, or low) And: an assessment of the overall uncertainty associated with the score (high, medium or low)				
A2 Knock-on Effects	**1** No knock-on effects		**2** Likely moderate knock-on effects		**3** Significant and costly knock-on effects
	1	**2**	**3**	**4**	**5**
A3 Spatial Extent	Point Source	Local Area	Regional	National	International/ Global
A4 Heterogeneity	0 - 20% of spatial extent affected – local hotspots		40 - 60% of spatial extent affected – uneven spread		80 - 100% of spatial extent affected – even spread
A5 Sensitivity of Receptor	0 - 20% - minority		40 - 60% - about half		80 - 100% - majority
A6 Severity of Effect	Little damage	Low impact, minor discomfort	Medium impact, significant discomfort	High impact, major discomfort	Terminal impact, fatal
A7 Temporal Extent	Instant	Short/cyclical	Annual	Decades	Long-term (over generations)
A8 Latency	Delayed for decades		Delayed for years		Instant effect
A9 Accumulation	No effect of Accumulation	Little effect of accumulation	Harm and/or extent of harm worsen slowly/slightly with accumulation	Harm and/or extent of harm worsen considerably with accumulation	Harm and/or extent of harm worsen rapidly/strongly with accumulation
A10 Irreversibility	Harm rapidly Reversed	Harm reversed over weeks	Harm reversed over years	Harm reversed over decades	Harm irreversible
A11 Scarcity	Widespread	Common	Scarce but replaceable	Scarce and irreplaceable	Unique

Table 3.2b Attribute scaling for the "B" attributes

Attribute	Scale				
	1	2	3	4	5
B1 Dread	No obvious anxiety	Some local concerns associated with dreaded risk potential	Local community anxiety strongly felt about exposure to a possible feared calamity	General public anxiety about exposure to a possible dreaded event or long-term exposure	Widespread public fear associated with key characteristics of the potential harm – catastrophic, dread effects with long-term social impacts
B3 Unfamiliarity	Very familiar, well understood cause and effect relationship	Some degree of familiarity, some understanding of underlying mechanisms	Limited knowledge, not much understanding of underlying mechanisms	Not a familiar issue, some similarities with other issues but underlying mechanisms not fully understood	Unfamiliar, raising novel concerns and scientific explanations seen as complex and / or untried
B6 Notoriety / Publicity	No public or Media interest In the issue	Past history of, but no current press or media interest	Current local press and media interest	Current national and regional press / media interest; poor history of similar events	Heightened international and national press and media interest; notorious for recent past history
B2 Unfairness / Inequity	Impact Distributed equally, not perceived to be inherently unfair	Unequal impact, but few benefit/ few suffer disproportionately	Unequal impact, some benefit/ some suffer disproportionately; perceived as inequitable by independent observers	Apparent inequity in distribution of costs and benefits: patently unfair	Few benefit/ majority suffer; perceived as inherently and patently unfair by the majority of observers
B4 Imposition	Voluntary Exposure Entered into willingly and knowingly	Neither imposed by others nor willingly entered into – but seen as a fact of life / nature	Involuntary; imposed from outside, but resulting from due process and full provision of information	Involuntary exposure; imposed from the outside and with limited consent only	Involuntary exposure to harm; imposed from the outside and without "informed consent"
B5 Distrust	Trusted Processes and sources of independent information	Decision processes and sources of information seen as reliable	Decision processes and sources of information seen as unreliable and treated with scepticism	Decision processes and sources of information seen as untrustworthy; poor track record in this regard	Highly distrusted decision processes and sources of information

3.2 Characterisation – Applying the SRA Tool

The selection of risk issues and the basis for the assigning of scores to characterise each risk issue is recorded in a pre-defined format. This allows users to record and justify the scoring of the attributes. A template scoring report has been designed for this purpose, and examples of this report, as used for the case studies under this project, are provided in the appendices to this report.

3.2.1 Approach

The recommended approach in applying the SRA tool is illustrated in Figure 3.1.

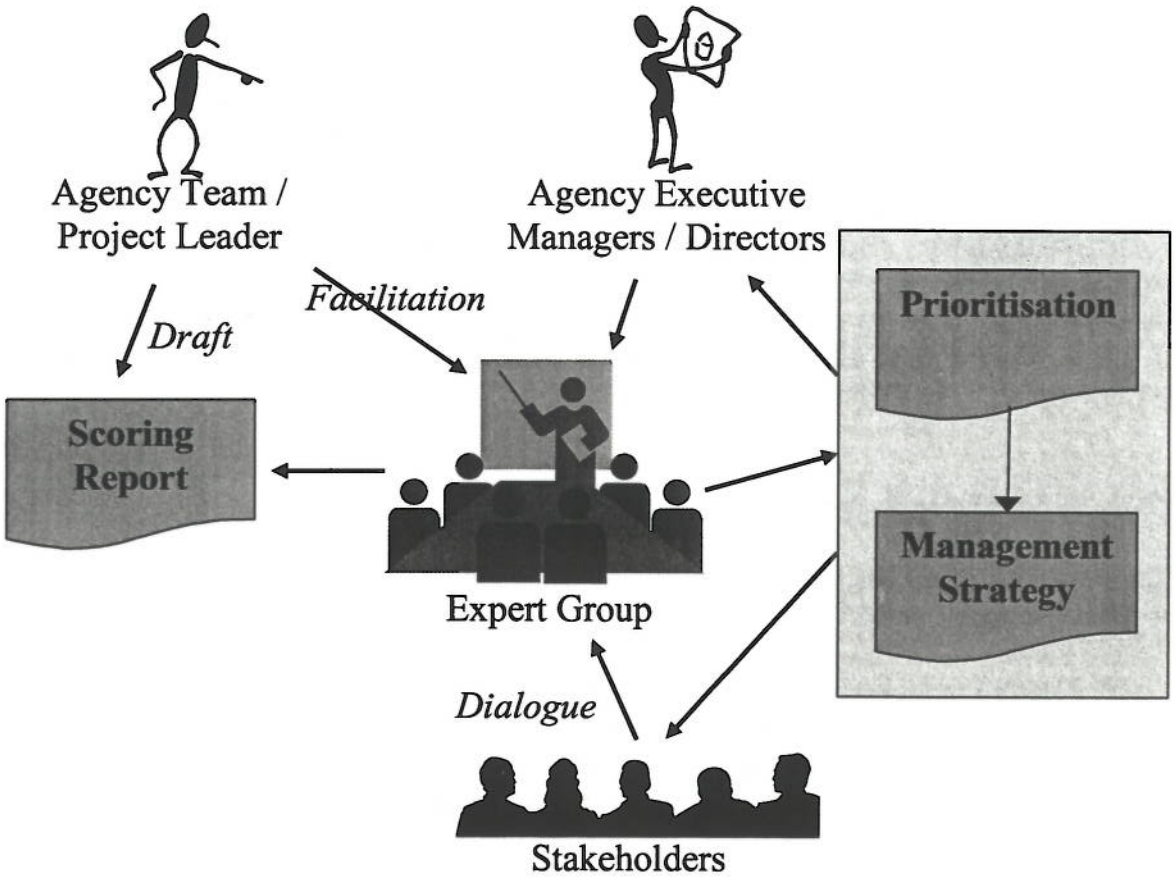


Figure 3.1 **Illustration of the recommended approach to applying the SRA tool. Under the direction of the Agency Team Leader, and taking account of any input from Agency Executives and stakeholders, the Expert Group applies the SRA tool to assist in the prioritisation of risk issues and the development of risk management strategy. These output are communicated back to the stakeholders.**

Because the scoring of the attributes can be contentious and relies on technical, social, and economic knowledge of the environmental harm, the best method of using the framework is to assemble an expert group. To save time, the SRA tool can be applied by an individual (e.g., the Agency Project Leader) and a draft of the scoring report circulated to the other expert parties prior to the group meeting. The group can include personnel with expertise that covers

the physical, social, and economic aspects of the risk issues and the associated environmental harm. Experience in presenting the tool to an expert group has shown that, although the attribute definitions and scoring scales are written to be as clear as possible, there is still scope for the interpretation of the meaning of the attributes to vary. Therefore, the expert group meetings should be overseen and facilitated by an individual who has experience of the framework so as to promote proper and consistent use between groups.

As was stated earlier, the intention is that the scoring is undertaken by Agency personnel. Through experience and dialogue, such personnel will have some understanding or perception of the values that might be placed on harm by various stakeholder groups and can, therefore, accommodate stakeholder views in the scoring. The scoring report details the basis for the scores and, therefore, can also be used to get input on the chosen scores from other stakeholder groups, Agency executives, and/or experts. In some cases, stakeholder representatives could be included in the scoring group.

The approach to scoring will depend, largely, on the range of issues being covered and the intended use of the results. However, in general, it is better in general to score each attribute for all of the risk issues, before moving on to the next attribute. This will promote consistency in the scoring. However, it is also beneficial to consider certain attributes in pairs, thereby helping to ensure that the scoring of the attributes is applied consistently with regard to each other. "Spatial Extent" and "Heterogeneity" should be considered together so that consistent scores are given for particular distribution patterns, such as multiple point sources spread across a region. Similarly, the pairs of "Stock at Risk" and "Knock-on Effects", "Sensitivity of Receptor" and "Severity of Effect", and "Latency" and "Accumulation" should be scored together.

3.2.2 Identifying Risk Issues

The first step in applying the SRA tool (top left of Figure 2.2) involves identifying what risk issues are being assessed. The risk issues should be described in terms of:

- a hazard (a property or event that could lead to harm), e.g., flooding, radon;
- the sources or causes of the hazard (to feed into development of risk management strategies), e.g., traffic, agriculture; and
- the key receptors that can be harmed by the hazard and the consequences of the harm (to allow the characterisation of the risk issue), e.g., human fatalities can be used to assess the pressure of radioactivity release, potable water resources can be used to assess the pressure of use of pesticides.

Within the group of risk issues to be assessed, it is beneficial to attempt to identify similar key receptors where possible. This helps to prevent disparity between the scores for some attributes. For example, "Severity of Effect" will score the same for environmental harm that leads to the potential adverse impact of a plant species or a human, assuming that the plant species or the human is identified as the key receptor. However, the significance of the attribute score to a stakeholder will depend on the value that they attach to the different receptors.

3.2.3 Costing the Risk Issues

The second step in applying the SRA tool involves attempting to quantify the value of the harm associated with each risk issue, assuming the harm from the hazard is realised (the scoring of Attribute A1 – "Stock at Risk"). This step is potentially the most difficult in the application of the tool, partly because of the lack of data, and partly because of the often widely varying estimates of the costs of environmental harm. Because of these difficulties, the SRA tool only uses a very broad evaluation of the harm, on a scale of high, medium and low value relative to the other risk issues being assessed. The actual value represented by "high", "medium" or "low" will vary between each application of the tool, depending on the risk issues being evaluated. Different types of information can be used to place the risk issues on this scale, such as the economic cost of the consequences of each risk, the number of people affected, budgetary provisions per year to counteract or reduce the hazard. However, the value should attempt to capture the consequences of key concern (e.g., cost, deaths). The scoring report allows the information supporting the valuation to be recorded. If good information is available, then a more quantitative scale could be used, and different applications of the SRA tool can then be compared.

It is also necessary to specify:

- the probability of each risk issue leading to harm, i.e., the probability of the hazard occurring, the receptors being exposed to the hazard, and the harm being realised from the exposure, on a scale of high, medium, and low;
- the overall uncertainty associated with each value estimate, in terms of high, medium, and low confidence; and
- whether any knock-on effects of the harm are covered by the value estimate, or whether a multiplier needs to be applied (the scoring of Attribute A2 – "Knock-on Effects").

3.2.4 Characterising the Risk Issues

For each risk issue, all of the SRA tool attributes except "Stock at Risk" and "Knock-on Effects" are given a qualitative score to characterise the environmental harm associated with each risk issue. A simple Likert scale running from 1 to 5 has been adopted, where 1 represents a low level of impact or concern and 5 a high level of impact or concern (Table 3.2). The attributes that are scored qualitatively are divided into those characterising the impact, temporal and scarcity properties of the harm (A3 to A11), and those characterising the social responses to, or valuation of, the risk issue and the associated harm (B1 to B6). Some scales may benefit from adjustment for the particular assessment, e.g., 1 to 5 for "Spatial Extent" might cover a point to a region for a regional assessment, and a point to international extent for a global assessment. For each application, the scales should be checked for attributes such as "Heterogeneity" and "Latency" to ensure that the scoring of 1 to 5 always reflects low to high impact or concern.

3.3 Communication

The main record of the application of the SRA tool is the scoring report. However, in addition to the scoring report, the attribute scores can be presented using schematic graphs to assist in the communication and application of the results. A number of schematics are

discussed below. However, other schematics combining and presenting attributes of key interest could also be developed on a case-by-case basis.

The schematics represent a compromise between consolidation of the attribute scores, in order to reduce complexity and assist in communication and interpretation, and over-simplification of the attribute scores, thereby losing valuable information on the character and differences between the risk issues. The appropriate balance between complexity and over-simplification is related partly to the needs of the different audiences. To this end, the schematics suggested below are split into two groups:

- Summary schematics, providing a strategic overview for decision-makers and public audiences (the Probability - Relative Value - Social Response and Social Response - Physical Harm schematics). These are the main schematics for communication arising from use of the tool.

- Analysis schematics, comparing characterisation of risk issues to inform options appraisal within the risk management team (the Social Response and Harm Characteristics schematics, and the bar charts). These schematics are potentially more complex to understand, and may be produced only on an as-needed basis. The form of these schematics will also be more variable, reflecting different needs for information from different uses of the tool.

3.3.1 Primary Summary Schematics

The Probability - Relative Value - Social Response schematic is intended as the primary overall summary graph for communicating risk prioritisation from the SRA tool. It captures the overall physical and social valuation of the harm, the probability of the harm being realised, and the associated uncertainty. The Social Response - Physical Harm schematic is a useful supporting schematic showing the more detailed social versus physical valuation of the harm associated with each risk issue, as derived from scores elicited using the SRA tool[3].

[3] **Note on eliciting scores from groups**
The process of expert elicitation is well established in decision making. For our practical purposes here, the method of ascertaining the harm associated with a specific issue relies on eliciting judgements from experts. This process is qualitative and could be regarded as lacking scientific robustness and too reliant on the specific personalities gathered together. In order to ensure the process is a robust one, it is important to have the key experts as part of the process, an experienced facilitator, someone to scribe for the faciliator and a rapporteur. Having the key experts is crucial as it means that the SRA proces will be regarded as credible to non-participants. The faciliator will ensure that the balance of views are heard, the scribe will ensure that key issues are noted on flip charts, a process that ensures there is common understanding of agreed points. The rapporteur will take notes throughout to provide a detailed record of the meeting. Taken together this should ensure that a detailed commentary can be written which will support and explain any scoring. Considered expert judgement is used frequently within Agency business, this process of SRA formalises those judgements through scoring and makes them transparent through the management of the process. In addition, the judgements made about harm are a summary of thinking at a specific time and given a specific context and those judgements, may be different given changes in time and context. Use of the method will test out its limits and possibilities.

Probability - Relative Value - Social Response Summary Schematic

The WGBU study (WGBU 1999) used a summary schematic that showed probability of damage occurring versus an indication of the extent of damage. The extent of damage reflects social issues as well as a financial or physical cost of the harm. Using the SRA tool attributes, a similar overall risk comparison schematic can be derived. It shows the risk issues in terms of their likely probability of occurrence, the value of the resultant environmental harm or damage, the uncertainty associated with these measures, and the overall social attitude or response to the risk (Figure 3.2).

The x-axis on Figure 3.2 presents the *relative value* of the environmental harm, calculated from the "Stock at Risk" attribute multiplied by the "Knock-on Effects" attribute [A1xA2]. The y-axis on Figure 3.2 presents the probability of occurrence, as rated on a scale of high, medium or low. Rather than plotting exact points, the risk issues are presented as qualitatively drawn areas on the graph to reflect the inexact nature of the probability and value data. The size of the area representing each risk issue reflects the uncertainty (high, medium, or low) assigned to the estimates of value and probability. The area for each risk issue is shaded in red, orange or green colours to reflect the social responses to the issue as presented by its position on the Social Response analysis schematic (see below).

To assist in communication, the Probability - Relative Value - Social Response schematic can be shaded into three regions, reflecting issues of higher, medium, and lower relative priorities. The shading is intended to help illustrate the relative importance of risk issues plotting in different areas of the schematic. A similar shading was applied in the WGBU presentation. However, the ranking of the relative value of the environmental harm as high, medium, or low and, therefore, the value covered by each of the priority regions on the schematic, will vary from study to study, depending on the range of values covered by the risk issues being compared. Therefore, Probability - Relative Value - Social Response schematics from different studies cannot necessarily be simply overlain to compare priorities.

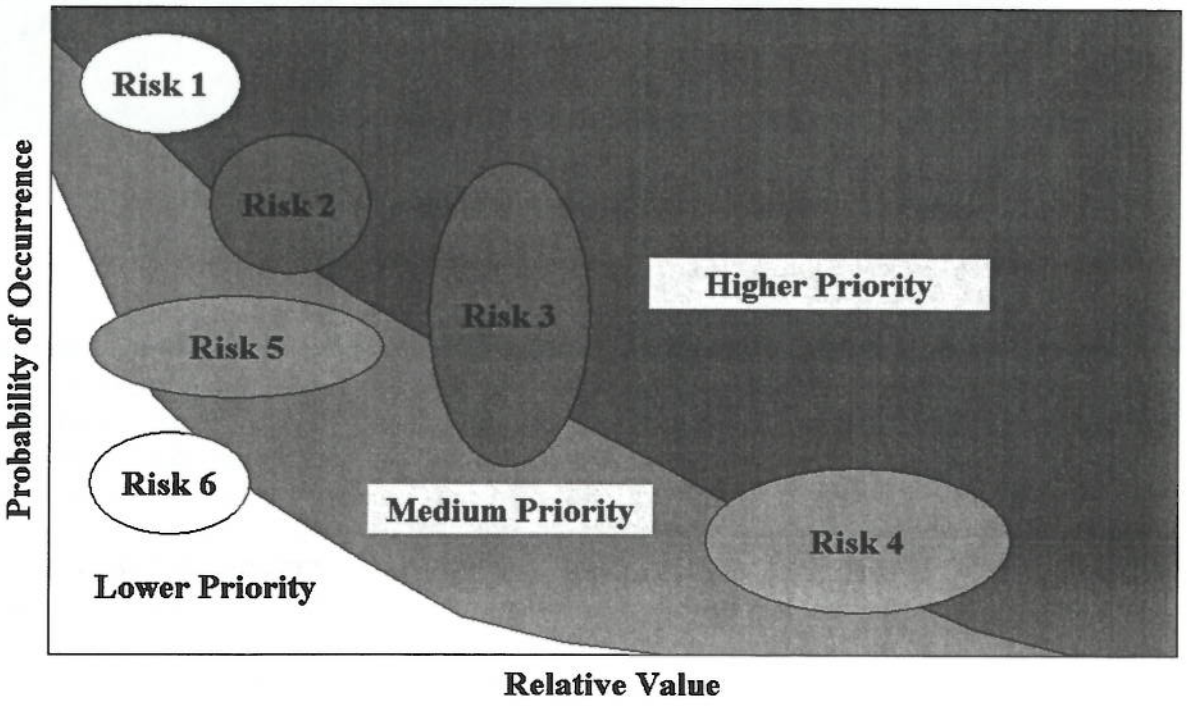


Figure 3.2 Probability - Relative Value - Social Response summary schematic

Social Response - Physical Harm Summary Schematic

Presentation of the attributes scores was not fully explored in Pollard *et al.* (2000). However, the suggestion was made that the social response or "B" attribute scores could be plotted on one axis and the physical or "A" attribute scores on the other axis of a 2-D schematic. Where the majority of attribute scores lay, e.g., mostly 3 or 4, would give the overall position of each risk issue relative to each axis. This is a potentially useful method of showing social versus physical valuation of the harm associated with each risk issue. However, for risk issues that have a range of scores, the clear position on the axis is not apparent, and the plots become cluttered. Presenting the attribute scores separately is appropriate for a detailed presentation, but may be too complex for a summary.

The concept of plotting social versus physical attribute scores can be developed by plotting the averages of the "B" attribute versus "A" attributes scores, and by plotting error bars based on the standard deviation (Figure 3.3). This gives an overall assessment of the characterisation of the environmental harm, and the variability of the scoring.

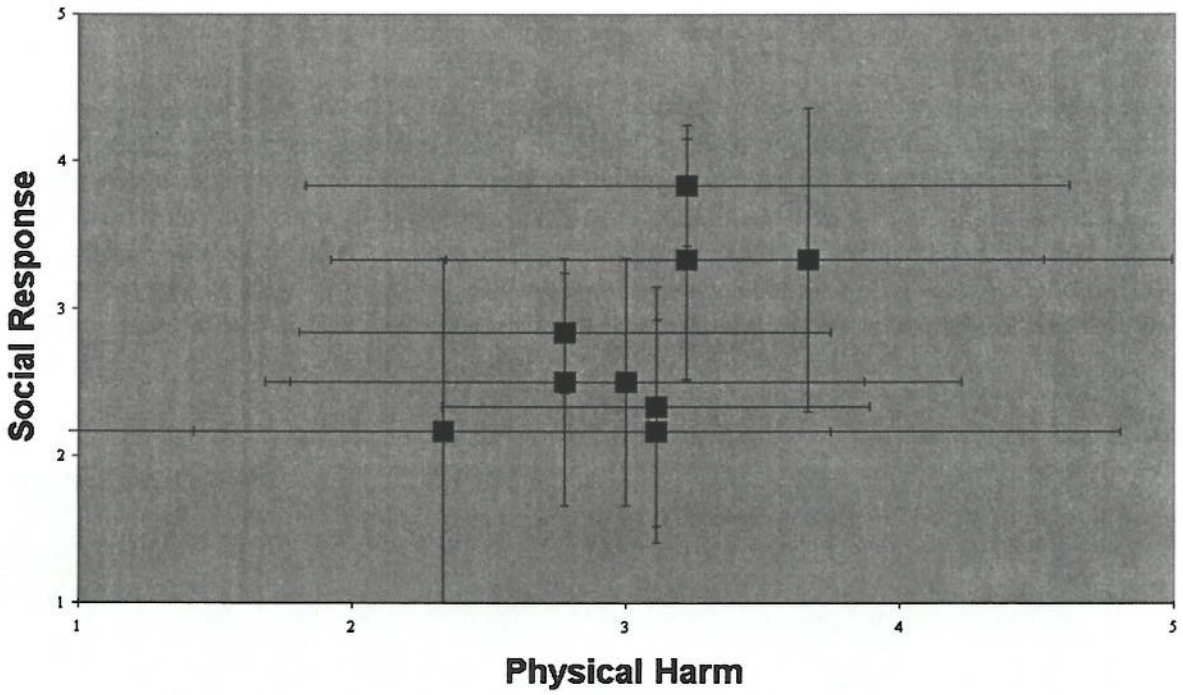


Figure 3.3 Social Response - Physical Harm summary schematic

Note that the "Stock at Risk" (A1) and "Knock-on Effects" (A2) attributes are not included in the average for the "A" attributes because they are scored on a different scale (1 to 3, rather than 1 to 5). The main problem with the Social Response - Physical Harm schematic as a summary is that it does not differentiate strongly between risk issues that cause harm of significantly differing values, and it does not take into account the probability of the harm being realised. It also does not differentiate strongly between the middle-ground issues that cluster towards the centre of the schematic. However, it is a potentially useful summary schematic to support the Probability - Relative Value - Social Response schematic, particularly where the valuation of the risk issues is uncertain, undiscriminating, or is considered to be of secondary importance for prioritisation (see Section 4.1).

3.3.2 Secondary Analysis Schematics

Numerous different analysis schematics can be devised, depending largely on the attributes of interest and the intended use of the information conveyed by the attributes. For illustration, the analysis schematic that supports the colouring of risk issues on the Probability - Relative Value - Social Response schematic is discussed first below, followed by a series of other analysis schematics that can be used to display the physical harm characteristics.

Social Response Schematic

The social response or B-attributes are grouped to reflect the potential level of personal concern ("Dread", "Unfamiliarity" and "Notoriety" [B1+B3+B6]), and the potential level of discontent associated with the risk issue ("Unfairness", "Imposition", and "Distrust" [B2+B4+B5]). These two groups are plotted on the x-axis and y-axis of the Social Response schematic, respectively. The Social Response schematic is divided into areas of low (yellow), medium (orange), and high (red) priority, as shown in Figure 3.4. These areas are based on an evaluation of the scores that would be achieved by risk issues using the descriptors for the scale set out in Table 3.2b. The non-uniform shape of the areas of priority reflects our expert judgement of the likely inter-relationship between the sets of factors for different types of risk issue which will not be on an equal basis. This is because where stakeholders feel relatively high levels of discontent about the fairness or the handling of an issue, this will raise levels of social response even where the individual level of personal concern may not be so high. For example, the outbreak of foot and mouth disease or rail transport safety. Conversely, even where personal and social concerns about the impact of a risk issue may be high, trust in those responsible for managing the issue may temper feelings of anxiety and lack of understanding. A good example here is the effect of the emergency services in responding to an unusual natural disaster – a hurricane, or flash flooding for instance.

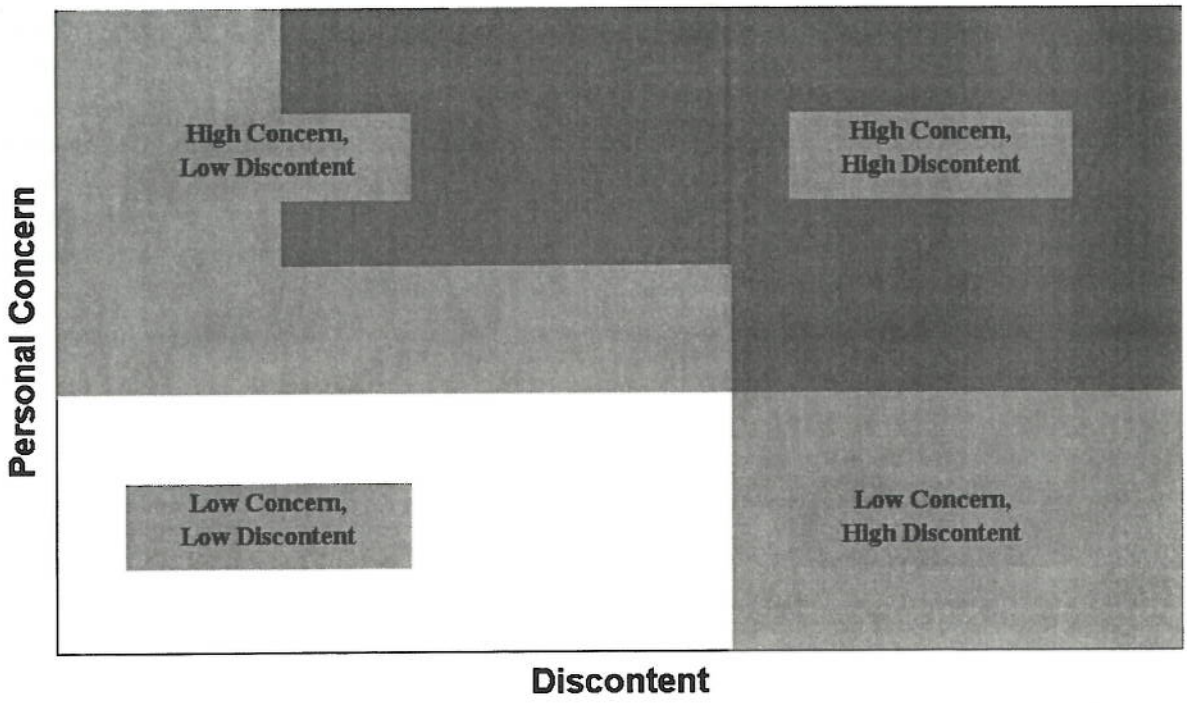


Figure 3.4 Social Response analysis schematic

The position of a risk issue on the Social Response schematic is transposed in the colour used to plot a risk issue area on the Probability-Value-Response schematic. The Social Response schematic is also intended to help users identify risk management techniques appropriate to social priorities (see Section 4).

Physical Harm Characteristics Analysis Schematics

The attributes describing the physical characteristics of the environmental harm (A3 to A11) can be presented on three Harm Characteristics schematics, reflecting the three main groups of characteristics: impact characteristics; temporal characteristics; and scarcity characteristics.

- The Impact Characteristics schematic (Figure 3.5) plots the *coverage* of the harm ("Spatial Extent" x "Heterogeneity" [A3xA4]) against the *impact* of the harm ("Sensitivity of Receptor" x "Severity of Impact" [A5xA6]). Figure 3.5 indicates where risk issues with the attribute scores shown on the bar charts (red = 5, green = 1) would plot.

- The Temporal Characteristics schematic (Figure 3.6) plots the *temporal extent* of the harm ("Temporal Extent" [A7]) against the *urgency* of the harm ("Latency" + "Rate of Accumulation" [A8+A9]). Figure 3.6 indicates where risk issues with the attribute scores shown on the bar charts (red = 5, green = 1) would plot.

- The Scarcity Characteristics schematic (Figure 3.7) plots "Reversibility" [A10] against "Scarcity" [A11]. Figure 3.7 indicates where risk issues with the attribute scores shown on the bar charts (red = 5, green = 1) would plot.

As with the Social Response analysis schematic, the Harm Characteristics analysis schematics are divided into areas of low (yellow), medium (orange), and high (red) priority, with the different areas being based on an evaluation of the scores that would be achieved by issues using the scale described in Table 3.2a. However, the designation of these areas is for comparison purposes only, and is based only on an approximate evaluation of the position of low, average, and high attribute scores. The Harm Characteristics analysis schematics are primarily intended to help users identify particular features of the harm associated with each risk issue. These features can then form an input to options appraisal to help consider the most appropriate risk management techniques (see Section 4).

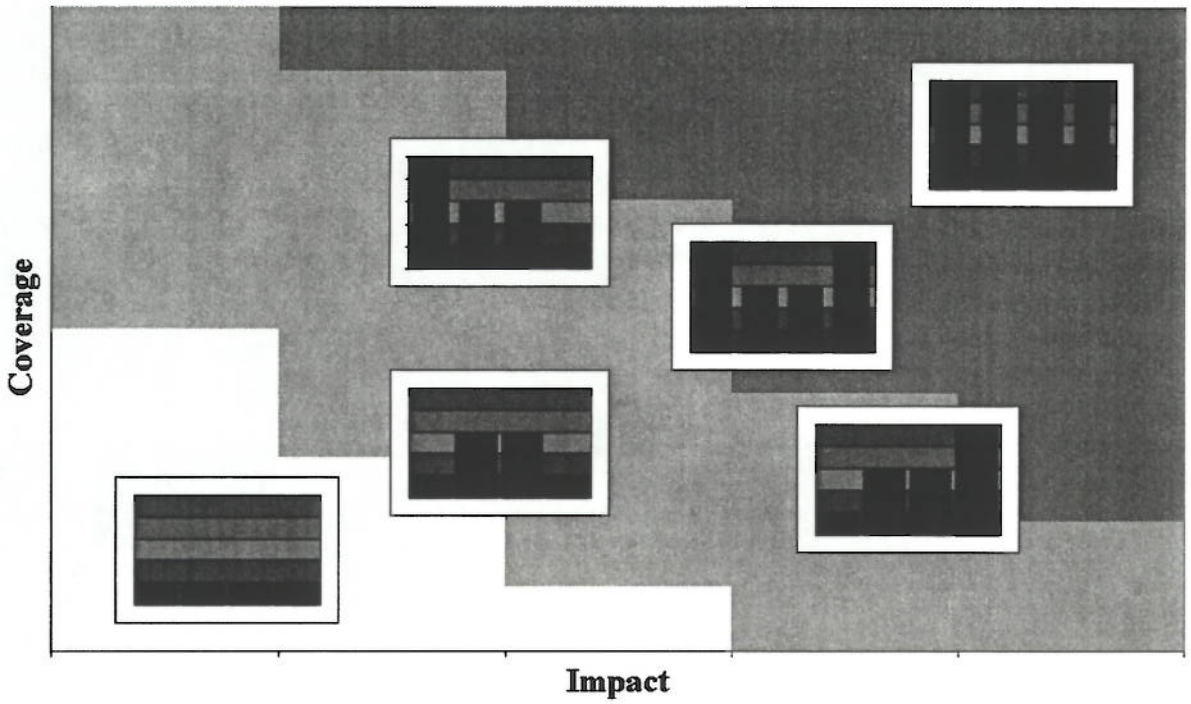


Figure 3.5 **Impact Characteristics analysis schematic – bar charts show position of issues with indicated scores (red = 5, green = 1) for attributes A3 to A6**

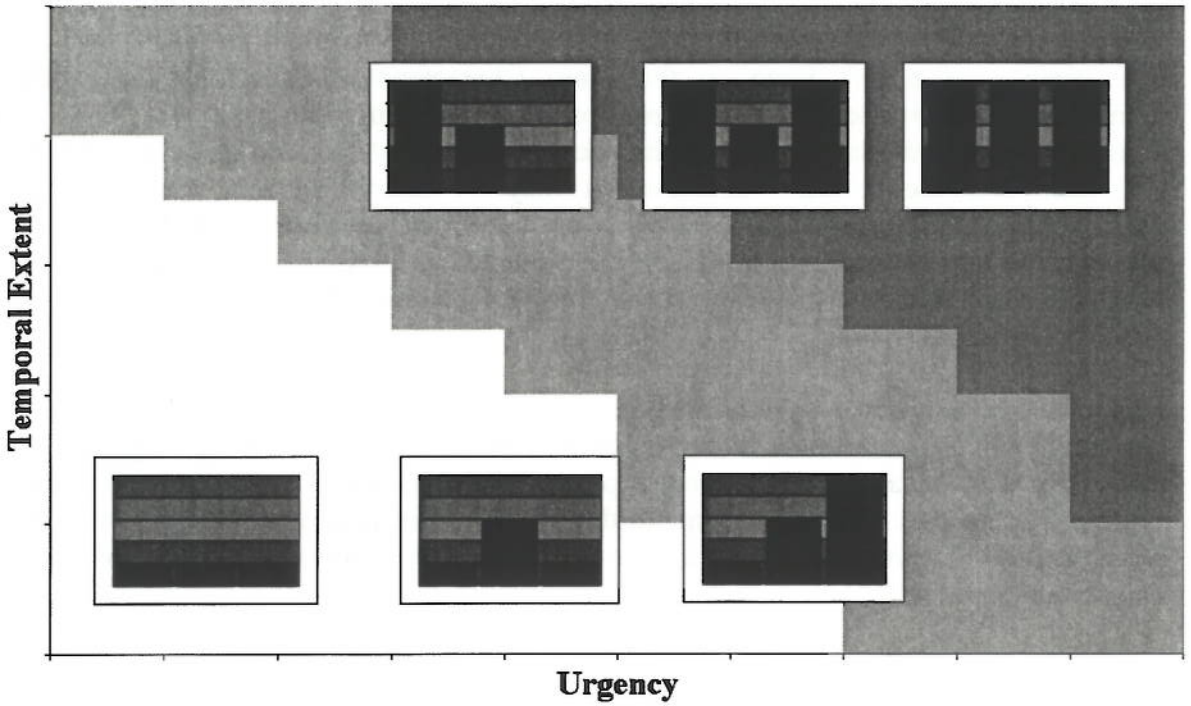


Figure 3.6 **Temporal Characteristics analysis schematic – bar charts show position of issues with indicated scores (red = 5, green = 1) for attributes A7 to A9**

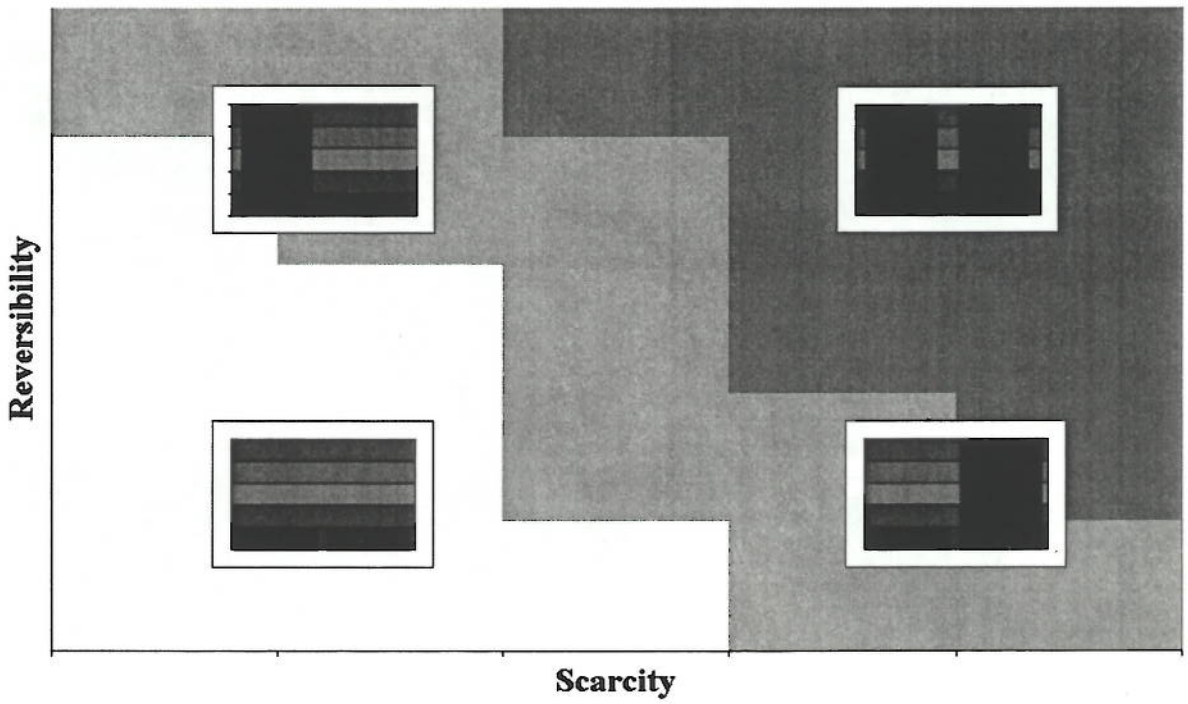


Figure 3.7 Scarcity Characteristics schematic – bar charts show position of issues with indicated scores (red = 5, green = 1) for attributes A10 and A11

Harm Bar Chart

The position of a risk issue on the Harm Characteristics schematics can reflect the combination of a number of "A" attribute scores, as shown on Figures 3.5 to 3.7. To assist in consideration of risk management techniques, it may assist the user to be able to view the individual attribute scores. Therefore, it may be desired to plot the physical harm-characterising attributes (A3 to A11) for each risk issue on a bar chart (Figure 3.8). The attributes or bars on the Harm Bar Chart are presented as three groups which reflect the three Harm Characteristics analysis schematics: impact characteristics; temporal characteristics; and scarcity characteristics.

A similar bar chart could be presented for the "B" or social response attributes. Further, the bar charts could be presented in combination with the other schematics. Figure 3.9 shows Harm Bar Charts for the "A" attributes plotted with the Social Response - Physical Harm summary schematic. Such a schematic does prevent the loss of information though over-simplification. However, the schematic is also difficult to interpret and does not convey any single message clearly.

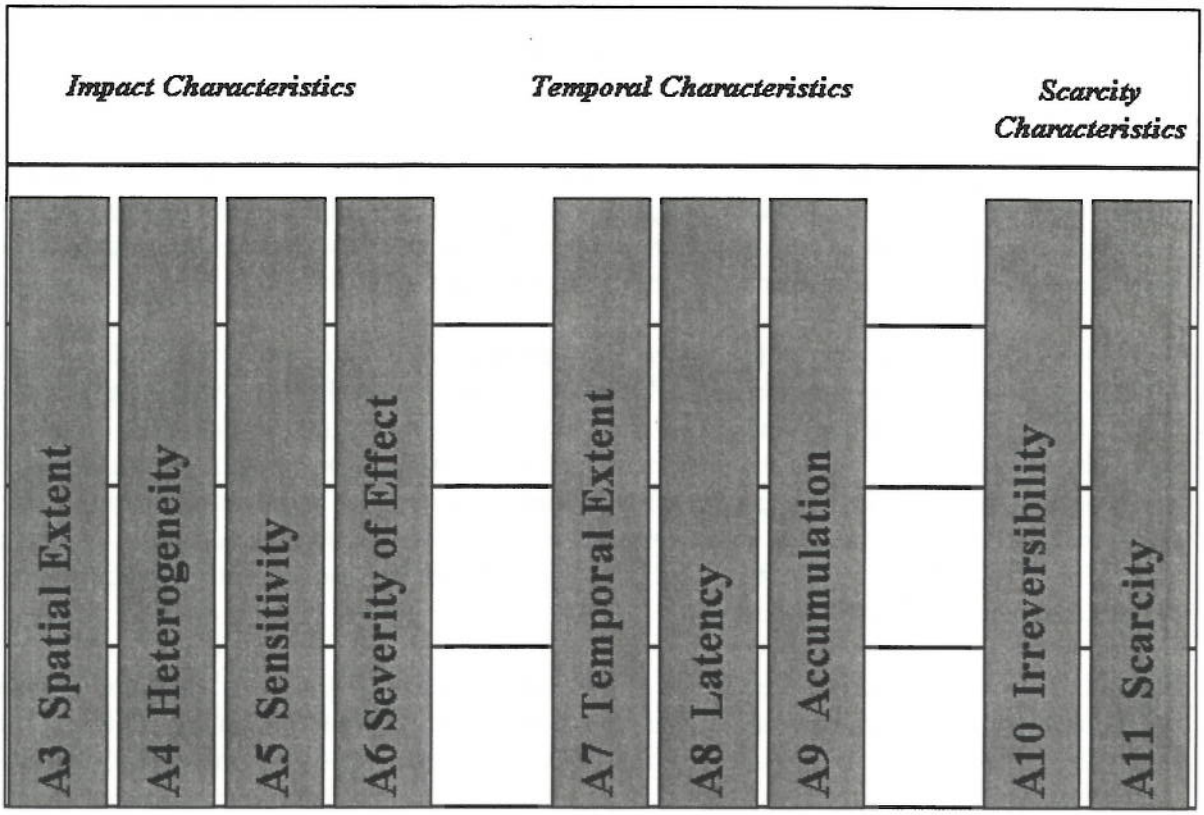


Figure 3.8 Harm Bar Chart – "A" Attributes

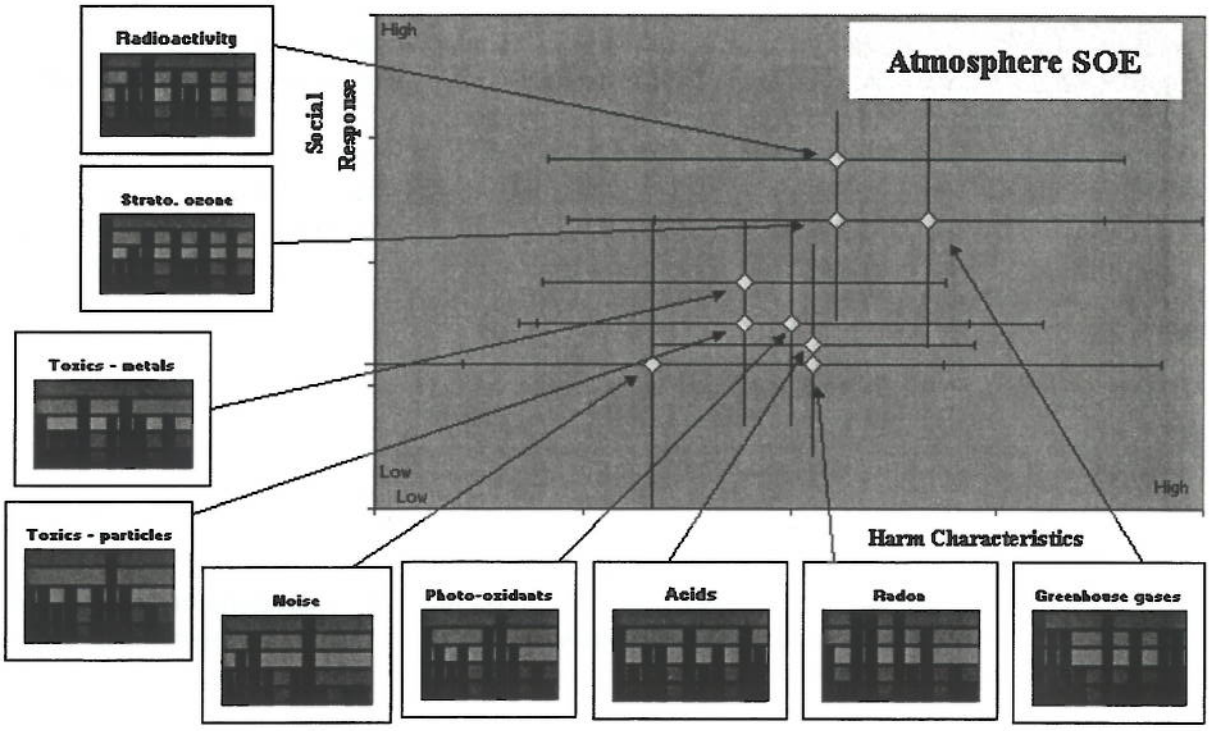


Figure 3.9 Harm bar charts for the "A" attribute scores for each risk issue plotted in combination with the Social Response - Physical Harm summary schematic for one of the case studies presented in Section 5

4. USE OF THE SRA TOOL RESULTS

4.1 Risk Screening and Prioritisation

The SRA tool schematics and supporting scores can be used to help prioritise risk issues. However, they cannot be used to simply rank issues according to their aggregate scores. Although the derivation of a single score with which to prioritise issues might, at first sight, seem desirable for decision-makers, such a goal is fraught with difficulty.

First, derivation of a score would require weightings or values to be attached to the attributes to reflect their relative importance. However, different stakeholders will attach different values to different attributes, and the values may also change from application to application (e.g., the spatial extent attribute may be less important for comparison of risk issues at a regional or local level). The effects of different values could be evaluated using standard decision analysis software, but no one single set of values can be recommended beforehand. This is not to say that a consensus on weightings could not be reached among stakeholders for any one application of the SRA tool.

Second, if the application of the SRA tool is focused on deriving a score, then the temptation might be to arrive at a prioritisation without considering fully the information that the tool is presenting. The main benefit of using the SRA tool is that all of the information about the risk issues is methodically documented and considered, both in arriving at an assessment of the issues and in considering how best to manage the issues.

The position of issues on the two summary schematics provides the basis for prioritisation. Higher priority issues will lie in the high value areas of both schematics. The Probability - Relative Value - Social Response schematics places emphasis (i.e., priority) on high probability – high value risk issues, with distinction between issues with similar value and probability being provided by social responses to the risk. The Social Response - Physical Harm summary schematic places emphasis on social responses and the overall physical character of the harm associated with the risk issues, rather than comparing the actual cost or value of the harm. Risk issues with high coverage and impact, with harm that is immediate, ongoing, and hard to reverse, and with associated high social concern will plot at high values on the Social Response - Physical Harm summary schematic.

4.2 Options Appraisal and Risk Management

The most valuable aspect of the SRA tool is in the characterisation of risk: what kind of risk is this?; what drives it as a risk issue? Armed with this information, the characterisation of the risk issues using the attributes and schematics described in Section 3 can be input into the consideration of options and to help identify possible risk management techniques and strategies. To illustrate and assist in this process, we consider below broad techniques for managing the risks of environmental harm, categorised as shown in Table 4.1. For guidance, the techniques listed are intended to reduce the assessed level of environmental harm (or attribute scores) associated with a risk issue. That is, both the assessed level of harm and the nature and range of harm characteristics ought to be amenable to reduction by the focused use of risk management techniques, and the transparency of the SRA tool encourages the development of such a focus.

Table 4.1 Categories of risk management techniques

Management Technique Category	Examples
Communication	Stakeholder dialogue Information reporting Stakeholder involvement in decisions
Education	School and adult education Training Technical assistance
Technical engineering	Research into basic processes Development of technology to reduce or counter harm Development of alternative technology Monitoring
Environmental management	Management systems (ISO 14001, EMAS) Environmental auditing
Market incentives	Pollution levies and charges Tradable emissions Subsidies
Regulation	Environmental standards Technology-forcing regulations Product bans IPC, BPEO Emergency procedures
Enforcement	Liability Compulsory insurance
Co-operation	International collaboration Inter-organisational action Regulator-polluter dialogue

Risk management techniques appropriate to moving risk issues from higher to lower priority on the schematics shown in Section 3.3 are summarised in the following sections.

4.1.1 Social Responses

Reducing concern

Communication

- Clear presentation of the cause-effect relationships between triggers and consequences.
- Direct feedback of measured data to the public.

Education

- Intensified environmental education in schools and in adult education.
- Training.

Technical engineering

- Research aimed at reducing the uncertainties regarding the assessment of risks.

Regulation

- Application of a precautionary approach.
- Regulatory focus on risk issues affecting public health.

Enforcement

- Compulsory insurance for risk generators (e.g. floods, settlements).

Handling discontent

Communication

- Improvement of opportunities for individuals to participate in decisions affecting their own lives.
- Early stakeholder involvement in the regulatory and licensing processes.

Education

- Establishment of independent institutions for information and public education.
- Licensing procedures with participation rights for parties affected.

Enforcement

- Stringent liability regimes.

Co-operation

- International and national safety standards authorities.

4.1.2 Impact Characteristics

Handling coverage

Education

- Education of source/cause to reduce output.

Technical engineering

- Containment (minimising the spread of damage).
- Improvement and implementation of retention/containment technologies.

Market incentives

- Control of output, e.g., through tradable emissions.

Regulation

- Regulatory limitation of quantities, e.g., through environmental standards.

Co-operation

- International co-ordination.

Handling impact

Technical engineering

- Research aimed at developing substitutes and reducing the impact potential.
- Human-resource and institutional capacity building (licensing procedures, monitoring, training, etc.).
- Development and implementation of blueprint for resilient organisations/receptors.
- Expansion of technological procedures by which to improve resilience (redundancy, diversity).

Market incentives

- Incentive schemes (e.g., pollution charges, levies, subsidies for environmentally-preferable products).

Regulation

- Introduction of technological measures and technology-forcing regulations for reducing the impact potential.
- Introduction of environmental standards for safe exposure.

Enforcement

- Stringent liability regimes and international liability commitments.
- Compulsory insurance for risk generators (e.g. floods, settlements).

4.1.3 Temporal Characteristics

Handling temporal extent
Technical engineering
- Development and phasing-in of alternatives.
- Development of remediation technologies.
- Research to improve foresight.

Market incentives
- Incentive schemes (certificates and levies) for reduction.
- Subsidisation of environmentally preferable alternatives.

Regulation
- Encouraging voluntary commitments to reduction.
- Precautionary policies.

Co-operation
- Coupling participation, empowerment and the institutional bolstering of long-term strategies.

Handling urgency
Communication
- Reporting on emergency procedures.

Education
- Effective emergency response training and co-ordination.

Market incentives
- Application of overall limits and market incentives, e.g., emissions trading.

Regulation
- Regulatory limitation of quantities, through environmental standards.

4.1.4 Scarcity

Handling reversibility
Technical engineering
- Development of remediation technologies.
- Priority application of environmental economics, e.g., managed retreats and substitution mechanisms.

Regulation
- Application of precautionary control measures.

Handling scarcity
Education
- Promotion of recycling.
- Education on consequences of loss.

Technical engineering
- Promotion of diversification and protection schemes.

Environmental management
- IPC and BPEO.

Regulation
- Strict application of environmental protection measures for priority species and sites.

4.1.5 Probability and Uncertainty

Handling low probability

Communication

- Emergency procedure information (emergency prevention, preparedness and response).

Education

- Education, training, empowerment.

Technical engineering

- Technological protective measures, including containment strategies.
- Technological measures aimed at estimating probabilities.

Environmental management

- Emergency management (emergency prevention, preparedness and response).
- Monitoring and review (watch carefully and wait).

Co-operation

- International emergency groups.
- International monitoring.

Handling uncertainty

Technical engineering

- Research to reduce uncertainty.

Regulation

- Institutionalised, precautionary technical standards such as ALARA.

Co-operation

- International agreements on control, monitoring and safety measures.
- International early warning structure.

4.3 Mapping of Regulatory Approaches to Risk Management

In addition to the risk management techniques set out above, it is helpful to consider the more strategic forms of approach (i.e., groupings of management techniques) to environmental risk regulation to which identified issue types appear to be vulnerable.

Four main regulatory approaches to risk management can be identified that can apply across the range of potential environmental harm issues to be addressed by the Agency. The approaches are not mutually exclusive, but we can broadly characterise the types of risk issue the approaches are used to address in terms of position on the Probability - Relative Value - Social Response schematic (Figure 4.1). These broad approaches map across a regulatory ladder of available approaches (Figure 4.2). The four approaches are:

1. *A Precautionary Approach.* Low to medium probability, potentially high but uncertain and irreversible consequence risks with high latency. Often high social concern. Similar to the low probability-high extent of damage and unknown probability-damage risk classes in the WGBU approach (Damocles and Pandora risk classes, such as nuclear energy and endocrine disruptors; WGBU 1999).

2. *Firm Enforcement / Strict Liability.* High-probability, high-consequence risks. Usually high social concern. Similar to the unknown probability-high extent of damage and high probability-high damage, but long delay risk classes in the WGBU

approach (Cyclops and Cassandra risk classes, such as earthquakes and human-induced climate change; WGBU 1999).

3. *Risk Communication and Participatory Regulation.* High social concern. Low consequence, and low to high probability. Similar to the low probability-low extent of damage, but with high mobilisation potential risk class in the WGBU approach (Medusa risk class, such as electromagnetic fields; WGBU 1999).

4. *Environmental Monitoring and Education.* Uncertain probability and consequence, but unlikely to be so high as to require firm enforcement. Low to moderate social concern. Similar to the unknown probability-damage risk classes in the WGBU approach (Pythia and Pandora risk classes, such as self-reinforcing global warming; WGBU 1999).

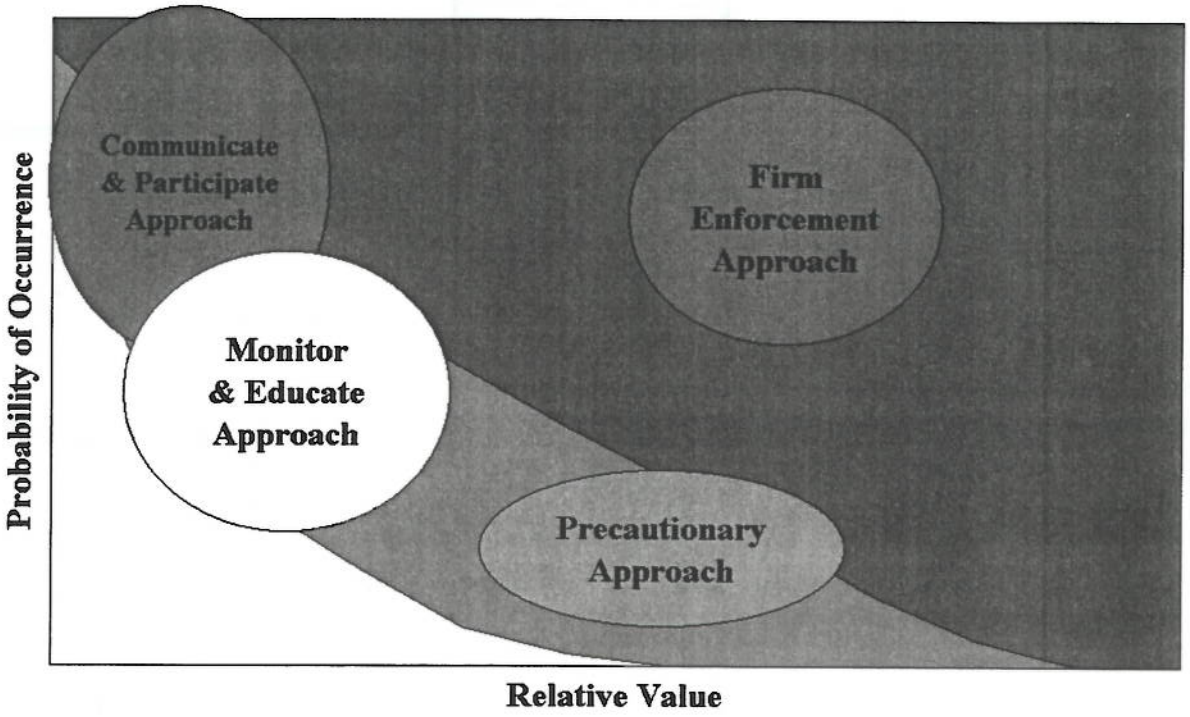


Figure 4.1 Regulatory approaches to risk management plotted on the Probability - Relative Value - Social Response schematic

THE REGULATORY LADDER

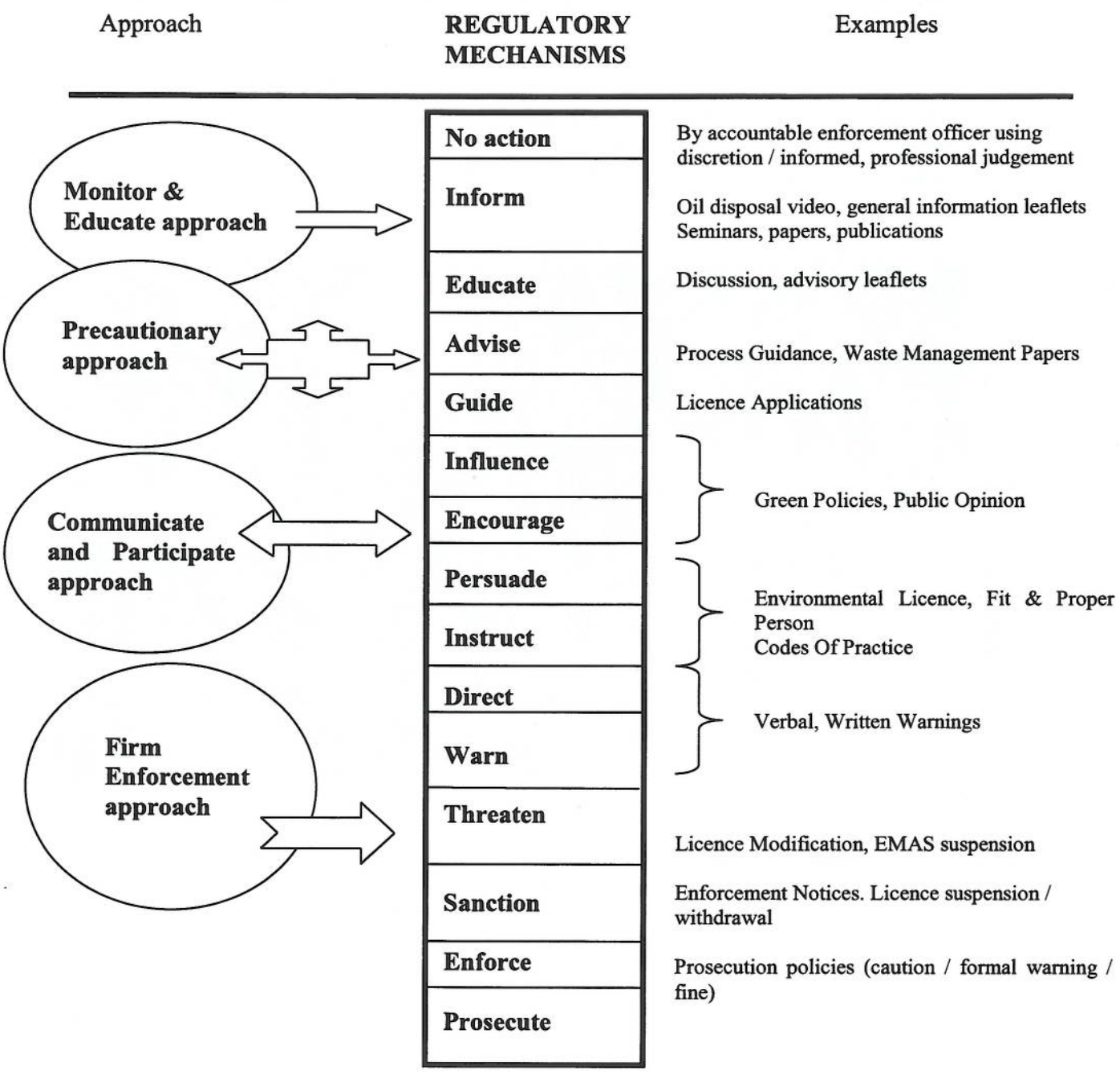


Figure 4.2 Mapping of risk management approaches to the Agency's "Regulatory Ladder" of available regulatory mechanisms (after Leinster, 2001)

5. EXPERIENCE OF USING THE SRA TOOL

The development of the SRA tool has been based in part on the conduct and evaluation of three case studies, described below:

- A State of the Environment Report (Section 5.1).
- A Regional Strategic Plan (Section 5.2).
- A Local Environment Agency Plan – LEAP (Section 5.3).

Note that the scoring of risk issues in the case studies has not been conducted using a workshop and has not formally involved Agency personnel. Therefore, the results presented do not represent an Agency position, but are provided simply to illustrate the working of the SRA tool.

5.1 Case Study A - State of the Environment of England and Wales: The Atmosphere Report

5.1.1 Conduct of Case Study A

This case study was chosen to test the application of the SRA tool to a strategic national study. Assistance with the presentation of results in the Agency's State of the Environment Reports and the comparison of risk issues in the reports is a potential key use of the tool. The schematics for this case study are presented below. The supporting report of the scoring basis is provided in Appendix A.

The risk issues chosen reflect the major air pollution risks to the atmospheric environment as set out in Section 5.2 of the State of the Environment Report (Environment Agency 2000c):

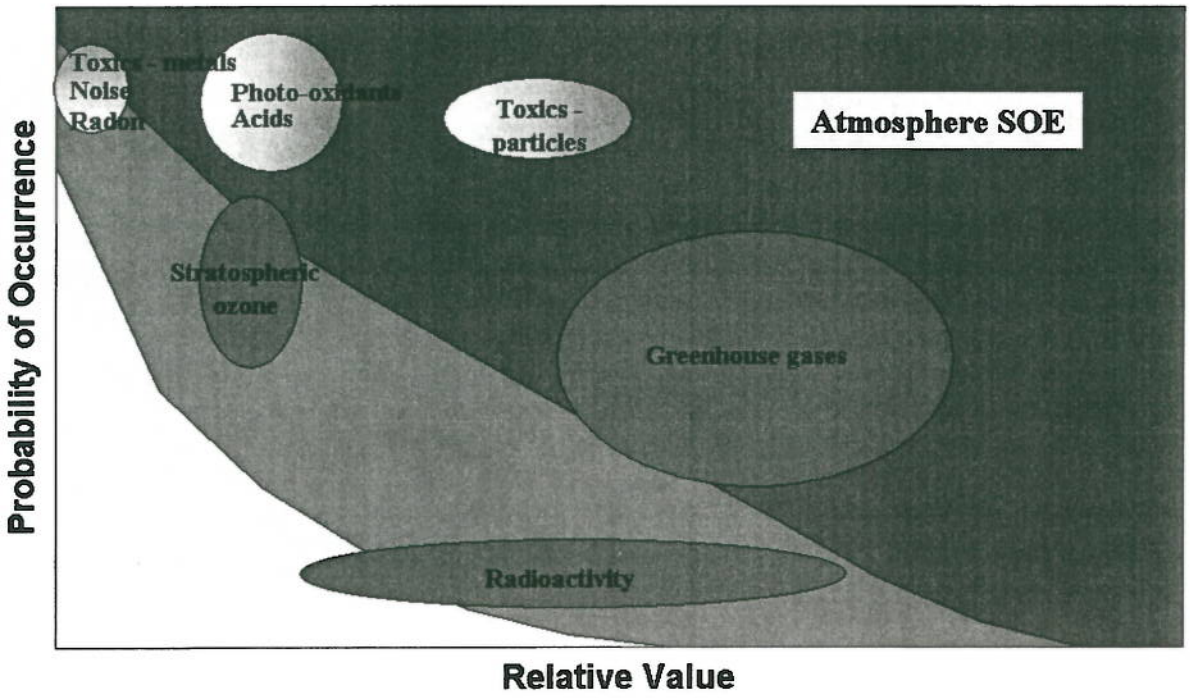
- toxic air pollutants - smoke and particles;
- toxic air pollutants - lead, other metals, organics;
- nuisance pollutants - dust and dirt, odour, noise and light;
- acidifying pollutants;
- photo-oxidants - ground-level ozone;
- radioactive substances - accidental releases;
- radioactive substances – radon;
- stratospheric ozone depleting substances – CFCs; and
- greenhouse gases.

The characterisation of the issues is largely based on information in the same report.

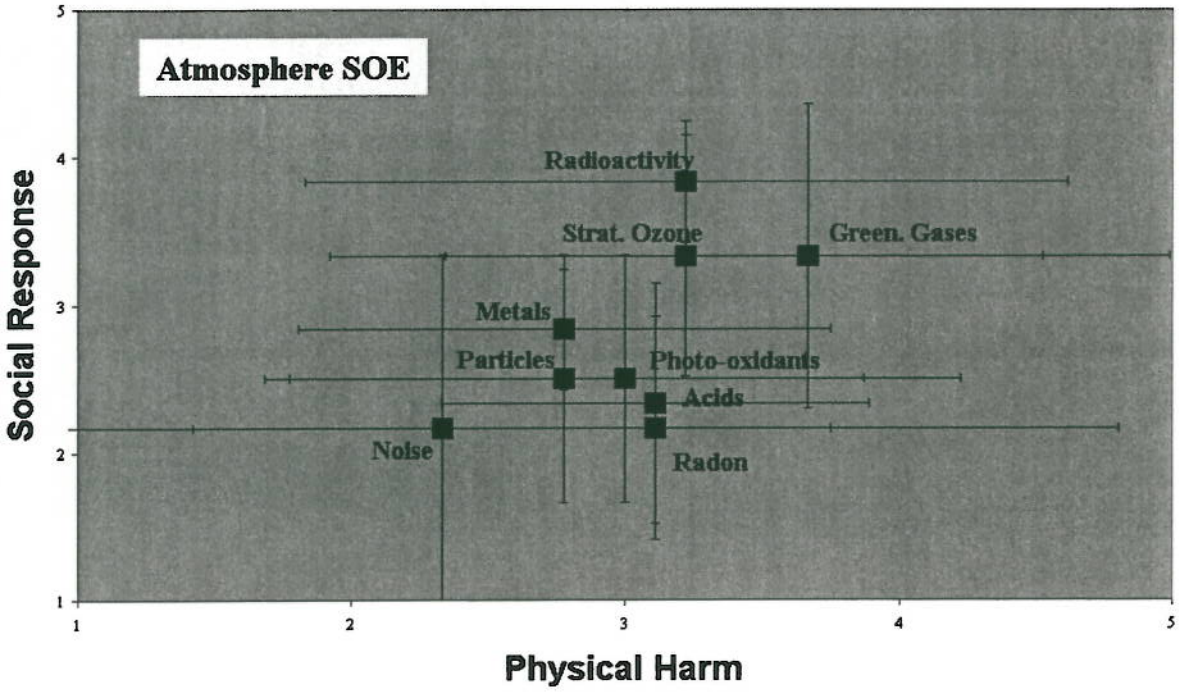
The relative valuation of the risk issues is based on economic cost. The costs associated with the majority of the issues are largely taken from data in the State of the Environment Report. This document references several pieces of work carried out for UK Government agencies that attempt to cost the environmental harm associated with each issue in terms of annual UK expenditure (e.g., Watkiss *et al.* 1999). Work of this type appears to be a good, and readily useable, source of information for the SRA tool. However, two key difficulties were

encountered. First, the costs of radioactive releases and ozone depletion were not discussed in the State of the Environment Report and had to be estimated from analogy to worldwide expenditure. However, expenditure is not, necessarily, a good analogy for the actual cost of the harm, and this needs to be reflected in the uncertainty attached to the valuation. Second, the costs are for different incidences of harm, e.g., the costs estimates for the consequences of Chernobyl represent a major nuclear accident covering several countries, while the costs for traffic pollution are for a common hazard within the UK only. Therefore, some allowance has to be made for these differences. However, the costs are only used to value the issues relative to each other on a broad scale of high, medium, and low, and the information was sufficient for this purpose.

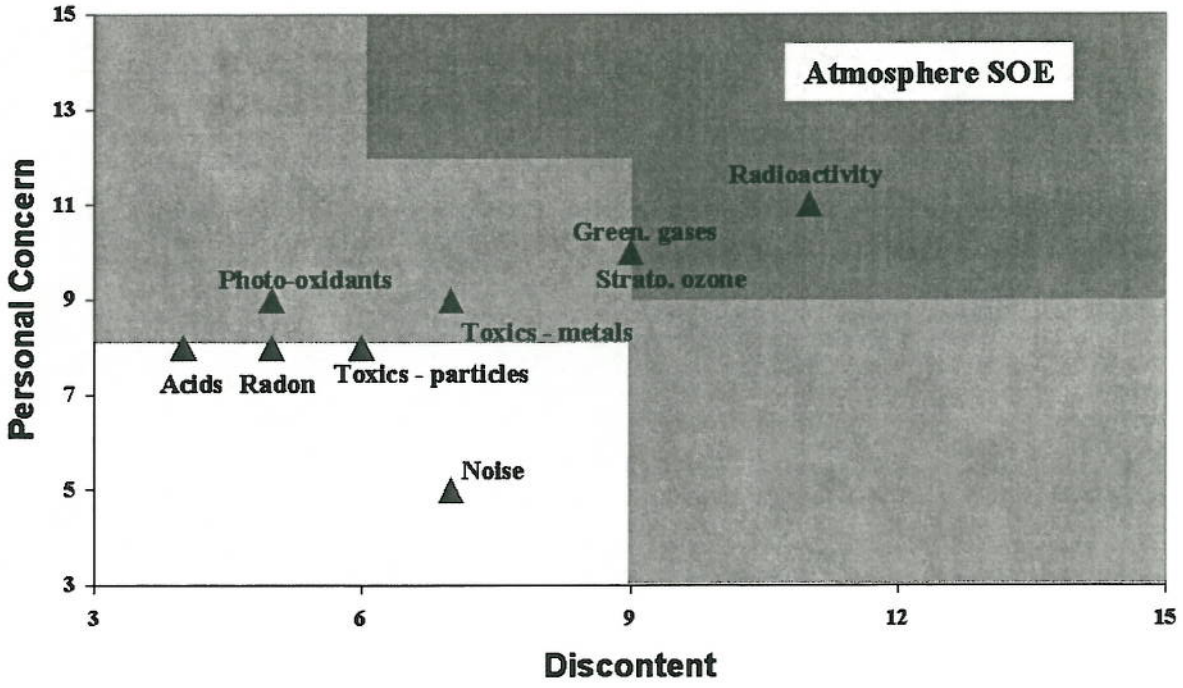
The social attribute scores (B1 to B6) were derived principally through judgement of social opinions and attitudes based on the experience of the scorers. The State of the Environment Report also provides some data on social concern regarding the different risk issues (e.g., Table 5.1; Environment Agency 2000c).



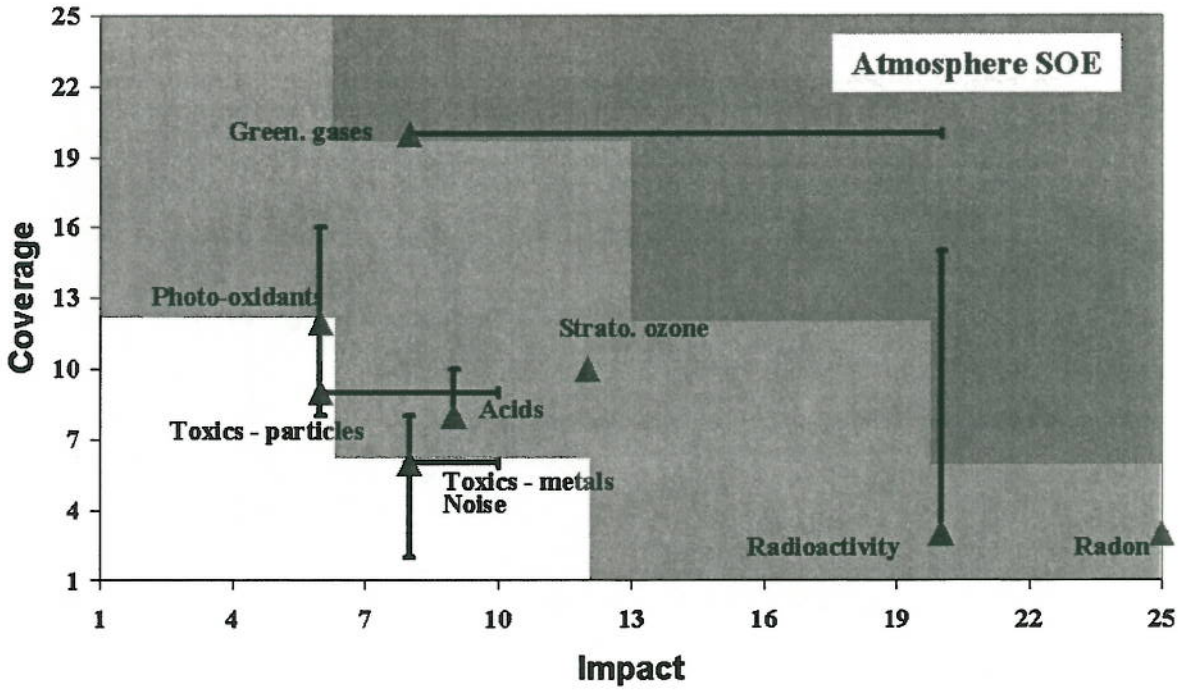
Probability - Relative Value - Social Response schematic for Case Study A – The Atmosphere State of the Environment report. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position. The grey shading illustrates areas of potential higher, medium, and lower priority. The colours reflect social response (red = high, yellow = low).



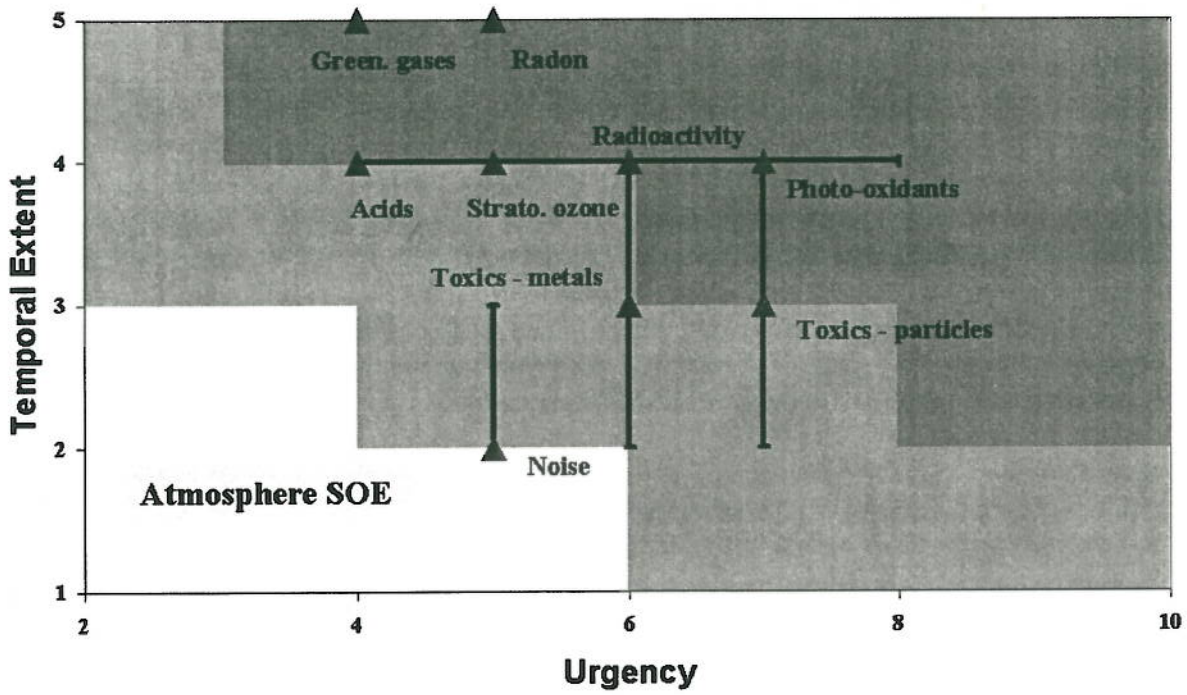
Social Response - Physical Harm schematic for Case Study A – The Atmosphere State of the Environment report. The error bars represent the standard deviation around the mean score and reflect the variability between all of the attribute scores, rather than the uncertainty associated with individual attribute scores. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



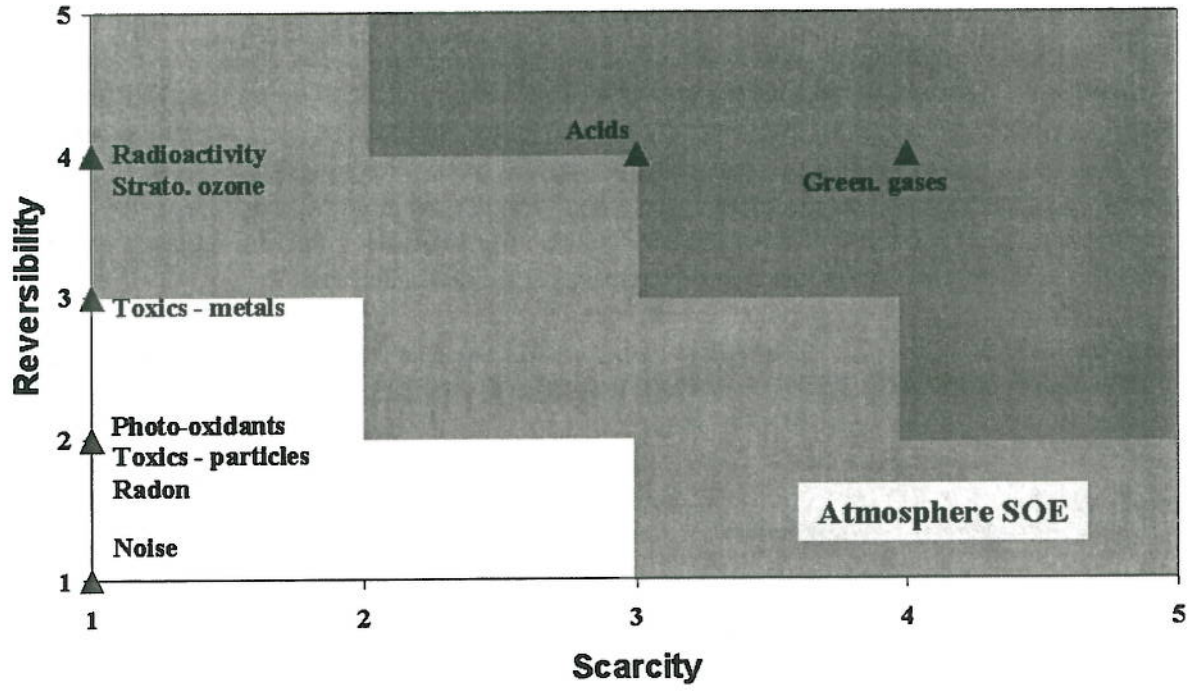
Social Response schematic for Case Study A – The Atmosphere State of the Environment report. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Spatial Characteristics schematic for Case Study A – The Atmosphere State of the Environment report. The black lines show the uncertainty associated with some of the scores, represented by the green triangles. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Temporal Characteristics schematic for Case Study A – The Atmosphere State of the Environment report. The black lines show the uncertainty associated with some of the scores, represented by the green triangles. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Scarcity Characteristics schematic for Case Study A – The Atmosphere State of the Environment report. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.

5.1.2 Findings from Case Study A

As is intended, the different schematics show some variation between the issues in terms of their positions relative to each other and relative to the zones of higher, medium, and lower priority. However, overall, the issues of climate change related to greenhouse gases, radioactivity, ground-level ozone (photo-oxidants), stratospheric ozone depletion, and acidification all tend to score in the higher (red and orange) priority zones on the schematics. Toxic metals, toxic particles, and noise, which are largely related to transport and industrial emissions, tend to plot in the lower (yellow) priority zones, although the issue of toxic particles plots at a high relative cost on the Probability - Relative Value - Social Response schematic. These two groups reflect well the priority issues listed in Section 4.6 of the State of the Environment Report (Environment Agency 2000c).

With regard to the development of a risk management strategy, the Probability - Relative Value - Social Response summary schematic indicates that climate change related to greenhouse gases may be the highest priority issue. However, although being a lower probability, accidental radioactive releases may also merit attention because of the high social concern.

Looking at the position of greenhouse gases on the Harm Characteristics analysis schematics, risk management techniques may focus on reducing the coverage, reducing the temporal extent, and improving reversibility. From the examples provided in Section 4.1, appropriate possible techniques to reduce coverage include control of output, regulatory limitation of quantities, and international co-ordination. Appropriate possible techniques to reduce temporal extent include development of alternatives, incentive schemes, and encouraging voluntary commitments to reduction.

For accidental radioactive releases, risk management techniques need to aim at reducing concern and discontent, reducing impact, and reducing temporal extent and urgency. From the examples provided in Section 4.1, appropriate techniques to handle social concerns include education, focusing on risk affecting public health, and stringent liability. Appropriate possible techniques to handle impact include standards for safe exposure, and development of technological procedures improving resilience. Appropriate possible techniques to handle urgency include effective emergency planning and communication.

Similar analysis of the schematics to identify appropriate possible risk management techniques could be performed for the other risk issues. Prioritisation of the different techniques would then need to be undertaken by considering resources, timescales, efficacy, and the relative positions of the issues on the tool schematics. The majority of the techniques listed above are already listed as priority actions in Section 6.4 of the State of the Environment Report (Environment Agency 2000c).

5.2 Case Study B - State of the Environment for London

5.2.1 Conduct of Case Study B

This case study was chosen to test the application of the SRA tool to a strategic risk assessment at a regional level. The schematics for this case study are presented below. The supporting report of the scoring basis is provided in Appendix B.

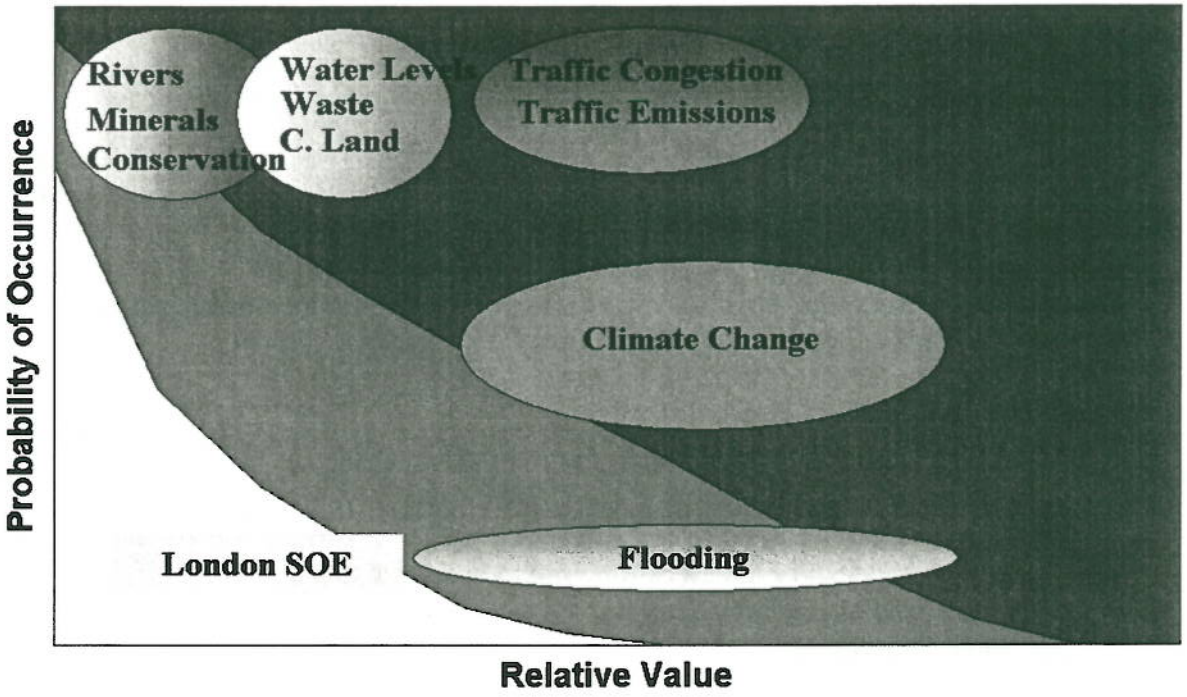
The risk issues considered here are based on the key areas for action identified in "A Greenprint for London" produced by the Environment Agency (1998a):

- river pollution;
- rising groundwater levels related to reduced abstraction;
- consumption of non-renewable mineral resources;
- lack of remediation of contaminated land;
- destruction and lack of conservation of natural habitat and greenbelt;
- production and landfilling of waste;
- emissions from traffic;
- traffic congestion and accidents;
- emissions from energy use contributing to climate change; and
- flooding.

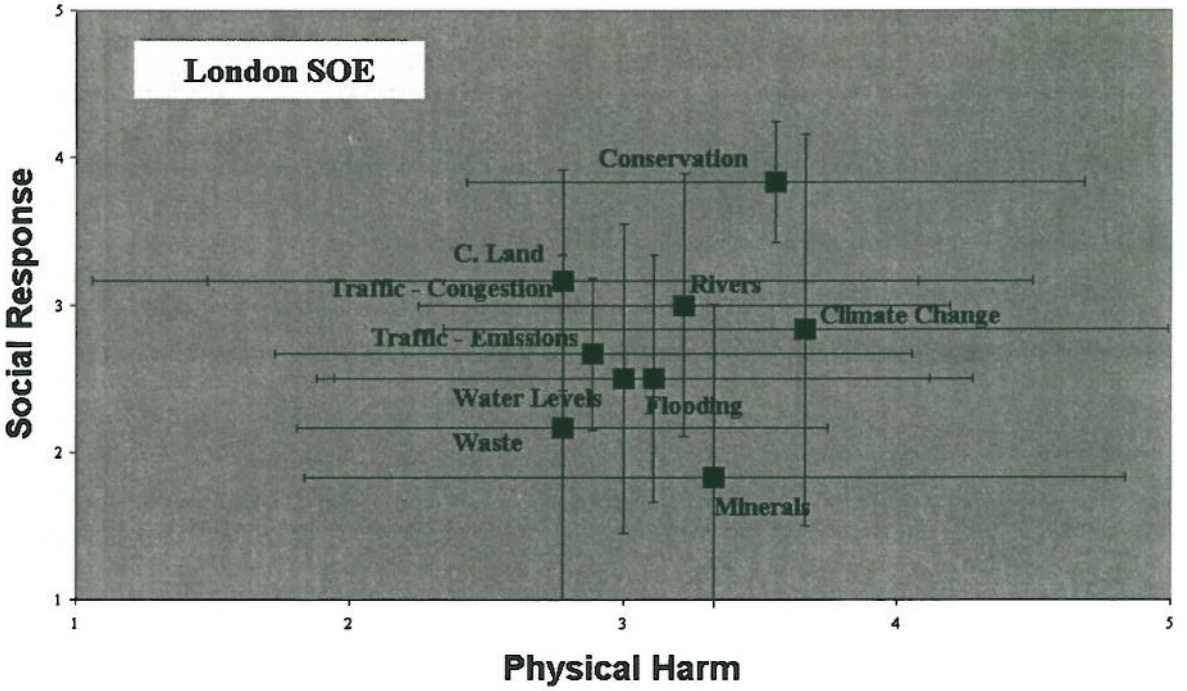
The London Planning Advisory Council (LPAC) (now superseded by the Greater London Authority [GLA]) compiled a State of the Environment Report for London in 1995 (LPAC 1995), and updated the report in 1996 and 1999. The report contains data for a series of environmental indicators. The information to characterise the risk issues for this case study has been taken largely from the State of the Environment Report indicators.

The relative value of the environmental harm for each of the risk issues was difficult to estimate. Several values are provided in the "A Greenprint for London" report (Environment Agency 1998a), while others were taken from other Agency State of the Environment Reports. Overall, six of the issues seem to fall into a low cost group compared to four issues that had an order-of-magnitude greater cost. This leads to a lack of differentiation within the two groups on the Probability - Relative Value - Social Response schematic. More information might allow two schematics to be drawn, differentiating between relative values within the two groups.

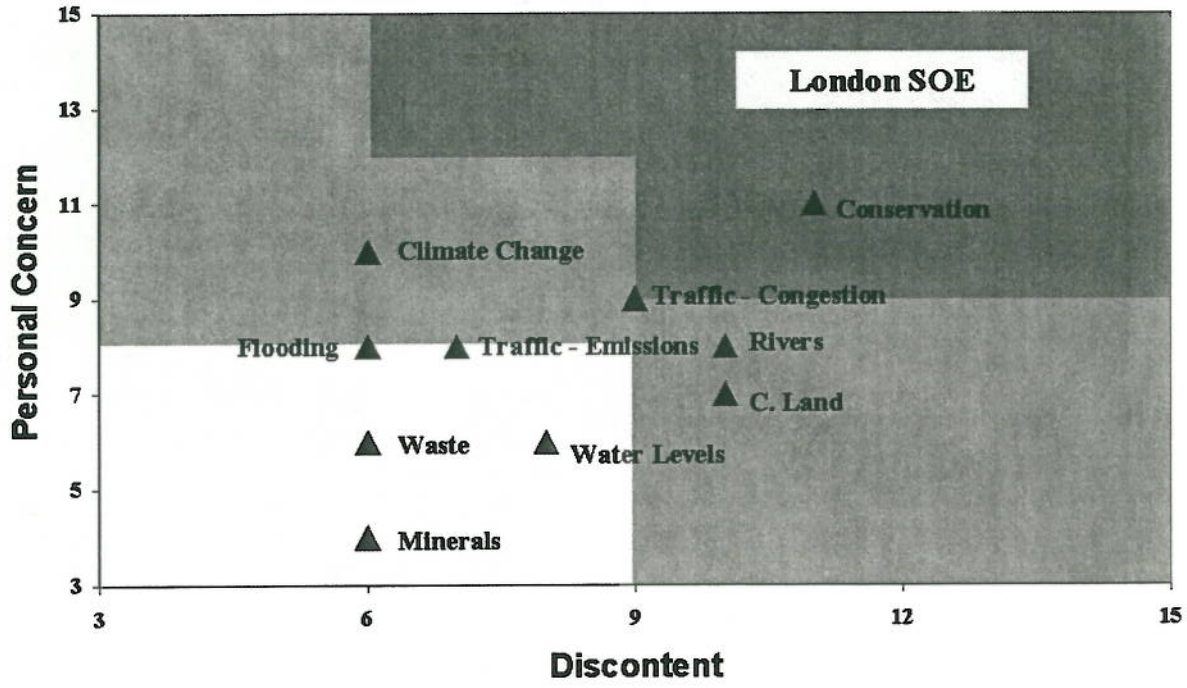
The remainder of the attribute scores were based on the experience of the scorers. As emphasised at the beginning of this section, the scores do not represent an Agency position, but are provided simply to illustrate the working of the SRA tool. In a real application of the SRA tool, the scores would be derived / agreed collectively by a group with diverse expertise.



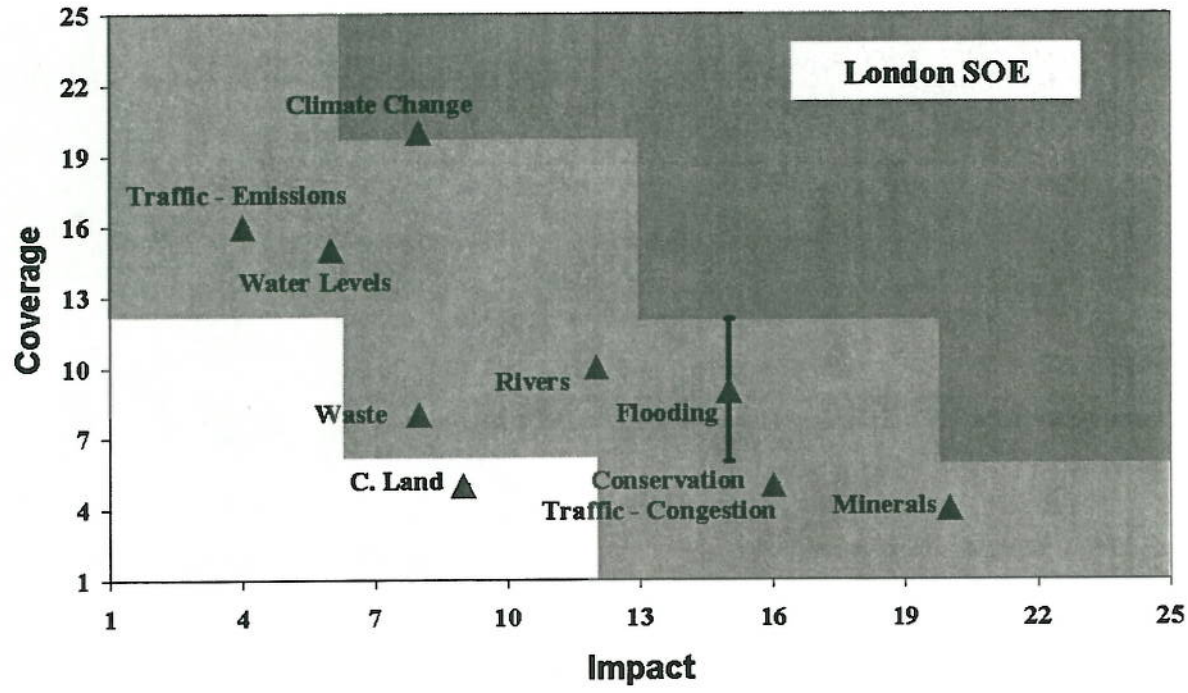
Probability - Relative Value - Social Response schematic for Case Study B – State of the Environment for London. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position. The grey shading illustrates areas of potential higher, medium, and lower priority. The colours reflect social response (red = high, yellow = low).



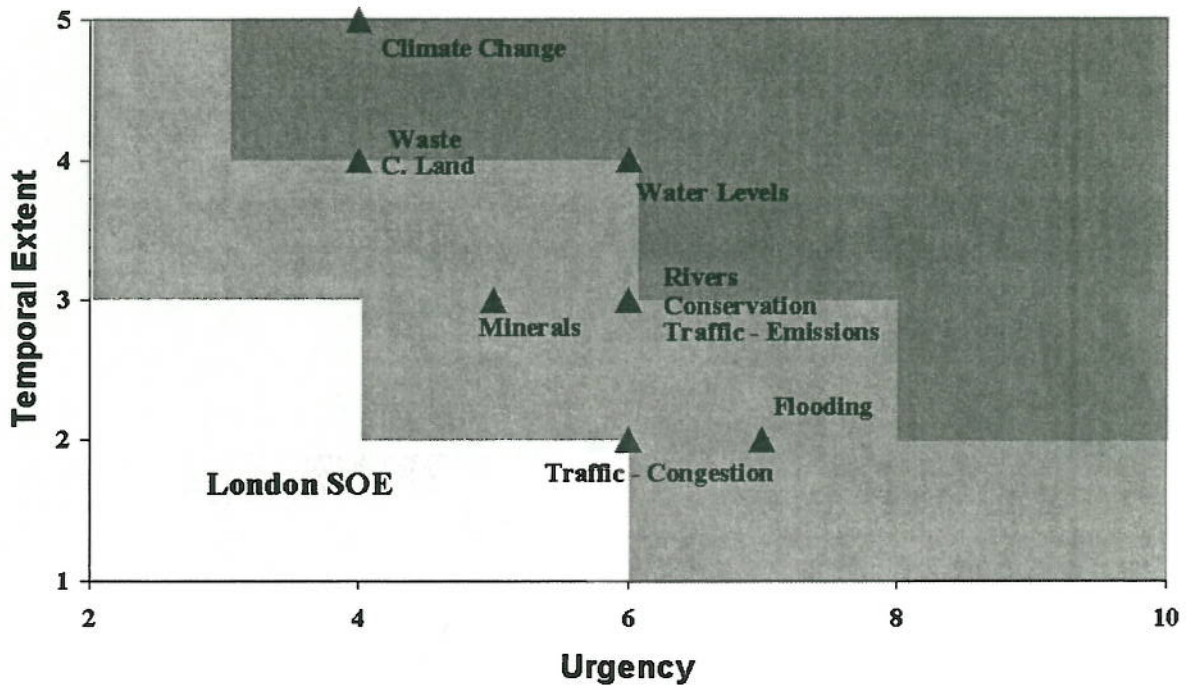
Social Response - Physical Harm schematic for Case Study B – State of the Environment for London. The error bars represent the standard deviation around the mean score and reflect the variability between all of the attribute scores, rather than the uncertainty associated with individual attribute scores. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



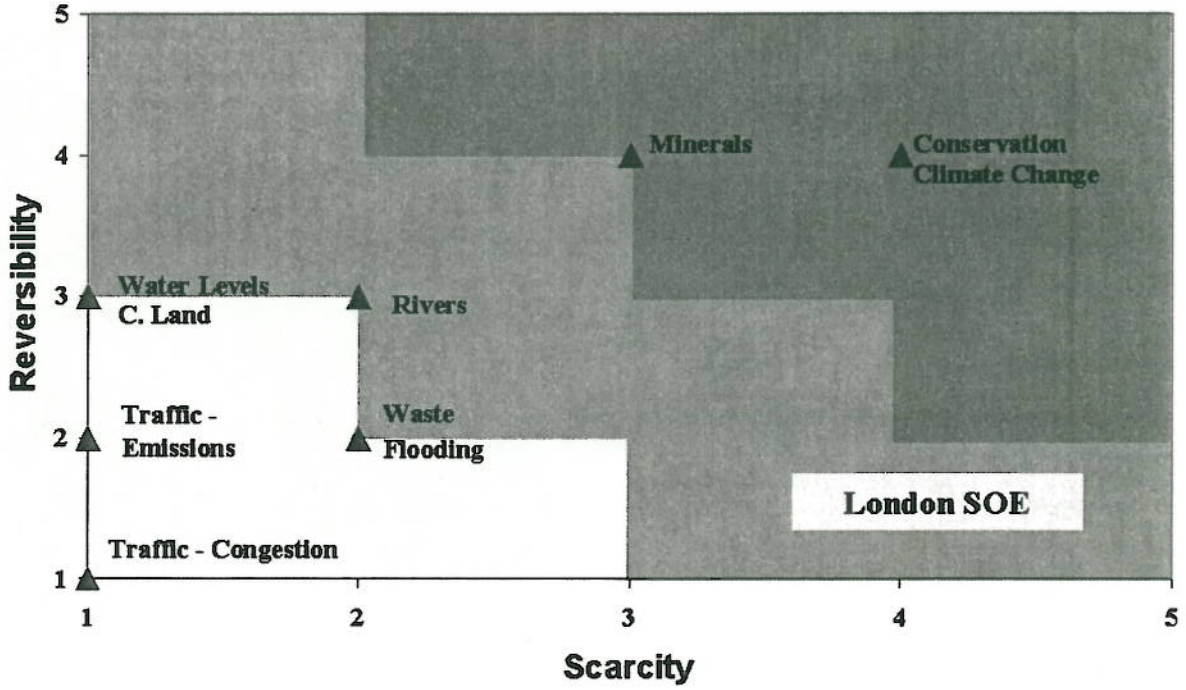
Social Response schematic for Case Study B – State of the Environment for London. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Spatial Characteristics schematic for Case Study B – State of the Environment for London. The black lines show the uncertainty associated with some of the scores, represented by the green triangles. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Temporal Characteristics schematic for Case Study B – State of the Environment for London. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Scarcity Characteristics schematic for Case Study B – State of the Environment for London. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.

5.2.2 Findings from Case Study B

Unlike Case Study A, there are significant differences between the tool schematics as to which issues plot in the higher, medium, and lower priority areas. From the Probability - Relative Value - Social Response schematic, the main issues in terms of cost are flooding, greenhouse gas emissions, and traffic congestion and pollution. However, the uncertainty associated with the relative value estimates for all of these issues is significant. Flooding and traffic issues also rate highly in terms of social responses, as do some of the lower cost issues, such as conservation. The issue of mineral extraction is a good example of an issue that plots in the lower priority areas on the Social Response and the Probability - Relative Value - Social Response schematics, but plots at higher priority levels on the Impact and Scarcity characteristic schematics.

To tackle the issue of mineral extraction, the schematics show that risk management would be most appropriately focused on reducing impact and handling reversibility and scarcity. Therefore, from Section 4.1, appropriate possible techniques include development of substitutes, and promotion of recycling. A point to note, however, is that such techniques might actually raise public awareness and thereby increase some of the social response attribute scores, and this is a matter for effective risk communication to address. In an options appraisal exercise, the selection of any of the identified risk management techniques to tackle the issue of mineral extraction would ultimately depend on a comparison of resources (costs, manpower), timescales, and efficacy of techniques, and the relative positions of the mineral extraction issue versus the other risk issues on the tool's schematics.

5.3 Case Study C – New Forest LEAP

5.3.1 Conduct of Case Study C

This case study was chosen to evaluate the potential utility of the SRA tool to a risk prioritisation process that was primarily conducted through stakeholder consultation. The schematics for this case study are presented below. The supporting report of the scoring basis is provided in Appendix C.

The New Forest LEAP Consultation Report (Environment Agency 1998b) presented environmental data for the New Forest, and summarised the prioritisation of environmental issues, as derived through a process of stakeholder dialogue (Clark *et al.* 1998). The Consultation Report also identified possible options for addressing the environmental issues, and invited comment. The New Forest LEAP action plan (Environment Agency 1999b) refined the issues and actions as a result of the consultation process.

The issues listed in the New Forest LEAP documents are a mixture of hazards and their consequences, management approaches and practices, Agency duties, public concerns, and issues related to lack of knowledge. The SRA tool defines risk issues for comparison in terms of hazards and their potential consequences only. Therefore, the SRA tool cannot be used to compare all of the issues as set out in the New Forest LEAP, although it can be used to examine the environmental harm underlying all of the issues. To evaluate the use of the SRA tool in comparing *local* environmental issues, a subset of the issues from the New Forest LEAP has been used. Only those issues that are presented in the New Forest LEAP as an environmental pressure imposed by a hazard have been used. Four issues related to the

different Agency environmental themes set out in the LEAP, and four issues within a single theme have been used (italicised text indicates titles used on the schematics):

- Managing water resources – low summer *stream flow* rates in certain New Forest streams (denoted by **M7** in the New Forest LEAP – stakeholder ranking = 2).

- Addressing climate change – the impact of sea level rise on intertidal areas, creating *coastal squeeze* through coastal defence (**M15** – stakeholder ranking = 9).

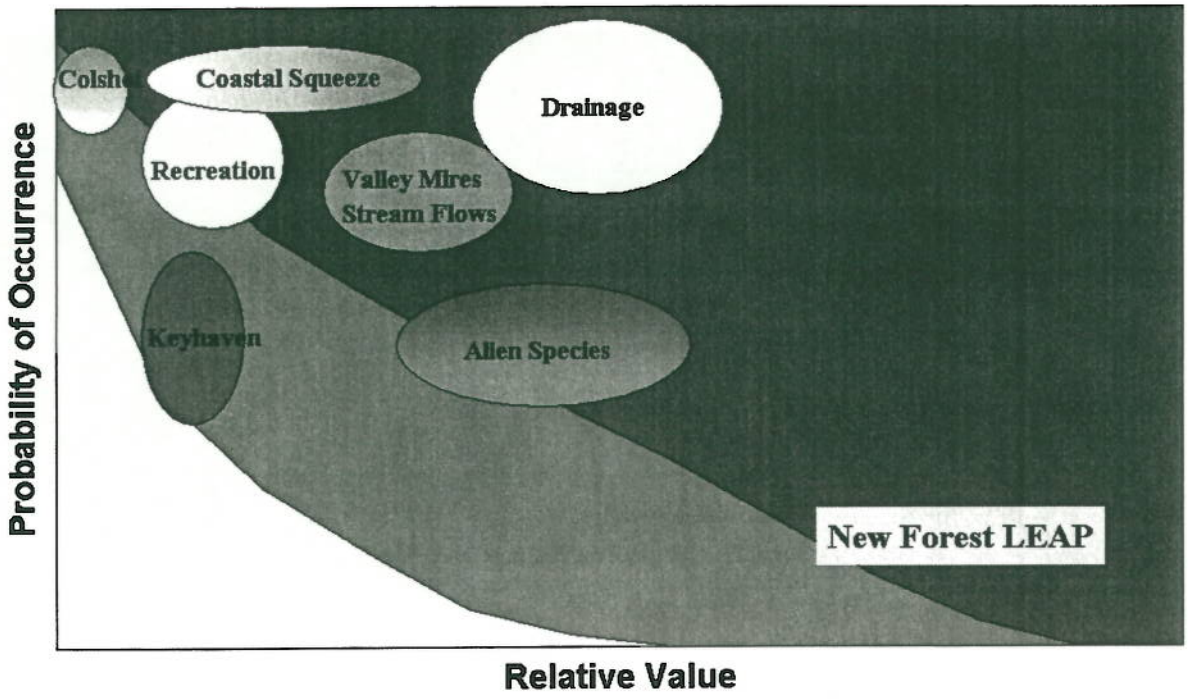
- Enhancing biodiversity – the threat to aquatic ecology caused by the spread of *alien species* of flora and fauna (**S4** – stakeholder ranking = 1).

- Managing waste – deterioration of the *Keyhaven* Pond at the Lymington and Keyhaven Nature Reserve through leakage from waste management facility (**M11** – stakeholder ranking = 8).

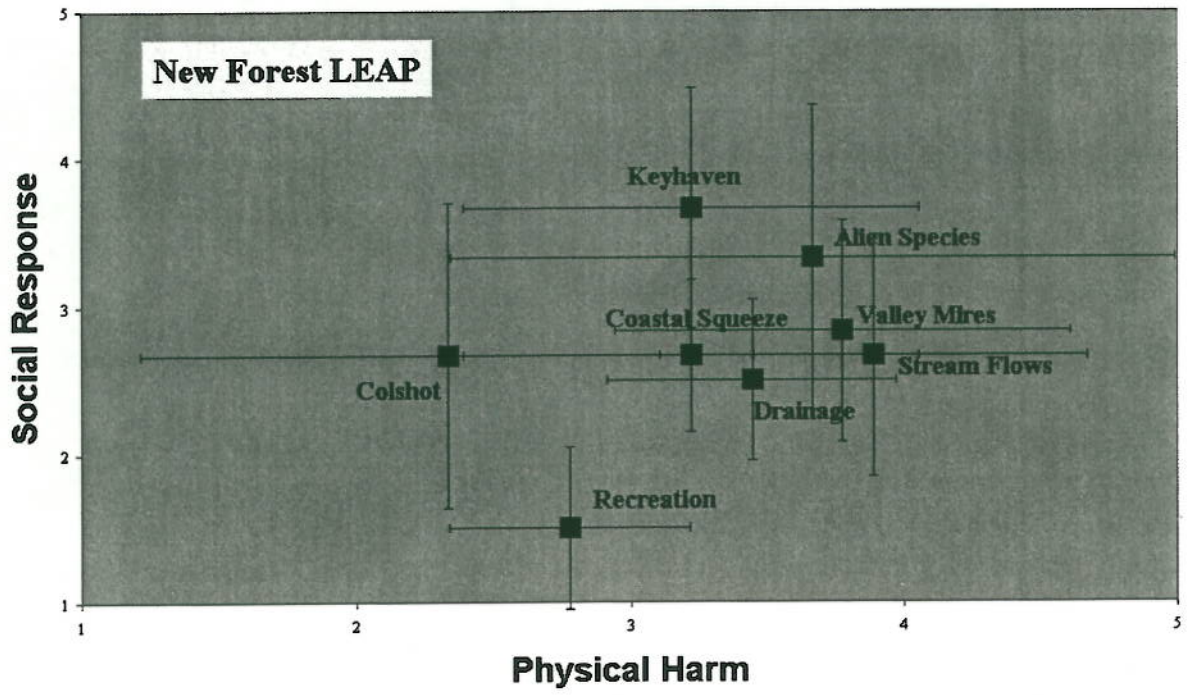
- Integrated river basin management:
  - loss of biodiversity associated with damage to *valley mire* systems (**M3** – stakeholder ranking = 5);
  - loss of biodiversity associated with engineering works on natural river courses to alter *drainage* (**M4** – stakeholder ranking = 12);
  - loss of biodiversity associated with use of watercourses for *recreation* (**M5** – stakeholder ranking = 17); and
  - reduced recreational water quality at *Calshot* (**M10** – stakeholder ranking = 6).

Given that assessment of the comparative importance of the New Forest Leap issues is intended as a within-LEAP appraisal, as opposed to a comparison against other, wider environmental issues of concern, the scoring of issues within the assessment was adjusted accordingly. This means that issues affecting the area as a whole were scored in an equivalent manner to "global" issues in Case Study A. This enables a more accurate reflection of the stakeholder weighting of issues carried out for the New Forest LEAP. However, it also precludes the comparison of schematics and the associated scoring of issues between the case studies. For example, an issue that scores highly in Case Study C might only yield a moderate to low score on the attribute scoring scales used in Case Study A.

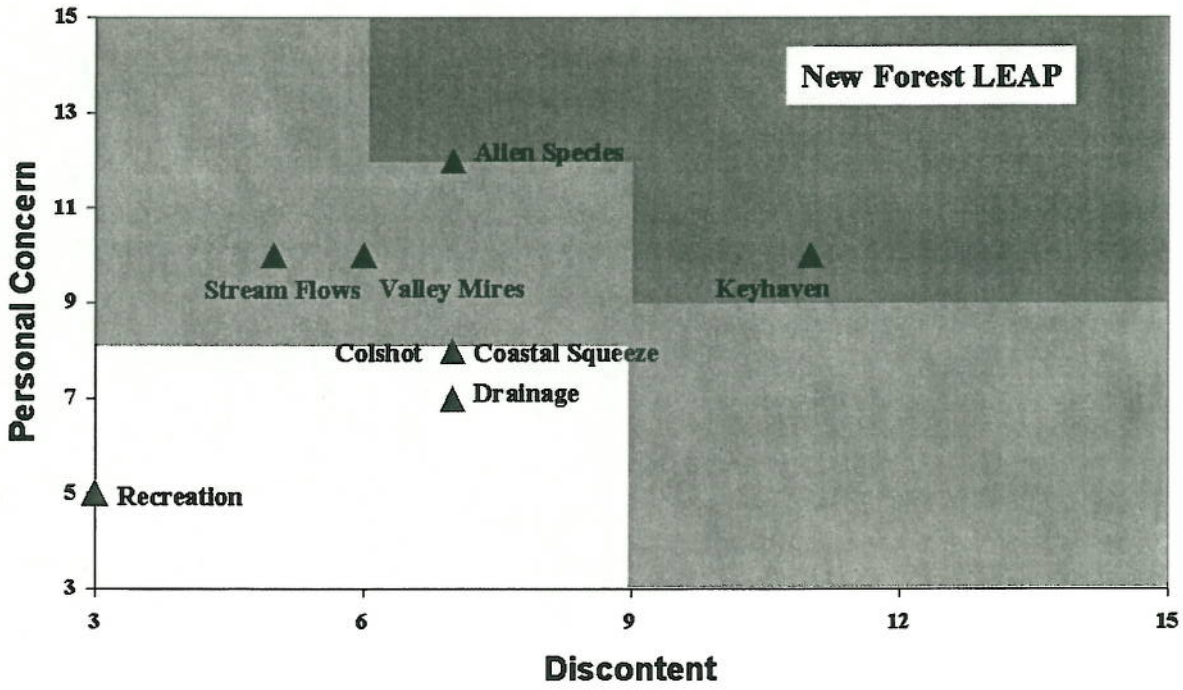
Owing to few data, the relative value of the environmental harm associated with each risk issue proved hard to estimate. A common scale of damage to biodiversity was used for the purposes of the case study. However, this scale does not capture the consequences of the harm in terms of a variety of other potentially important receptors, such as human quality of life, damage to property, and loss of earnings. The limited valuation of the risk issues is reflected in the high priority assigned to some issues in the LEAP relative to their scoring in the SRA tool (see below).



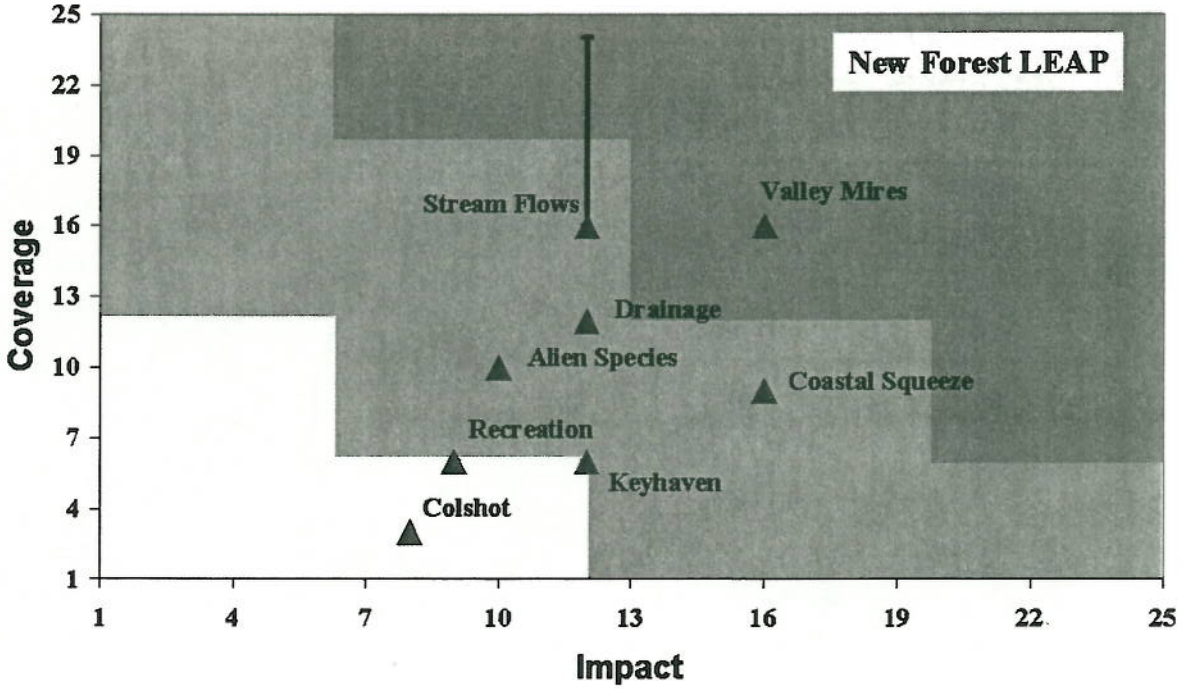
Probability - Relative Value - Social Response schematic for Case Study C – The New Forest LEAP. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position. The grey shading illustrates areas of potential higher, medium, and lower priority. The colours reflect social response (red = high, yellow = low).



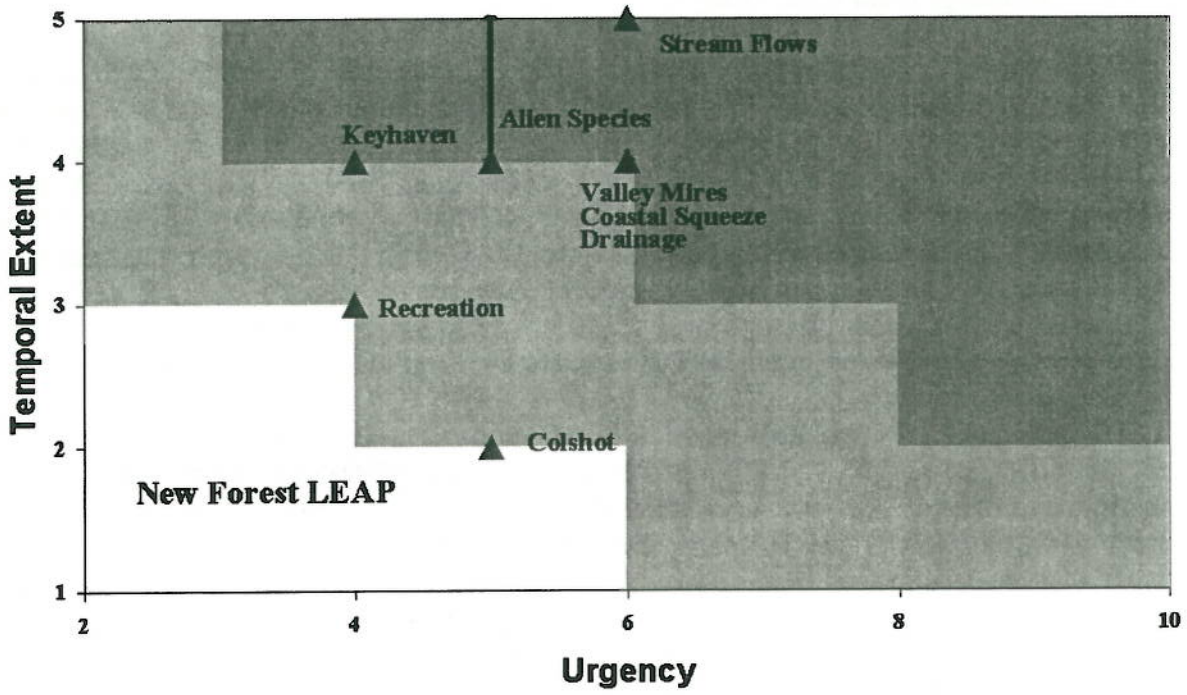
Social Response - Physical Harm schematic for Case Study C – The New Forest LEAP. The error bars represent the standard deviation around the mean score and reflect the variability between all of the attribute scores, rather than the uncertainty associated with individual attribute scores. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



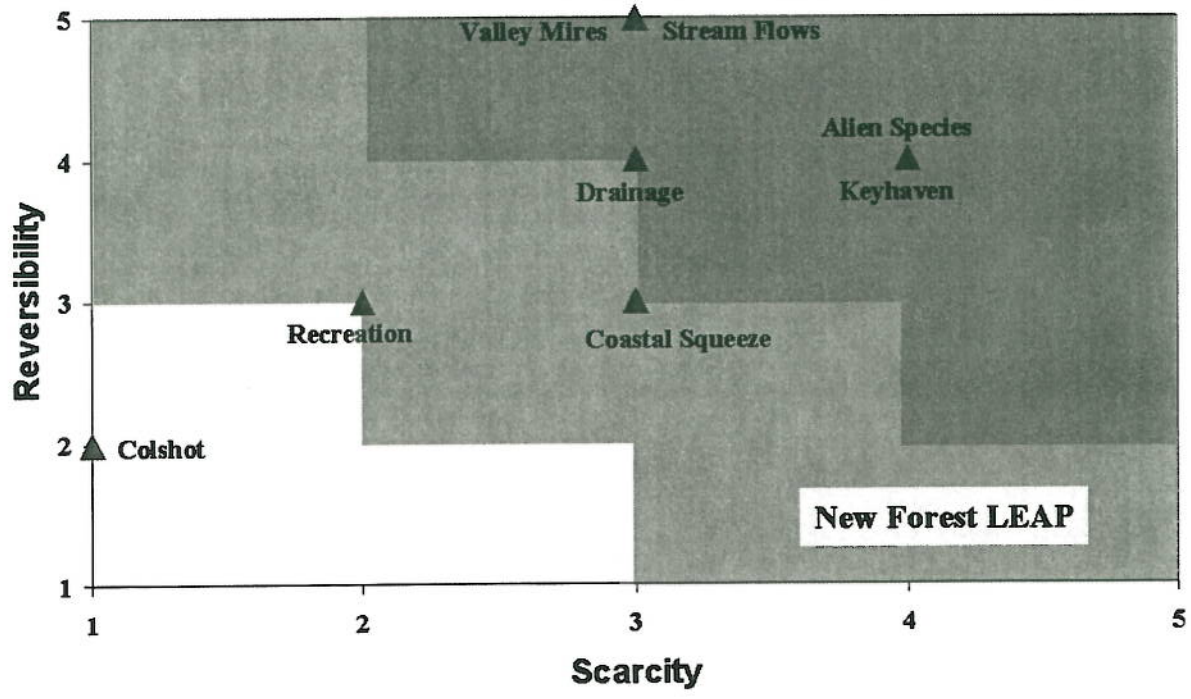
Social Response schematic for Case Study C – The New Forest LEAP. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Spatial Characteristics schematic for Case Study C – The New Forest LEAP. The black lines show the uncertainty associated with some of the scores, represented by the green triangles. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Temporal Characteristics schematic for Case Study C – The New Forest LEAP. The black lines show the uncertainty associated with some of the scores, represented by the green triangles. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.



Scarcity Characteristics schematic for Case Study C – The New Forest LEAP. The characterisation is for the purposes of the case study only, and does not necessarily reflect the Agency position.

5.3.2 Findings from Case Study C

The New Forest LEAP used stakeholder weightings to combine criteria scores for each issue and arrive at a prioritisation. The SRA tool does not use weightings and does not aim to provide a single score for prioritisation purposes. The position of the issues on the summary schematics in this case study does not always reflect the prioritisation given in the New Forest LEAP. This probably reflects weighting of certain characteristics of risk issues by stakeholders that was not captured in the case study scoring. In particular, the relative value of the issues in Case Study C shown in the Probability - Relative Value - Social Response schematic was based on the potential impact on biodiversity. However, biodiversity may have been given a low weighting by some stakeholders in the LEAP dialogue process.

The issues of alien species, derogation of the Keyhaven Pond and loss of valley mires do tend to plot at high values on the Character–Response schematic, reflecting their high prioritisation in the New Forest LEAP. However, the Colshot issue is a relatively high priority in the LEAP (rank = 6), but plots at low values on the tool schematics, reflecting a local issue that has a relatively small impact on biodiversity, the main receptor evaluated in the tool's application. Conversely, engineering work on river courses might have a similar impact on biodiversity to low summer flows, as reflected in a similar characterisation in the SRA tool, but engineering work receives a much lower prioritisation than low summer flows in the New Forest LEAP (rank = 12, as opposed to 5).

In a real application of the SRA tool to a LEAP prioritisation, stakeholders may be included in the scoring group to more accurately capture social opinions and valuation. Further, data would be compiled to allow the full range of receptors to be considered in order to account for the full extent of damage related to each risk issue.

6. REVIEW OF THE SRA TOOL

The SRA tool has been reviewed during its development, and several aspects have been refined or introduced to address comments. The tool has also been presented and discussed at a workshop in Reading in January 2001 comprising Agency staff and external experts. Some of the main outstanding points raised by the reviews and the workshop are summarised below.

6.1 Simplification

During the development of the SRA tool, the complexity of the presentation of the results has increased from one to several schematics. This reflects the range of information that might need to be presented to support decisions on risk management options, approaches, and priorities. The schematics break out the SRA tool's attributes into similar groups or types of information, helping to identify the key attributes of each risk issue that may need to be focused on by risk management programmes. The underlying documentation justifying the scoring is equally important.

The amalgamation of the information into a single "score" has been avoided as this would lead to a loss of information and would involve weighting (see Section 6.3). As a result, the application of the tool to deliver a strict list-type ("top-ten") prioritisation of issues is limited. Its value is in allowing comparison of diverse issues at a more detailed level, and in helping to identify appropriate possible techniques for risk management of issues of key concern.

6.2 Attributes

Some reviewers have commented that there are too many attributes in the SRA tool. In group discussions, no consensus is ever obtained on which attributes to include or exclude. The attributes presented here are all distinct, and reflect a discrete piece of information about the environmental harm related to a risk issue that can be addressed by focused risk management. However, to simplify presentation (see above), several attributes are presented together on the tool schematics. When more case studies have been completed, a statistical evaluation of attribute inter-dependencies could be undertaken to evaluate whether any attributes are redundant.

6.3 Scoring and Subjectivity

No weighting is applied in the SRA tool, although "Stock at Risk" and the social response attributes are used on the summary-level Probability - Relative Value - Social Response schematic and may, therefore, be considered as of key importance. However, the weight the decision-maker applies to each graph is not pre-judged by the SRA tool. This is not to say that, on a case-by-case basis, weightings could not be used to arrive at a single score for each issue. However, such weightings will be case-specific and will probably involve stakeholder dialogue (e.g., see Case Study C). Further, decision analysis tools should be used to evaluate the sensitivity associated with the weighting.

6.4 Presentation

The majority of reviewers of the SRA tool favoured use of more than one schematic, although some favoured use of only one summary schematic to communicate results, and some suggested combinations of attributes different to those suggested in Section 3 in order to communicate particular findings.

The schematics presented in Section 3 are only for guidance. Different schematics could be suggested for different audiences and for communicating different messages. Partly for this reason, the schematics presented in Section 3 are split into two groups:

- summaries providing a strategic overview for decision-makers and public audiences (the Probability - Relative Value - Social Response and Social Response - Physical Harm schematics);
- supporting analysis schematics comparing characterisation of risk issues to assist options appraisal within the risk management team.

In particular, the analysis schematics may be altered to focus on issues and combinations of attributes of key interest.

6.5 Treatment of Uncertainty

Uncertainty about environmental harm can be divided into four categories:

- Variability (observed or predicted variation of responses to an identical stimulus among the individual receptors within a relevant population such as humans, animals, plants, and landscapes).

- Measurement errors (imprecision or imperfection of measurement, problems of drawing inferences from small statistical samples or other experimental data, uncertainties of modelling).

- Indeterminacy (resulting from a genuine stochastic relationship between cause and effect(s), apparently non-causal or non-cyclical random events, or badly understood non-linear, chaotic relationships).

- Lack of knowledge (resulting from ignorance, from the definition of system boundaries and hence exclusion from external influences, measurement impossibilities).

The SRA tool treats uncertainty in three principal ways:

1. In a generic way, through its attributes: e.g., "Heterogeneity" and "Sensitivity of Receptors" capture the variability of the harm; "Latency" captures uncertainty about the timing of the harm.

2. Through the scoring of the attributes: each attribute score is based on best knowledge. If there is uncertainty about the data (i.e., measurement error), or about the effects (i.e.,

indeterminacy), then the score can be given an "error" range to reflect the uncertainty. Lack of knowledge can also be treated in this way.

3. Through the assessment of probability: the SRA tool's attributes generally characterise the environmental harm, assuming it is realised. The tool also allows the specification of probability to account for the uncertainty in whether receptors are exposed to the hazard, thereby leading to the environmental harm.

The weight the user attaches to the assigned uncertainty is not pre-determined and should be justified in the documentation of any decisions based on the SRA tool scoring.

A further development of the SRA tool might be to introduce an attribute that deals explicitly with uncertainty related to lack of knowledge. This attribute could be used to preclude the characterisation of an undefined harm using the other attributes and to advocate a precautionary regulatory approach.

7. CONCLUSIONS AND OBSERVATIONS

7.1 Conclusions

The SRA tool has been developed over a period of time through expert review, peer review, workshop application and case studies. Our intention has been to provide an additional aid to strategic decision-making on environmental issues – and not the sole or preferred method. However, it is clear that given a number of important *caveats*, the SRA tool represents a significant step forward in the development of such tools.

First and foremost, the SRA tool seeks to bridge the gap between technical assessments of the characteristics of environmental risk issues on the one hand, and the social responses to those risk issues on the other. This has particular benefits when moving from risk assessment to the role of helping to consider risk management options. Second, it works at a number of strategic levels by allowing a high-level view of current and potential issues facing society, supported by assessments tied to established empirical data where available. Third, it has the potential to incorporate economic data to establish the "relative value" of risk issues in economic terms – albeit such data are not yet always available. Finally, it pays particular attention to the issues of transparency in assessment and the communicability of findings. These characteristics are judged to be of critical importance if the tool is to be used as an aid to decision-making by senior managers in the Agency.

The caveats associated with the SRA tool are no more stringent than for many other assessment tools – but in this case they do translate into some clear rules for guiding the correct application of the SRA tool. In general terms, the central caveats are:

- The results from using the SRA tool merely reflect the quality of the input data available, and the use of generalised data or assumptions will generate less meaningful results. The tool provides clear guidance on scoring, but it is incumbent upon the user to be realistic about the quality of information available and to record all relevant assumptions on the spreadsheets for the sake of transparency and traceability.

- The user needs to think carefully about what s/he is trying to assess when undertaking the scoring – not only for the sake of internal consistency and validity, but also because the scoring scale suggested in Table 3.2 may need to be adjusted to suit the assessment. This issue is reflected in Case Study C, where it became clear that the scoring needed to reflect strength of *local* or "within LEAP" impacts and concerns, and not seek any more generalised ranking of the issues within a national context.

Key Features of the SRA tool

1) The SRA tool helps to formalise the analysis of risk issues and provides traceability to the reasoning behind the analysis results.

2) The SRA tool provides a sound basis for comparing disparate risk issues by identifying common attributes of the environmental harm associated with the risk issues and scoring these attributes on a common scale.

3) The output of the SRA tool can be used by technically aware users to analyse different issues, attach priorities, and communicate such information to non-expert groups. The output cannot be used to prioritise issues "at a glance".

4) The presentation of the SRA tool utilises a series of schematic presentations focused towards their intended audience and use:
   - Summary schematics are used for high-level communication of risk prioritisation.
   - Other schematics grouping attributes and individual attribute scores are used to assist in options appraisal and development of risk management strategies.

5) The SRA tool favours the advantages of an unweighted and essentially qualitative approach, although there is the potential for more quantitative expression of the framework analyses if the data are available.

7.2 Observations

- The SRA tool should be applied by someone fully versed in the issues under assessment. The initial assessment should then be reviewed in an open forum with colleagues with different skills and perspectives on the issues. There appears to be some potential for this open forum to involve different stakeholders, both as a means of generating dialogue, but also as a means of generating alternative risk prioritisations for the Agency.

- When undertaking the assessment, it is essential to think clearly about the issues and the "context" of the assessment – for example, is this for broad comparative purposes and wide dissemination, or is it a more detailed, local review of risk issues to support the generation of risk management options?

- The SRA tool is essentially a qualitative assessment tool and there are dangers in seeking to move towards more quantitative methods when comparing environmental risk issues according to quite disparate (but comprehensive) characteristics. Application of the SRA tool should be as expressly intended: as an aid to decision-making only.

- Finally, the advantages of the SRA tool as set out in this report deserve testing in real cases, for it is not until strategic methods such as the SRA tool have been championed with a serious intent, that the true potential benefits of the approach will be realised.

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Environment Agency

Informing Strategic Decisions with Comparative Risk Assessment: a Literature Review

RIS-05-01

The Environment Agency is the leading public body protecting and improving the environment in England and Wales.

It's our job to make sure that air, land and water are looked after by everyone in today's society, so that tomorrow's generations inherit a cleaner, healthier world.

Our work includes tackling flooding and pollution incidents, reducing industry's impacts on the environment, cleaning up rivers, coastal waters and contaminated land, and improving wildlife habitats.

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Science at the Environment Agency

Science underpins the work of the Environment Agency. It provides an up-to-date understanding of the world about us and helps us to develop monitoring tools and techniques to manage our environment as efficiently and effectively as possible.

The work of the Environment Agency's Science Group is a key ingredient in the partnership between research, policy and operations that enables the Environment Agency to protect and restore our environment.

The science programme focuses on five main areas of activity:

- **Setting the agenda,** by identifying where strategic science can inform our evidence-based policies, advisory and regulatory roles;
- **Funding science,** by supporting programmes, projects and people in response to long-term strategic needs, medium-term policy priorities and shorter-term operational requirements;
- **Managing science,** by ensuring that our programmes and projects are fit for purpose and executed according to international scientific standards;
- **Carrying out science**, by undertaking research – either by contracting it out to research organisations and consultancies or by doing it ourselves;
- **Delivering information, advice, tools and techniques,** by making appropriate products available to our policy and operations staff.

Steve Killeen

Head of Science

Executive Summary

The Environment Agency is responsible for managing the risks arising from issues such as high water levels, waste, chemical emissions to air/land/water and agricultural activities. We do this by undertaking a wide range of activities that include direct regulation, advising government, flood warning, building new flood defences, monitoring, education and influencing.

We need to take decisions on the relative importance of environmental risks to help us decide where best to focus our efforts. Comparative risk analysis techniques can provide the information we need to make changes for the good of the environment. However, the data that we need to compare different environmental risks are rarely available in a common format. This makes comparison difficult.

We have been working on the development of a practical, comparative risk assessment tool for a number of years. Our work has involved:

- reviewing the scientific literature;
- developing a framework and methods for collecting and interpreting data to inform decisions;
- using our findings to assist in state-of-the-environment reporting and to support the prioritisation of regional environment programmes.

Much of this work has been published and peer-reviewed by leading practitioners. But we have not yet succeeded in developing a framework that is easy to use.

This report brings our understanding of relevant published literature up-to-date. It focuses on the last five years and highlights important developments in strategic risk assessment from around the world. Additionally, it reflects on our experiences to date and brings all this information together to make recommendations for future work.

We will use this report to inform our ongoing work to develop our ability to undertake comparative assessments of environmental risk at all levels. We aspire to making robust comparative assessments of risk to inform strategic, policy and operational decisions.

Dr Phil Irving
Risk Analysis Manager
Environmental Policy – Risk and Forecasting

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1 Introduction

1.1 Background

This document provides an overview of the Environment Agency's research to date on comparative risk assessment and reviews recent literature from around the world. Its main aim is to:

- inform the future development of comparative risk assessment within the Environment Agency;
- identify the developments required to take the tools from the pilot stage to where they can be of practical routine use.

The Environment Agency prioritises its actions across a diverse range of environmental pressures to secure environmental improvements and protection in keeping with modern and risk-based regulation.

Information on environmental issues to inform strategic analyses can be disparate because data on a wide range of issues are rarely presented in a common format that allows easy analysis and comparison. Nevertheless, the Environment Agency frequently requires defensible judgements on the significance of various environmental pressures. Practical examples include:

- strategic national and regional level assessments such as state of the environment reports;
- targeting regulated activities as part of a risk-based approach to permitting where comparative risk analysis is required on activities across the board;
- distinguishing between classes of regulated risks that can be managed through standard rules and those requiring more detailed assessments;
- catchment-scale river basin planning under the Water Framework Directive where many pressures act on the water environment;
- comparisons of anthropogenic and natural hazards, e.g. the importance of flooding relative to other natural (and indeed man-made) hazards;
- workforce planning for environmental management decisions at a local level;
- strategic analysis to inform national information campaigns, e.g. by comparing perceived risks of various regulated activities.

In an attempt to provide practical tools for the comparative analysis of environmental risks, the Environment Agency and its predecessors have conducted a long-term programme of developmental research on comparative risk assessment.

This research theme began with a study of the ranking of harm from accidental releases to the aquatic environment. It progressed in 1996 to a broader, quantitative comparative risk assessment tool intended for use at a strategic level.

Since 1999, there has been a requirement to encompass less tangible aspects of harm and to deal with the inherent uncertainty of socio-economic impacts. The approach therefore developed a semi-quantitative and richer description of harm. Arguably, however, no single approach has fulfilled a unifying practical purpose. Quantitation, though offering an easy ranking of environmental risks, belies the uncertainty of environmental consequences and their likelihoods of occurrence– let alone those of broader socio-economic impacts. Conversely, the semi-quantitative tools – though well received by peer-review and recently referenced to specific risk management strategies – have proved challenging for non-specialists because of the perceived subjectivity.

The assessment tool developed under this programme use the concept of 'environmental harm' as a common measure – viewed most recently from technical, social and economic perspectives – to analyse impacts from a range of environmental pressures. Critical to an informed debate on the relative importance of these perspectives is an understanding and analysis of:

- the various characteristics of harm (spatial and temporal extent, reversibility, latency, etc.);
- the social response to actual or potential environmental harm from a range of hazards.

Recent research outputs from the Environment Agency and its collaborators include:

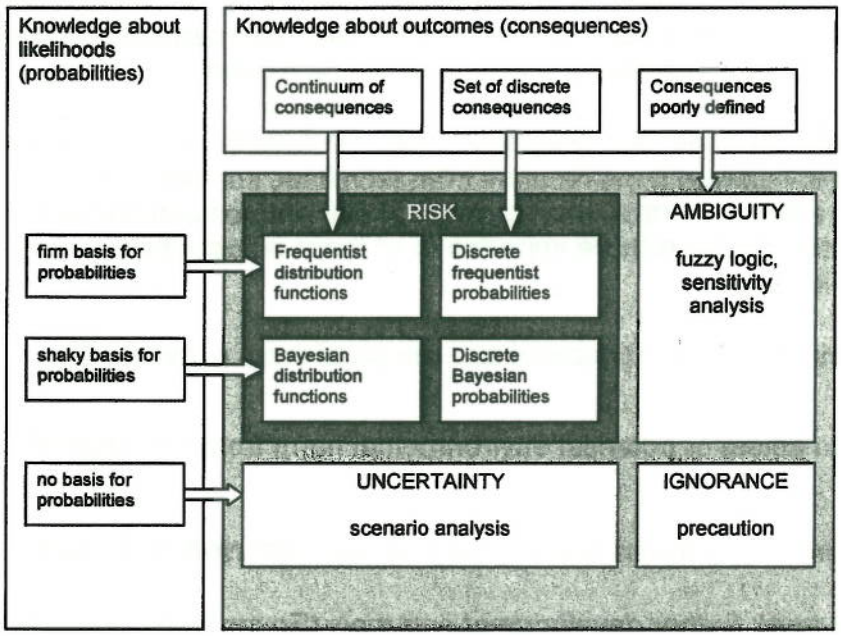
- *Strategic risk assessment: further development and trials* (Environment Agency, 1999);
- *A strategic approach to the consideration of environmental harm* (Environment Agency, 2000a);
- *Strategic risk assessment: a decision tool for complex decisions* (Pollard *et al.*, 2001);
- *Strategic risk assessment: phase II* (Environment Agency, 2002);
- *Agricultural Strategic Risk Workshop report* (Environment Agency, 2004);
- *Characterising environmental harm: developments in an approach to strategic risk assessment and risk management* (Pollard *et al.*, 2004a).

This document updates the open literature since 2000 with a view to preparing the foundation for a new phase of work, which will translate the conceptual research undertaken to date into practical, useable tools for policy and regulatory staff.

1.2 Drivers for comparative risk analysis

Environmental policy-makers and regulators require decision tools to help them prioritise a diverse range of risks to and from the environment to ensure effective environmental protection consistent with the goals of sustainable development. Risk assessment allows the prioritisation of resources and can be applied when the probabilities and consequences of adverse events are known but poorly characterised together (Figure 1).

Figure 1 Role of risk analysis in decision-making (after Stirling, 2001)



Risk assessment (van Asselt, 1999; Pollard *et al.*, 2004b) has a role in state-of-the-environment reporting and can inform strategic environmental management decisions. Environmental management involves monitoring, evaluating data, making decisions and reviewing decisions. Monitoring and evaluating data results in an understanding of pressures and the identification of risks from which options for risk management can be identified (Figure 2).

Such tools are also increasingly required to straddle the interface between environmental policies, regulatory processes and operational plans e.g.

- in brownfield redevelopment strategies (Figure 3);
- the preparation of pollution reduction plans;
- the preparation of river basin management plans;
- regulatory risk assessments under the Pollution, Prevention and Control (PPC) regime for landfills.

Figure 2 Role of risk analysis within state-of-the-environment reporting (after Pollard *et al.*, 2004a; Environment Agency, 2000b).

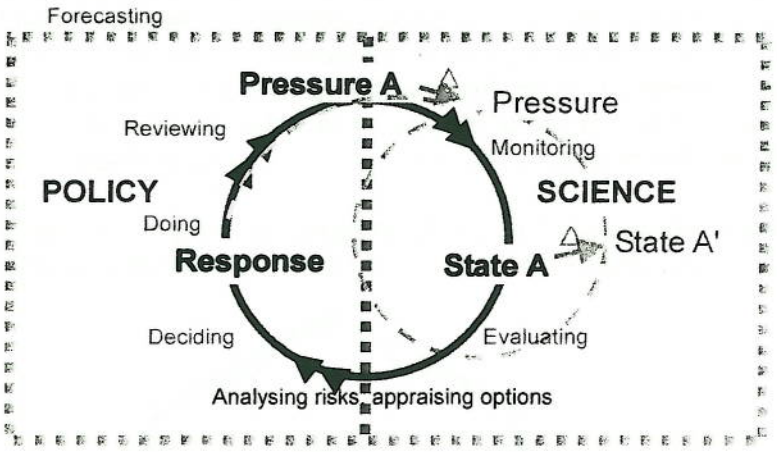
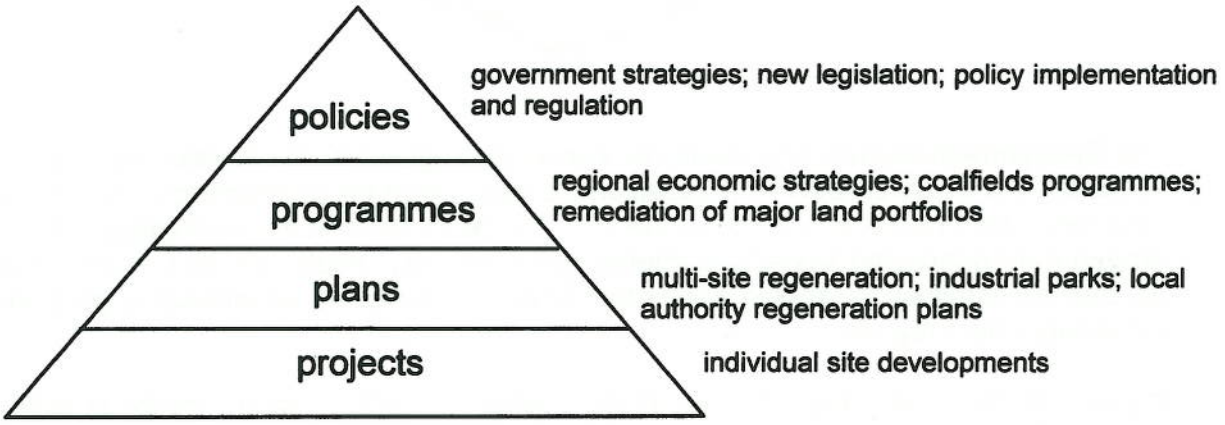


Figure 3 Policies, programmes, plans and projects – four tiers of risk, illustrated here for contaminated land (after Pollard *et al.*, 2004b)



The way we manage environmental risks is changing. There is an expectation of active stakeholder input (Figure 4), a need to consider risks to the multimedia environment within regulatory assessments, and recognition of the need to integrate risks from source through to receptor.

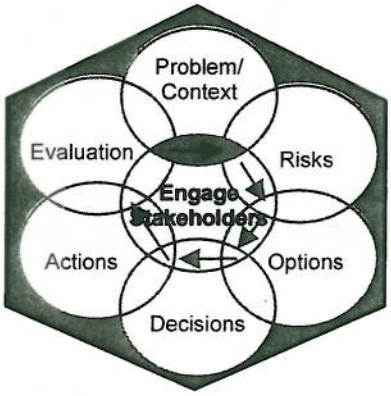
The current approach to environmental risk management recognises the importance of:

- good problem definition;
- management feedback;
- the central role of stakeholders to the decision-making process.

Risk analysis is not viewed as an end in its own right, but as a means of prioritising options for risk management – which require evaluation after implementation – within the context of making better decisions.

These developments have in common a practical requirement to express and compare the value of environmental harm that might arise from a multitude of sources to a range of receptors. Comparisons have to be scientifically defensible, practical and offer demonstrable outcomes for a better environment (Environment Agency, 2000b). However, the expression of environmental harm is by its nature controversial because it requires an explicit statement of values – the value one places on environmental components and the relative value one assigns between them.

Figure 4 Risk management in the 21st century – the expectation of stakeholder engagement in decisions on risk (after US Presidential Commission, 1997)



The Environment Agency has made considerable progress in the development and application of a comparative risk assessment tool. A number of structured workshops have been held to test and improve the tool. Topics covered at the workshops have ranged from prioritising key environmental risks that may result from air pollution and agricultural activities to ranking issues that feature in the Environment Agency's state of the environment reports.

In practice, the Environment Agency faces a range of institutional drivers for its work on comparative risk analysis, and particularly its use in strategic decision-making. These include:

- its response to the Hampton review of regulatory inspections and enforcement commissioned by the Chancellor of the Exchequer in his Budget 2004, and the need to focus on efficiency and effectiveness;
- the role of comprehensive risk assessment to underpin and evidence proportionate regulatory action;
- its response to:
  - the Government agenda on risk;
  - the drive towards better risk management;
  - implementing the Cabinet Office and HM Treasury principles of managing risks to the public (i.e. proportionality and consistency, openness and transparency, evidence and involvement);

- delivering its vision and strategy of protecting and enhancing the environment in the context of its contribution to sustainable development;
- a need to lead the debate on environmental risk in the context of societal views on risk and new technology.

1.2.1 Purpose of this document

Although the workshops were instructive, they identified a number of practical challenges in using the approach described in R&D Technical Report E2-041/TR (Environment Agency, 2002). These challenges were articulated within a recent workshop on risks from agriculture (Environment Agency, 2004), which led to the recommendations shown in Box 1.

Box 1 Recommendations for future improvements to the Environment Agency's comparative risk assessment tool following the workshop on agricultural activities

Tool design

- *Number of attributes*
  - the number of harm attributes could perhaps be reduced
  - once users were familiar with its application, some work might be undertaken by a smaller representative group trained in the tool's use.
- *Flow chart for the risk assessment process.* A schematic flowsheet of the process would provide a 'map' to new users.
- *Definitions and terminology.* A glossary is required.
- *Worst case scenarios.* The validity of adopting reasonable worst case assumptions was questioned. It was noted that, in this application, a further filter of information on the local environmental setting would act to augment the risks characterised by using default assumptions.

Using and implementing the tool

- *Representativeness of expert group (especially with respect to representing social concerns).* Assessing the harm attributes requires expertise across the environmental and social sciences. Concern was expressed that social concerns may not be adequately represented in the assessment. However, the use of surrogates, e.g. views of policy colleagues aware of agendas of non-governmental organisations (NGOs) and others, was deemed better than these factors not being included .
- *Supporting evidence for scoring.* A desire was expressed to access hard data to lend additional support to the scoring of attributes. Sometimes data are too voluminous or not available. Nevertheless, it was agreed that, where available, data should be accessed.
- *Requirement for a facilitator.* The process was deemed to be sufficiently sophisticated to require a facilitator to assist in building consensus and challenging received views.
- *Involvement of local Area teams in tool refinement.* The scoring of attributes requires input from local Environment Agency Area teams who are often in an ideal position to present the reality of environmental harm.
- *Scale of assessment.* This requires attention during the problem definition stage.
- *The tool needs active communication.* The tool is sophisticated and not readily understood by those less familiar with risk issues. It is therefore important to stress the benefits of the approach and where the assessment is leading, i.e. to informing risk management activity.

Issues relating to other risk tools used in the Environment Agency

- *Integration with other risk prioritisation work, e.g. Operator and Pollution Risk Appraisal (OPRA) for PPC.*

These challenges need to be addressed to make the tool user friendly and practical for use by Environment Agency staff and others.

Application of the tool to date suggests that:

- The tool offers a systematic approach to characterising strategic risks. Similar tools are in use internationally and it is appropriate that the Environment Agency develops a tool that can be used by its staff to prioritise risk issues at a high level. Without such tools, strategic analyses can become subject to the biases of individual or specific interests and may not be transparent.

- There is a need to balance the resourcing of comparative risk assessments by reference to the implications of the decisions they inform. The concepts developed within the tool take time to assimilate and become practised in. Two-day workshops should ideally be used for the purpose.

- This study has allowed an exploration of the tool in practice. A number of issues have been identified that require attention in its further development. How scores are elicited, combined and presented is important and is the focus of research elsewhere (Andrews et al 2004a).

An important aspect is the elicitation of true stakeholder input. Many tools struggle to engage stakeholders or even offer surrogates during the analysis for external views (Perhac, 1998). Further development of the tool needs to address this issue.

Before progressing with an improved tool, the first step taken by the Environment Agency was to commission this international review of peer-reviewed articles and the grey literature (primarily for the period from 2000 to 2005) to update its knowledge and inform future developments. The review focused on:

- comparative risk assessment methodologies, metrics and presentational styles;
- applications of comparative risk assessment at a strategic, policy and programme level;
- involving stakeholders and the public in comparative risk assessments;
- valuing environmental harm;
- implementing comparative risk assessment.

1.2.2 Moving forward

The challenge in developing further the assessment tool used by the Environment Agency is to retain the power of analysis while improving ease of use, especially in the policy arena. Without these improvements, comparative risk assessments may be subject to rapid and ad hoc prioritisations of consequences rather than a more defensible analysis of strategic risk. This report examines the issues and provides an in-depth analysis of developments. A bibliography of cited and additional references is given in Section 7.

2 Comparative risk assessment

2.1 'Apples and oranges'

The issue of comparing different risks with disparate characteristics is not new. The difficulty is not so much the comparison of the relative likelihoods of occurrence, but the (adverse) impacts that may ensue; for example, how to compare ecosystem stress to the potential human health effects that might ensue from prolonged environmental exposure. The situation is especially difficult for environmental hazards because:

- their effects are felt both in a spatial and a temporal context;
- multiple effects are expressed when hazards are realised – frequently to many receptors at any one time.

Like many tools in environmental policy and regulation, comparative risk assessment has had its advocates and critics over the years following its emergence as a formal tool in the USA in the late 1980s. It is now realised that there needs to be some compromise from the theory in order to reap the benefits of application, but decision analysts continue to offer improved metrics and mathematically sound approaches (Long and Fischoff, 2000) to the combination of risks to allow a more justifiable and transparent presentation of risk priorities.

New developments in comparative risk analysis tend to be controversial because they force an explicit statement of values and, by virtue of the metrics used, infer (rightly or wrongly) varying degrees of understanding about the system under study. Tools can suffer from the following:

- an over-simplification of the problem through the use of user-selected surrogates for harm;
- over-sophisticated analysis through the use of sophisticated metrics and analytical precision that exceeds the level of information available about the risk being assessed;
- an absence within the tools of the expression of probability (perhaps because quantification is seen as too difficult, i.e. tools become solely impact focussed and thus lose their analytical power);
- a lack of empirical rigour to the comparison of risks;
- poor user-friendliness and a tendency to become bogged down in detail during application.

2.2 Literature review

The recent literature on comparative risk analysis is substantial. The tools have seen wide application across the policy and regulatory arenas, and are being used internationally to inform the prioritisation of regulatory (and other institutional) resources.

At a rudimentary level, comparisons between the different contributions of various everyday activities to an adverse effect, an exposure point concentration or a dose have been used to help contextualise relative risk. There is a long-standing debate as to whether these prove useful as a communication tool, but their application is usefully summarised for chemical exposures in the public health context by Williams (2004).

At the next level, risk-ranking matrices have been employed that adopt a simple probability consequence score. For example, Frodsham and Cardew (2000) use such an approach for evaluating new technologies for water treatment. Risk scores for a number of technologies are informed by a failure mode and thus allow analysis of the treatment technology combined with expert judgement on the likely impacts of failure.

Similar comparative risk analyses have been used widely in a range of adapted and sophisticated forms for:

- **Technology assessment** for:
  - energy supply technologies (Ramanathan, 2001);
  - the reliability of bridges (combined with reliability assessment) (Stewart, 2001; Stewart *et al.*, 2001);
  - environmental remediation technologies (Bonano *et al.*, 2000).

- **Managing chemicals and pathogens in the environment**, e.g.
  - by ranking pollution inventories (Gamo *et. al.*, 2003; Lerche *et al.*, 2004);
  - by raking pesticide products (Finzio *et al.*, 2001; Lee *et al.*, 2002; Low *et al.*, 2004);
  - assessing the relative risk from exposures to volatile organic compounds in drinking water (Williams *et al.*, 2002), and to consumers from seafood (Sumner and Ross, 2002) and chicken products (Brown, 2002);
  - for ranking the risk of pharmaceuticals in surface waters (Sanderson *et al.*, 2004) and exposures from landfills (Vrijheld *et al.*, 2002)
  - for prioritising contaminated site remediation (Grumbly, 1997).

- **Assessing project risks** in IT system acquisition (Lambert *et al.*, 2001).

- **Comparing ecosystem impacts** (only) in catchment-level impact assessments (Serveiss *et al.*, 2004).

- **Ranking occupational risks** in the mining industry (Donoghue, 2001).

- Developing the basis for **environmental health policy priorities** (Wong *et al.*, 2003).

Few consistencies emerge from these applications with bespoke systems being devised on an ad hoc basis. However, this report is concerned with the application of comparative risk analysis at the policy and programme levels where information can be more voluminous and disparate and, being more abstract, far less tangible.

2.2.1 Comparative risk analysis at the policy level

Policy level applications of comparative risk analysis include:

- informing the health impact assessment of transport policies in Australia (Dora, 2003; Kjellstrom *et al.*, 2003);
- as input to bans on asbestos (Camus, 2001);
- for informing pollution reduction strategies (Pennington and Bare, 2001; Lerche *et al.*, 2002);
- for informing regional catchment management plans (Tran *et al.*, 2002).

But other than the specificities of application, there is little to be gained from the individual studies in isolation.

Specialist practitioners, however, have kept a watching brief on the development and applications of comparative risk analysis over the years. Inspired by the comparative risk analysis carried out by the US Environmental Protection Agency (USEPA) in 1987 (USEPA, 1987) and application of its techniques to a myriad of different policy problems, consensus is developing on the relative merits and challenges of applying these techniques. For example, Andrews *et al.* (2004b) note:

- the use of spurious precision in comparative risk rankings – so-called 'analytical over-reaching';
- calls for normative approaches that are rarely applied in practice;
- an unease among practitioners regarding the presentation of uncertainty in strategic level analysis with a tendency, having acknowledged it, to ignore it in practice.

Perhaps the most serious attempt to tackle the issue of metrics and uncertainty under authentic conditions was undertaken by the New Jersey Comparative Risk Project (NJDEP, 2003). This identified 88 individual environmental stressors in 11 broad hazard categories. In their valuable summary, Andrews *et al.* (2004b) concluded that, despite considerable analysis and interrogation of data by multiple expert panels, the analytical 'constructed aggregation' methodology adopted threw little light on the multiplicity of these risks.

The Project Steering Committee resorted to a risk sorting approach whereby the 88 threats were assessed using a range of risk prioritisation techniques, e.g. environmental threats with high human health, ecological and socio-economic impacts were ranked higher than those with lower impacts. The results of the individual techniques used were compared and those threats of consistent high priority across a range of techniques were identified as high priority overall. Four clusters of threat were deemed of greatest importance, i.e. those associated with:

- land use change
- indoor pollution
- outdoor pollution
- invasive species.

The paper by Andrews *et al.* (2004a) offers valuable insights into the output of comparative risk analysis. They assert that:

- a ranked list of priorities has only limited value when the science is not in place to support such a list;
- for future exercises, emphasis should be on gathering evidence.

Involving a broader range of stakeholders forms a check on the trappings of analytical over-reaching.

2.2.2 Emerging lessons from cumulative effects assessment

The environmental assessment field has long been concerned with comparative analyses – of impacts, rather than risks – to inform options appraisal.

Recent developments in cumulative effects assessment (CEA) as required under the EU environmental impact assessment (EIA) directives (85/337/EEC and 97/11/EC) and strategic environmental assessment (SEA) directive (2001/42/EC) are forcing practitioners to manage the aggregation of environmental effects past, present and in the reasonably foreseeable future.

At the strategic level (Therivel, 2004), one plan or programme may be linked to infinite cumulative effects. The aggregation of impacts is focussed at the receptor level (James and Stewart, 2004) because the capacity of the receptor to accommodate further stress is the concern in CEA. Critical factors from a receptor standpoint are the sensitivity and vulnerability of receptors to withstand stress; taken together, these represent the vulnerability of a receptor.

Much of the guidance on the aggregated (cumulative) effects of past, present and future stresses, however, is light on the metrics of aggregation. Qualitative expressions of accumulated effects (not risks) may appear visually appealing appear, but currently lack empirical rigour. Nevertheless, practitioners still seek pragmatic delivery and are wary of 'academic' approaches that are perceived to over-sophisticate the analysis in the search for a more defensible basis for the metrics of aggregated impacts.

2.2.3 A synthesis of experience

The reflections on practice of a few long-standing observers of comparative risk analysis are noteworthy, e.g. Fischoff, 1995; Morgan *et al.*, 1996; van Asselt, 1999; Morgenstern *et al.*, 2000; DeKay *et al.*, 2001; Andrews *et al.*, 2004b Linkov *et al.*, 2005. These reflections are summarised below.

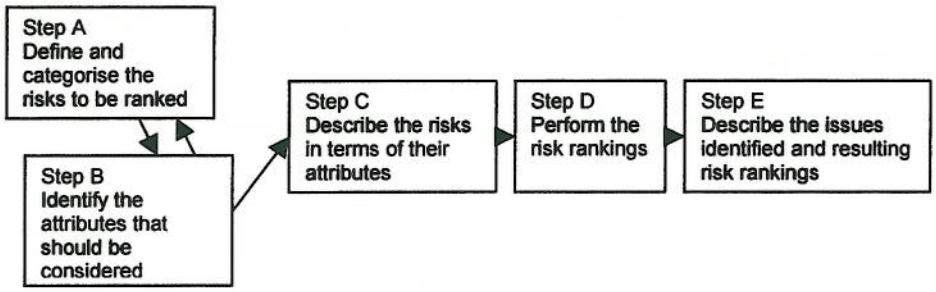
- Risk rankings are necessarily imperfect. At the strategic level, uncertainties are huge and stakeholder involvement in metrics and process offer no guarantee to the removal of this ambiguity.

- Few current exercises afford the time required to understand the process of ranking risks let alone the data upon which risks should be ranked. Morgan *et al.* (1996) suggested an approach involving five meetings and taking 9–11 days to complete. This contrasts with the typical 0.5–1 day workshops typically used to rank a plethora of strategic risks. The clustering of issues as performed in the New Jersey Comparative Risk Project (NJDEP, 2003) may offer real merits in terms of time spent on these exercises.

- There is a danger, as with all risk analyses, that prioritisation becomes the end in itself rather than what is done to manage the risk.

- Notwithstanding the myriad of metrics and project-specific approaches, there appears to be a developing consensus of the value of the following approach to ranking risks (Figure 5).

Figure 5 Steps in a risk ranking model (after Florig *et al.*, 2001)



- There appears to be a move towards adopting multicriteria analysis (MCA) in preference to comparative risk analysis – perhaps in recognition of the analytical complexities and the ready availability of methods for MCA (Linkov *et al.*, 2005). These authors also appear to reject the concept of a risk optimised option or set of priorities in favour of an adaptive management style where the dynamics of knowledge and data on risks are acknowledged and management strategies adapted accordingly.

3 Involving stakeholders and the public

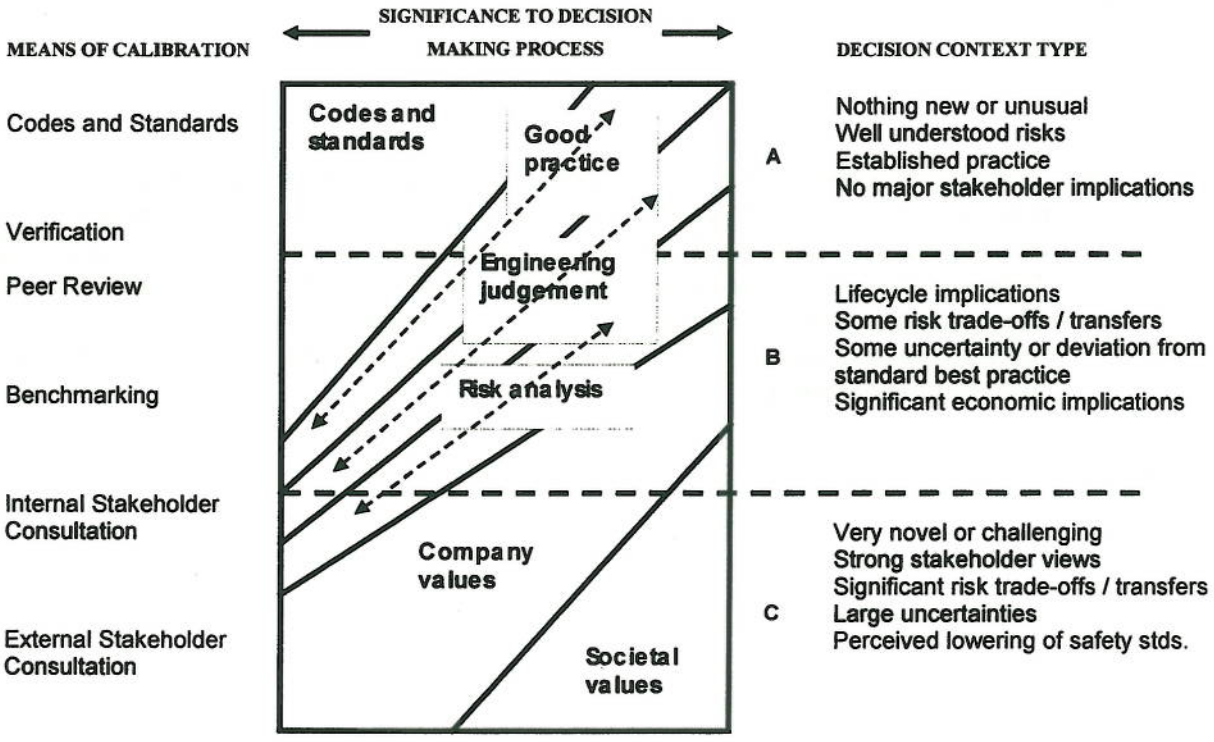
3.1 Engagement in strategic level thinking

Stakeholder participation in environmental decisions is expected in the 21st century (Figure 4). Most experience has been amassed at the project level, e.g. in project-specific EIAs that support decisions about future developments. Plans and programmes of work (e.g. regional development and flood defence strategies) are increasingly also subject to participative decision-making.

However, involving others in strategic choices and priorities is acknowledged to be difficult. Irrespective of their importance and likely impact, these higher level decisions can appear abstract and removed from the context in which they apply. It can also be difficult to attract a broader audience to such decisions. And yet, a broad perspective is essential because, by their very nature, strategic level priorities are set infrequently and have tremendous influence over the plans and projects that follow.

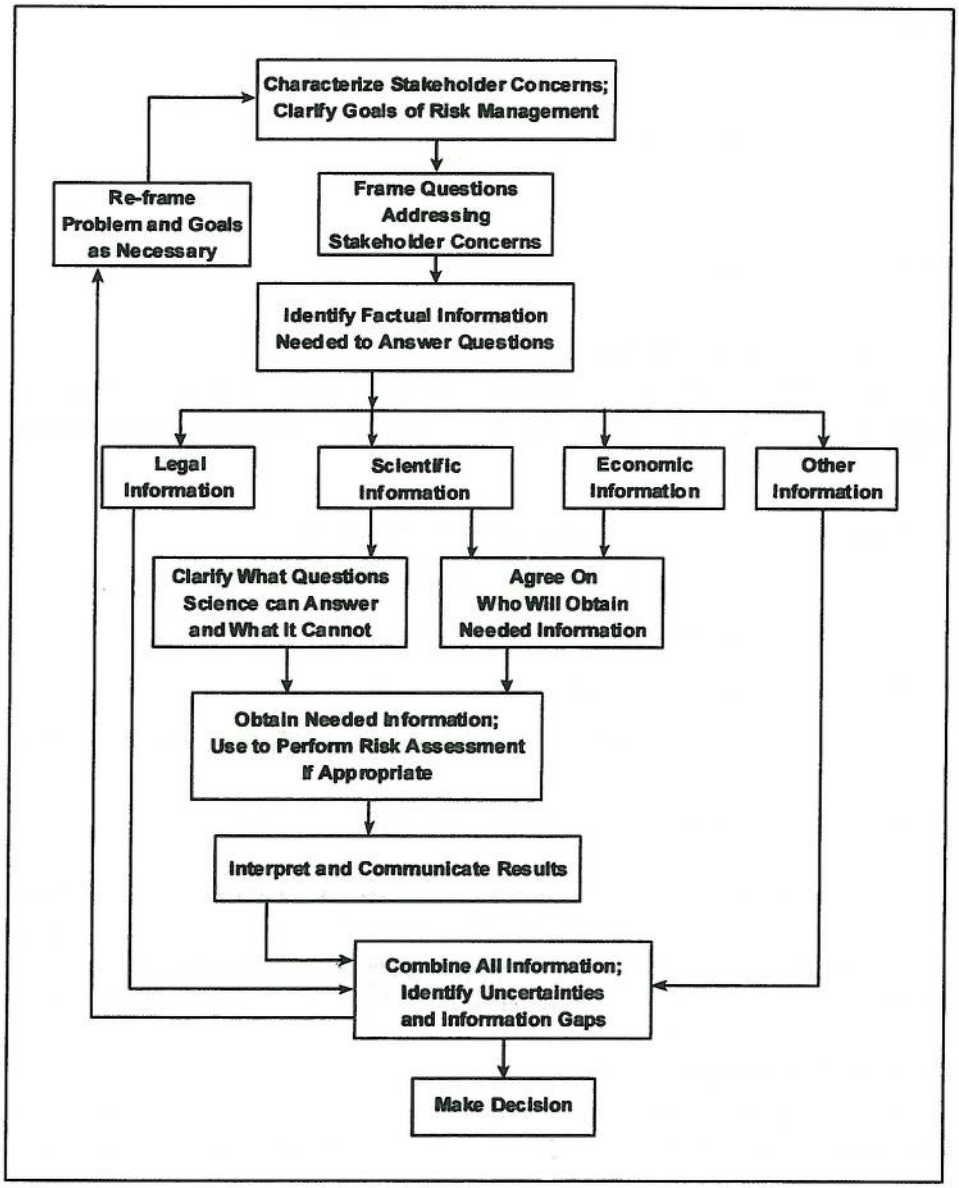
Situations where strong stakeholder views are held (e.g. with respect to environmental policy priorities or where visible trade-offs are being undertaken) demand the elicitation of stakeholder interests (Figure 6).

Figure 6 Role of company and stakeholder values in decision-making (after UKOOA, 1999)



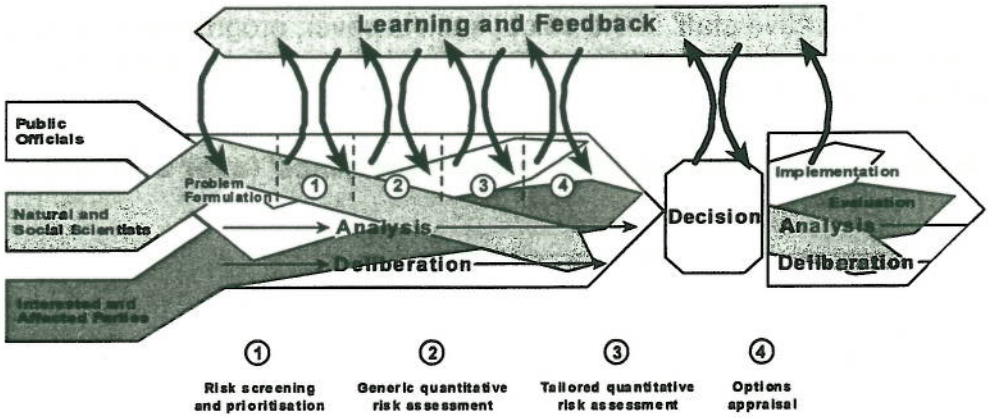
Comparative risk tools have not found an easy way of incorporating stakeholder views on the nature and character of environmental harm and the practice is still relatively rare in conventional project-based risk assessment. Most tools appear to adopt surrogate audiences for broader participation, e.g. the policy lead, the 'friendly' NGO representative, the 'administrative staff' in the office, etc. However, progress has been made in the development of frameworks that adopt a more 'democratic' approach to risk-based decision-making (Figure 7).

Figure 7 Proposed decision framework for 'democratic science' (after Charnley, 2000)



These frameworks (Stern and Fineberg, 1996; Charnley, 2000) emphasise the critical role of evidence and institutional knowledge (Figure 8), which is often absent from other models of participatory decision-making. Implementing them in practice, however, has proved difficult, with some of the most valuable recent literature focussing on the utility of stakeholder-based decisions.

Figure 8 Decision-making process with institutional learning (after Stern and Fineberg, 1996)



3.2 Literature review

3.2.1 Decision-making as a social process

Sexton *et al.* (1999) proposed six critical questions that require answering in order to better analyse and solve complex environmental problems. These questions presume decision-making to be a social process.

1. At what social level does the environmental decision occur?
2. What are the important substantive aspects of the environmental decision?
3. What is the social setting of the environmental setting?
4. What is the mode of environmental decision-making?
5. What are the assumptions about basic underlying causes of the environmental problem?
6. What criteria are used to evaluate the environmental decision?

Though dating from 1999, the adoption and application of these questions to decisions on risk is only just occurring in the UK. The USA's 10 years of experience has led to the development of a considerable discourse on the merits of, and approaches to, involving stakeholders in strategic decisions on environmental risk (Fischer, 1995, 2000).

3.2.2 Participation in risk assessment

The Environment Agency recently reviewed the literature on participation in risk assessment (Homan *et al.*, 2001; Petts *et al.*, 2003a); for a summary, see Petts *et al.* (2003b).

Risk assessment is increasingly viewed in participatory terms, in response to:

- the 'risk society' debate (Beck, 1992);

- the evidence from the risk communication literature;
- the environmental justice agenda;
- a growing understanding of scientific values.

There have been official calls for increased stakeholder involvement (e.g. DETR *et al.*, 2000) from 'problem definition' or 'framing' through to the evaluation of risk estimates. The transition to a 'right-to-know' society is requiring greater public access to risk assessments, which are increasingly being discussed in public.

It is difficult to define risk decisions and caution is needed when viewing public participation as a requirement limited to the risk assessment that informs the overall decision. In practice, risk issues can rarely be separated from the broader environmental, social and economic elements of decisions. Furthermore, examination of the decision contexts in which the Environment Agency is involved (Pollard, 2001) reveals that environmental regulators are rarely the sole decision-maker or use risk assessments in isolation as the only decision tool.

There is often no legal requirement to formally consult on issues of risk. As a result, the Environment Agency has rarely involved people in deliberative processes related to decisions that involve formal risk assessments – though it has engaged people widely in standard consultation and information provision exercises.

The US definition of the analytic–deliberative process in risk management terms (Stern and Fineberg, 1996; US Presidential/Congressional Commission, 1997a,b; Charnley, 2000) and the Royal Commission on Environmental Pollution's environmental policy decision process (RCEP, 1998) suggest that participatory risk assessment needs to be considered in terms of four stages, i.e.

- the initial framing or definition of the issue or problem;
- the identification of data and information needs, and how uncertainty will be managed;
- oversight of the assessment itself;
- the evaluation of the risk estimates.

There is a need to establish at which of these stages, and in what ways, participation can be incorporated. The challenge is to develop informed processes that enable decisions involving science to be debated widely in a social context (Sexton *et al.*, 1999; Fischer, 2000).

Current UK practice is that the public tends to become involved in the later stages of environmental decision processes, i.e. at the point of evaluating risk assessment output before the final decision is taken. Even then, there may be limited opportunities for the public to influence the decision that is made due to the inherent presumptions in the statute.

Mechanisms for stakeholder involvement in risk decisions still require evaluation in practice. Even at the international level experience is limited, though there are increasing

attempts to apply participative processes to policy, plan and project-level decisions involving risk. These more participatory processes can be effective in reaching decisions, but a more inclusive and deliberative process does not automatically result in lack of contention in relation to the decision. Indeed, involving the public may result in more diversity in opinion rather than consensus.

As part of the Environment Agency's research into these issues, criteria for effective participatory decision processes have been developed where risk is an important issue within the decision (Table 1) (Homan *et al.*, 2001). These reflect broader criteria for effective public participation incorporating the key principles of:

- clarity of objectives
- representativeness
- inclusivity
- openness
- deliberation
- social learning
- decision responsiveness.

For environmental regulators, these are complex issues with far reaching consequences for policy, resources and practical issues, which require careful deliberation.

Table 1 Criteria for effective participatory decision processes involving risk (after Homan *et al.*, 2001)

Criteria	Issues
Clarity of objectives	• Are the objectives of the overall participation activity clear to both active and non-active participants, including the limitations of what can be achieved, i.e is the connection made between purpose, process and outcome?
Clarity of legal process	• Are the legal process and linked processes (e.g. planning) which will influence the decision made clear to all participants, including the limitations but also the responsibilities of these other processes?
Potential decision responsiveness	• Is the decision open to amendment if agreed to be appropriate by participants (i.e. the decision has not already been taken)?
Clarity of linked processes	• Are all participants provided with information about other linked participatory and information processes that have been, or will be, undertaken by other responsible authorities and by the Environment Agency? • Is the process designed to integrate with rather than duplicate or conflict with any other participation activities organised by other authorities?
Consensus on agenda and procedures	• Is there sufficient opportunity for participants to contribute to the agenda for discussion and decisions on the procedures to be used, including the choice of facilitator/chairman/moderator? • If there is no opportunity for participant input before the process begins, are their opinions sought at the start? • Is there opportunity for participants to engage in the problem scoping, including agreement on the definition of the problem and the issues that will need to be addressed?

Criteria	Issues
	• Is there opportunity for participants to discuss likely data and information deficiencies in the assessment process and to agree how these will be rectified?
Consensus on effectiveness	• Is there opportunity for participants to give their views on what will make the participation process effective and for these criteria to be included in the evaluation?
Representation	• Are the participants in any participatory process representative of the full range of people and interests potentially affected? • Is the process of identification and selection of any specific participants objective and open? • Is opportunity provided for new or additional participants to take part in the process if identified by others and it is agreed that their participation would be beneficial?
Inclusivity	• Are the barriers to participation (physical, social, economic) removed or at least minimised as far as is possible? • Is the choice of location, times, venues, etc. undertaken with regard to local circumstances and participant preferences? • Is adequate notice given to participants of the dates and times of any event, and are their views sought on the latter as new events are arranged? • Are appropriate methods used to ensure that those who do not participate directly are made fully aware of the issue, the consultation being undertaken and where information can be obtained? Are a variety of appropriate opportunities provided by which they may make known their views if they wish to?
Transparency	• Is the participation process transparent and open from inception through operation to communication of its outcome? • Are the views, both for and against, of the majority and minority acknowledged in the outcome? • Are Environment Agency staff, officials from other authorities and people in the applicant company who are not directly involved made aware of the participation process?
Deliberation (general)	• Are adequate opportunities provided for participants to engage in dialogue, discussion and group interaction? • Are adequate opportunities provided to everyone to put forward their personal opinion if they wish? • Is sufficient time allocated throughout the process to allow effective deliberation to take place? Do participants feel that they have had sufficient time to take part to the extent that they wish? • Is disagreement acknowledged and dealt with openly, but also managed to ensure that it does not affect adversely on discussion? • Does the process enable participants to improve their own anecdotal and intuitive knowledge by being exposed to relevant experiences (e.g. visits to sites, discussion with people who live close to similar facilities, etc.)?
Technical deliberation	• Is information provided to ensure that all terms, definitions and technical details are available to everyone in advance? Are they clear enough to enable people to participate in discussion fully and critically? • Is a formal process involved that allows the concerns and values of participants to be captured and recorded such that the criteria relevant to the risk evaluation are agreed? • Is the technical assessment process sufficiently transparent and open to challenge and to the input of alternative assumptions if agreed appropriate by participants? • Are adequate opportunities provided for the uncertainty inherent in factual

Criteria	Issues
	information to be acknowledged, explained and discussed? • Are knowledge deficiencies openly acknowledged by the official contributors? • Are opportunities provided for expert knowledge and information to be challenged, and claims to be tested through discussion? • Are opportunities provided for other expert knowledge agreed by participants to be relevant to the discussion to be made available to the process and to be considered directly, i.e. peer review? • Where questions cannot be answered immediately, are adequate arrangements made to ensure that participants receive the information as soon as it is available? • Where it becomes apparent that information or knowledge is missing or insufficient, are resources made available for further work or assessment to be undertaken?
Capability	• Are all technical experts, organisers and others providing input to the process sufficiently skilled as communicators? Have they received appropriate training? • Are all technical experts able to communicate and explain complex science and risk data? • Are all technical experts willing to be open about limitations in current knowledge? • Are sufficient financial resources allocated to the process? • Does the process have sufficient time allocated within the overall timetable to allow for any unforeseen issues and needs to be dealt with and responded to?
Social learning	• Does the process make a difference to participants in terms of their understanding of the issue and knowledge gained, in particular their understanding of the risk assessment process and its role in decisions? • Does the process lead to an improvement in the public availability of information? • Does the process promote understanding of different viewpoints? • Do people enjoy taking part?
Actual decision responsiveness	• Does the process add value to the decision? • Are recommendations that represent a consensus of participants' and respondents' views taken on board in the decision? • If the process leads to challenge to existing Environment Agency risk assessment methods and/or decision criteria, is it prepared to revisit these? • Is the decision communicated to all participants, non-participants and to Environment Agency staff? • Is an evaluation (preferably independent) of the process completed? Are the results made known to participants and recorded for input to the design of future processes?
Enhancement of trust	• Does the process lead to an enhancement of the Environment Agency's credibility as an environmental regulator and promote trust in its risk decisions?

3.2.3 Moving on – the quality of stakeholder-based decisions

Recent literature (Fischer, 1995; Perhac, 1998; Apostolakis and Picket, 1998) has focussed on the quality of participatory decisions and deliberative tools for incorporating stakeholder views within risk characterisation exercises.

Beierle (2002) presents an optimistic account of 239 published case studies of stakeholder involvement in decision-making, ranking the quality of the decisions by reference to whether:

- decisions are more cost-effective than likely alternatives;
- decisions increase joint gains among parties compared with the likely alternatives;
- participants contribute innovative ideas, useful analysis or new information;
- participants have access to scientific information and expertise.

The more intensive forms of stakeholder involvement (processes involving negotiations and mediations) produce higher quality decisions. This suggests that more effort and time are required to engage stakeholders in strategic risk issues than is currently being provided.

The companion papers produced by Florig *et al.* (2001) and Morgan *et al.* (2001) discuss the value of deliberation itself within a group. Using a deliberative quantitative method for ranking 22 high school health and safety risks, first by individuals and then following a group discussion, these authors demonstrate the value of group discussion to fostering consensus. They make the point that, where risk rankings are to be used by regulatory agencies, they must be both normatively justifiable and empirically validated if the rankings are to have credibility. The authors set out criteria for good ranking methods. According to Florig *et al.* (2001), a good ranking method should:

- make use of available theory and empirical knowledge in behavioural social science, decision theory and risk analysis;
- encourage those ranking risks to systematically consider all relevant information;
- assist individual participants in expressing (or constructing) internally consistent rankings;
- ensure that participants understand the procedures and feel satisfied with both the process and products of a ranking exercise;
- describe the level of agreement and the sources of disagreement among participants.

Extending their approach to environmental risk ranking, these authors note the difficulty in characterising and representing environmental harm for stakeholder input (Willis *et al.*, 2004).

The multiplicity of environmental harm is more challenging at the strategic level where it is not possible to refer specifically to localised environmental damage. Although it is possible to imagine involving stakeholders in local, short-term risk issues (e.g. an incinerator, a contentious planning application, a new flood defence), engaging others in those diffuse, long-term strategic risk issues often is more challenging.

English (2000) argues that a shift towards emphasising the 'long term common good' in a spirit of 'collaborative learning' is required for those long-term, diffuse risk issues commonly addressed in a central fashion by policy-makers, regulators and their advisers. English (2000) also argues that, for strategic decision-making, the possibility of securing adequate representation of the interests and concerns of each stakeholder type and of

gaining a roughly equal balance of stakeholder types within the decision-making process diminishes substantially.

The proposal to consider the common good in a collaborative learning environment emphasises the value of multiple stakeholders making incremental steps towards the decision outcome together as environmental trustees, i.e. a more consensual, adaptive management paradigm. However, this is a long-term project that currently lacks the support of much methodological guidance.

Meanwhile, policy-makers and regulators face the practical challenge of how to defensively and robustly take account of a multitude of stakeholder views on issues of strategic importance – many of which are viewed by interest groups as contentious single issues in their own right.

3.2.4 Summary

- Stakeholder involvement in policy and regulatory decisions of strategic significance is expected in the 21st century.
- It seems inappropriate to rush deliberation in these cases – consensus and disagreement take time to develop.
- Sound metrics and equitable normative processes are required. Even seemingly straightforward procedures need to be communicated before they are used.
- The management of knowledge and the creation of an atmosphere of collaborative learning with opportunities for feedback are critical (Figure 8).
- Hazards need to be described in a clear, concise and consistent manner for the representation of public values in risk characterisation exercises.

4 Expressing the value of environmental harm

4.1 Valuing harm in comparative risk assessments

There is an extensive literature on the economics of willingness-to-pay and willingness-to-accept as a means of assessing the negative value of environmental harm. This report is more concerned with the explicit expression of values for the characterisation of environmental harm within risk analysis. This is required at the outset of the analysis in terms of the expression of what constitutes an acceptable risk:

- At what point should intervention be initiated in order to manage a risk?
- How much does a stakeholder group value a particular environmental good?
- Given a risk to that good of a certain magnitude, what priority might it have?

4.2 Risks and values

In the broadest sense, the term 'values' is used to mean a set of general principles that guide a person's actions. These principles are considered to reflect the importance a person places on moral and ethical perspectives. For social psychologists, an exploration of environmental values is important in order to establish relationships between values, action and beliefs. These tend to be general and are related to attitudes towards a specific environment and how they should be used.

In economic work, the term 'values' relates to the above definition. However, the focus has been on the extent to which issues, environments, objects, actions, etc. are valued, i.e. how important are they to the people concerned. There has been an associated methodological focus on the elicitation and systematising of values in order to incorporate them into decision-making processes and a trend to use monetary values to present social values in terms of a single common measure.

Values are a set of general principles that guide peoples' actions and attitudes and are manifested in environmental decision-making through the importance that people attach to environmental risks. To understand these manifestations, it is important to appreciate the formation and structure of those value systems as the context to environmental decision-making.

From the social psychological literature, it has been found that values do not predict action with accuracy; thus, it would be unwise to extrapolate from values to actions. Furthermore, attempts to 'discover' a set of separate environmental values have not been successful. Since environmental values appear to be part of a large set of values, to elicit environmental values in isolation may not provide the information necessary to reach an acceptable recommendation.

The process of environmental decision-making recognises that these values exist and that there is a range of values expressed within society. The goal then is to find methods of eliciting and representing values within that process. Focussing on the explicit use of values in decision-making processes raises a number of several key questions that need to be addressed. These are discussed below.

Why value?
Within environmental decision-making processes, different options and conflicts will form the basis of the determination of people's views made in order to prioritise and provide clear advice. Value articulation is crucial when considering:

- how to determine priorities;
- how to determine criteria to appraise options;
- how to determine trade-offs between conflicting implications of options to decide benefits.

What is being valued?
Within environmental decision-making, what is being valued will vary from case to case, e.g. from a view of a landscape to the use of a river for recreational purposes.

For some goods and services, it is easy to obtain monetary values as these are expressed through market price paid. But for others, it is not. There are debates on the extent to which values can be quantified or not, monetisable or not. The metric used for valuing has tended toward the quantifiable and monetisable.

However, many quality of life issues are not amenable to economic valuation. Work in social psychology suggests that there are important consequences for self-esteem, self-efficacy, continuity and distinctiveness associated with environmental decisions – both at the individual and group levels. Incorporating these types of values makes it more difficult to analyse situations, but this type of issue is often at the heart of problems with environmental decision-making.

The idea that some things are sacrosanct means that they will not be amenable to the type of decision-making process that aims to provide priorities and trade-offs among differently valued options. For various reasons, what is considered sacrosanct can appear to be contested; groups may disagree about the importance of an issue. In addition, traditional methods of environmental decision-making (public meetings, public inquiries) are fundamentally adversarial and thrive on argument and disagreement.

The task for the Environment Agency is twofold:

- to determine when valuing will be accepted as a meaningful input into the decision-making process;
- to develop better methods of determining people's views on risks and the implications for options for risk management.

Whose values?
Such issues lead to a debate on 'whose values' are to be considered. Environmental issues are often contested because there are often:

- a number of different stakeholders involved with the issues;
- imbalances in decision-making power.

The question of whose values are being considered is legitimate. The decision-making has to ensure that it is not dominated by the views of one group or institution, while aiming to seek the views of all members of society (present and future) affected by the issue.

In democratic decision-making (Figure 7), stakeholder values are given an equal status alongside the 'expert' concerns at the problem definition stage. This acknowledges that lay people will frame the risk differently and will tend to have different concerns. However, this may make the risk frame larger than traditionally defined by the scientists in the debate.

A sustained attack on science and a lack of regard for the complexity of inclusive processes could risk placing the desire for consensus above rigorous scientific evaluations of risk. It is essential that the rigours of scientific analysis are not ignored. The challenge is to develop informed and inclusive processes that enable decisions involving science to be widely debated in a social context.

How do we reflect different values within the decision-making process?
In general, the Environment Agency answers this question by collecting technical, economic and social data in order to make explicit values inherent in the process.

A particular challenge in comparative risk assessment is how to:

- summarise these data and associated uncertainties in a form that can help deliberative processes;
- subject those values to some method of deliberation in which options are considered and evaluated such that advice can be given to those who make the decisions on managing risk.

4.3 Literature review

The Environment Agency's research on comparative risk assessment has moved from expressions of harm (the loss of value) in terms of materials damage (loss of habitat expressed in hectares, loss of river quality expressed as kilometres of length), through attempts to monetise environmental damage through damage assessments and willingness to pay methods, to ranked multiple attributes of environmental harm (Klinke and Renn, 2002; Pollard *et al.*, 2004a).

Other contributors have also recognised the multiple dimensions of environmental harm – spatial and temporal extent, ecosystem, public health and quality of life indicators, etc. Gray and Wiedemann (1999) in a discussion of sustainability indicators, risk management and the incorporation of values examine the opportunity that exists to

aggregate sustainability indicators on the basis of agreed values. These authors state the importance of reaching beyond an expression and valuation of harm in a technical sense to social attributes of harm, together with an expression of its magnitude.

In environmental health policy analysis, the concepts of quality adjusted life years (QALY) and disability adjusted life years (DALY) have been adapted as metrics for comparing health impacts with wide-ranging endpoints (Ponce *et al.*, 2001; Hofstetter and Hammitt, 2002).

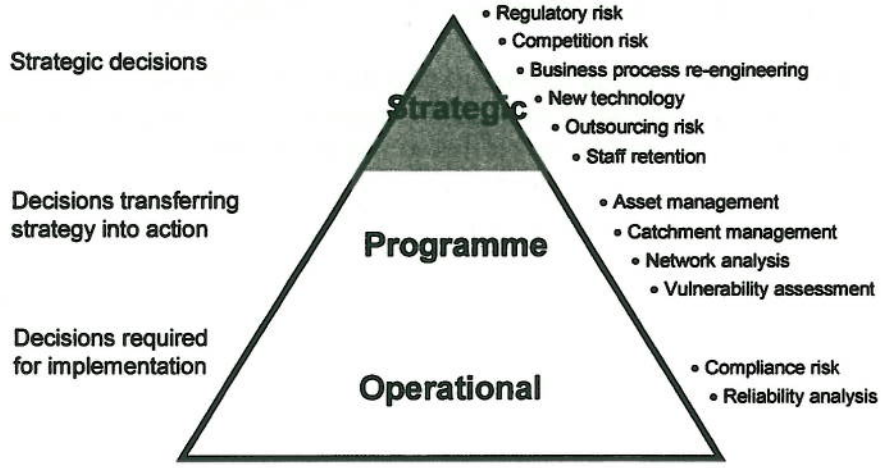
5 Implementation

5.1 Policies, programmes, plans and projects

A valuable contribution from the environmental assessment literature to comparative risk analysis has been the recognition of different tiers of environmental decision-making (Figure 8), in particular the report by the Prime Minister's Strategy Unit (Prime Minister's Strategy Unit, 2002).

Actions emanate at the project level through the translation of policies into programmes of activity and then, as implementation proceeds, through plans of work to individual projects. Risks are faced throughout this multiple level of organisation, although project-specific risks are far easier to contextualise and report on than those at the strategic level, which often seem more nebulous and poorly characterised.

Figure 8 Risk hierarchy applied for the water utility sector (after Prime Minister's Strategy Unit, 2002; Pollard *et al.*, 2004c)



This review is concerned with policy and programme level risks. These higher levels of decision have high decision stakes and often involve considerable flexibility over the course of action – one reason why scenario analysis has proved valuable as a means of speculating over the consequences of various proposed policy choices (Ringland, 2002).

However, the extent of information needed at these levels is often problematic. For example, consider the environmental risks from agricultural activities. The environment is subject to a wide range of threats from agriculture, but their relative positioning in terms of risk priority at the strategic level requires consideration of specific adverse consequences and an analysis of the likelihood of these coming to pass without site-specifics. As risks are temporally and spatially determined in practice, this can prove difficult in the abstract.

There appears to be some merit in considering issues from a range of perspectives and comparing the results of processing these risks through various methodologies, similar to

that adopted in the New Jersey Comparative Risk Project (NJDEP, 2003). Tukker (2002) provides a useful description of this in relation to chemicals policy and, in particular, for managing the distinct 'risk assessment', 'life cycle analysis' and 'precautionary principle' approaches to prioritising the potential effects of environmental chemicals.

The approach endorses a developing view that a single rationalisation of risk for complex issues leaves policy-makers and regulators vulnerable to methodological bias. This is made clear when viewing the vast number of methodologies for ranking risks on offer. However, it creates further work and may prove a harder 'sell' within organisations.

5.2 Risk management

The purpose of all risk assessments is to inform the management of risk. Risk assessments are of little value in their own right without translating into action the understanding they throw on the problem being studied. It follows, therefore, that risk assessments must be undertaken with a view to their practical utility.

Strategic level risk assessments – used to establish priorities – must be viewed similarly. Decision tools that inform these analyses need to be easy to use, with their outputs giving a clear picture of the priorities and mechanisms for risk management.

An important thread in the literature relates to the actions that follow the strategic analysis of environmental risks. In reviewing several comparative risk projects, Feldman *et al.* (1999) note the absence of 'follow-through' on risk management.

6 Summary and recommendations

6.1 Summary

The literature on comparative risk analysis is spread among the environmental, decision-science, regulatory and ecological sectors. There are good examples of comparative risk analysis from the health and environment sectors, and a long-standing history of experience, both good and bad, in risk ranking from the USA.

Few academic studies have successfully tackled the challenge of pragmatic delivery. The closest work of immediate value is the New Jersey Comparative Risk Project (NJDEP, 2003). However, there are lessons to be gleaned from attempts to rationalise the metrics of comparing incommensurate risks and some insights from the cumulative effects literature (EIA, SEA, CEA). Though comparative risk analysts are reaching beyond risk to MCA, the concept of risk in MCA is largely ignored to the detriment of the analysis. Likewise, those adopting a probabilistic or utility perspective invariably miss the multidimensional view of harm.

The key to the latter may be to harness IT solutions to improve the process of collating and synthesising the multiple dimensions of environmental harm. The schematics in the recent Environment Agency work on harm characterisation (Environment Agency, 2002) are difficult to interpret and should, perhaps, be made more straightforward by sacrificing some of the granularity of the method for the benefit of users. Various IT solutions (e.g. the use of voting software) are now available that could assist in this regard. There are also good examples within the corporate sustainability and risk reporting practices of some organisations that are directly applicable to the improvements required.

In summary:

- Comparative risk assessment tools provide a basis for comparing disparate risk issues by identifying common attributes of the environmental harm associated with the risk issues and scoring these attributes on a common scale.

- The value of these tools is in helping to formalise analysis and to provide traceability to decisions such as responses to risk issues raised by state-of-the-environment reports and the development of strategic plans.

- Many strategic issues, however, posses multiple dimensions. Practitioners are struggling to prioritise issues 'at a glance'. Stakeholder discussions frequently become 'bogged down' in the detail and subjective nature of the debate. In addition, these discussions can inadvertently undermine the value of these tools, resulting in a clamour for simplicity. This may result in key issues such as the latency of risks being ignored in an oversight.

- IT solutions can be brought to the needs of this problem. Certain commercial tools (e.g. for corporate risk evaluation and for stakeholder 'voting') have user-friendly

platforms that may help capture multiple, anonymous views and allow quick data processing. This has the value of providing quick feedback to stakeholder groups on their deliberations, allowing an emphasis of the value of the tool. This is preferable to waiting for offline processing.

- Tools of this nature are necessarily imperfect. The analysis they offer is only as good as the regulatory and policy decisions they inform.

- Notwithstanding the drive to develop practical tools and techniques to assist with complex decision-making, risk management should still reflect sensible and meaningful conclusions rather than theoretical perspectives that may run counter to sound judgement. The need is to capture the analytical power of decision tools alongside the wisdom, experience and common sense of practitioners.

6.2 Recommendations

This report provides a summary of the Environment Agency's progress to date in the design and implementation of strategic risk tools and an update of the literature since 2002.

The New Jersey study (NJDEP, 2003) is a useful reference point for further work and stresses that the goal of comparative risk tools should be to inform risk management rather than just prioritising. Stakeholder consultation is now expected in environmental policy and the setting of institutional priorities. Stakeholder views should be considered in placing a value on the environment and the significance of detriments (harm) that may be realised from a range of hazards.

The following recommendations are made.

1. The future focus of comparative risk tools should be on the design and implementation of a workable tool for Environment Agency decision-makers. **Consideration should be given to developing a software version of the existing comparative risk analysis tool that retains those functions that offer most insight.**

2. Users may not concern themselves with the in-depth aggregation of risks once they have gained the confidence that the approach has been peer-reviewed and has broad acceptance. The user aspects of most value are likely to be the opportunity to characterise risks by reference to their own knowledge. The Environment Agency could seek IT solutions that facilitate this. **The application of voting software or its equivalent could be considered and, where appropriate, incorporated in the tool.**

3. **A limited amount of 'hard-wiring' the aggregation of harm attributes into the tool should be considered.** This would facilitate quick processing and beneficial scenario analysis.

4. **The improved tool should be piloted by critical user groups within the Environment Agency** (e.g. its model of modern regulation, planning and reporting teams, and Regional Strategy Units).

5. **Previous commitments to external peer review of the tool and its developments should be retained.**

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List of acronyms

CEA	cumulative effects assessment
EIA	environmental impact assessment
MCA	multicriteria analysis
NJDEP	New Jersey Department of Environmental Protection
PPC	Pollution Prevention and Control
RCEP	Royal Commission on Environmental Pollution
SEA	strategic environmental assessment
USEPA	US Environmental Protection Agency

Department for Environment, Food and Rural Affairs

State Veterinary Service
Contingency Planning Division, Contingency Plans and Disposals Branch

A risk-based review of carcase disposal options in the event of a notifiable exotic animal disease – methodology and application to avian influenza

Peer reviewed draft 0.9 December 2006

Executive summary

Background

The Department for Environment, Food and Rural Affairs' (Defra's) exotic animal disease generic contingency plan (Defra, 2005) covers foot and mouth disease, avian influenza, Newcastle disease and classical swine fever.[1] The plan provides (paras. 4.34 - 4.50) for the implementation of a disposal hierarchy for carcases in the event of an exotic animal disease outbreak.

While the likelihood of humans acquiring avian influenza in the UK is considered to be very small at the time of writing, the disposal of carcases cannot be performed without risk to people, animal health and the environment. Decisions on carcase disposal therefore will be informed by risk assessments and expert advice from health Departments, health agencies, veterinary officials, environment agencies, emergency planners and other operational partners.

The State Veterinary Service (SVS), as the delivery agent in Great Britain (GB), recognises that several factors may impact on a disposal hierarchy, including the implementation of new environmental legislation and changes to the capacities and accessibility of disposal outlets. It is therefore intended that any hierarchy be regularly reviewed, in consultation with relevant stakeholders, to take account of these issues.

This study

This document is a peer-reviewed, risk-based review of disposal options for bird carcases to inform a review of the hierarchy in the generic contingency plan. It provides a methodology and applies it to assess the risks to human health, animal health and the environment for an avian influenza outbreak in poultry, reviewing and ranking a number of disposal options. It does not address other wastes such as manure/litter and bedding and does not take aspects such as the legality of disposal options; public acceptability, disposal capacity and cost into account, although a review of such constraints has been undertaken as part of the study.

This review assumes that site-specific assessments will be undertaken before any of the options discussed herein are used in practice. In undertaking the generic assessment

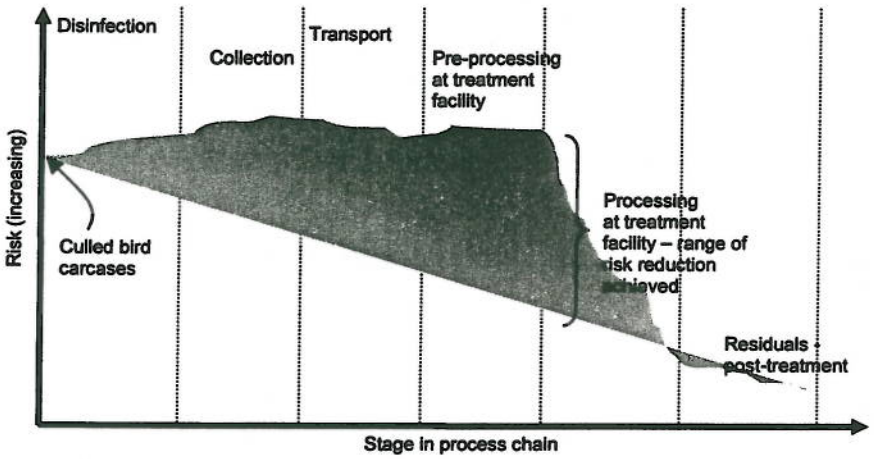
[1] The section on disposal can now be found in *Defra's Overview of Emergency Preparedness for Exotic Animal Diseases* due to be laid before Parliament in mid December 2006.

presented here it has not been possible to take site-specific factors into account. These can only be considered within a specific environmental setting. The study therefore has its limitations and these should be considered when basing site-specific decisions on the findings of this generic assessment. The report's findings will be used to determine policy and inform operational decisions on the disposal of carcases. This document has adapted the public health risk assessment methodology used during the 2001 foot and mouth outbreak (DoH, 2001) and it applies Defra's guidelines for environmental risk assessment and management (DETR *et al.* 2000; Defra, 2002).

Carcase disposal is a multistage process initiated by the culling of livestock (in this case, birds), with the subsequent disinfection of carcases, their transport to localised collection points and the potential off-site transport to waste processing (*e.g.* incineration, rendering) facilities. The characteristics of the early stages of the process are common to most disposal options and differences arise mainly in the extent to which the waste processing stage alters the containment of hazards, their relative destruction and the generation of waste residues (*e.g.* ash or meat and bone meal) requiring onward disposal. In this document we term the assembly of stages for carcase disposal a 'process chain' and identify five principal stages, namely:

- Disinfection and collection.
- Transport.
- Pre-processing.
- Processing.
- Dealing with residues.

The consideration of disposal options must recognise the range and distribution of risks along the process chain, in addition to the reductions in risk offered by individual waste process technologies. This is important because the stages that pose greatest risk may be those that precede waste processing. These risks can be reduced, but not entirely eliminated, by the proper use of protective measures. The potential risks to front-line workers and the possibility that they could pass on infection must also be considered and risk management measures put in place as routine. The importance of undertaking disposal according with agreed operating guidelines and protocols is highlighted. A generalised picture of the change in risk along the process chain is provided below. It is important to note that, whilst risks are generally expected to decrease along the chain, they may also increase at times, depending on the effectiveness of control measures.



Illustrative risk profile along a process chain for a single carcase disposal option showing range of possible risks and potential distribution along process chain

The methodology adopted in this study was developed by a working group and applied at an expert workshop facilitated by Cranfield University's Centre for Resource Management and Efficiency in March 2006. The workshop considered six tasks:

(i) hazard identification, screening and prioritisation;
(ii) representation of the process chain for a series of disposal options and consideration of the efficacy of barriers for risk reduction along each process chain;
(iii) a review of a master list of potential exposure pathways for hazards from carcases developed previously during the 2001 foot and mouth outbreak;
(iv) the development of conceptual exposure models for a series of process chains and a semi-quantitative exposure assessment for each option;
(v) development of a draft disposal hierarchy informed by (i) to (iv); and
(vi) a preliminary screening of operating constraints acting on the disposal options.

Disposal options were assessed with regard to risks from the following biological, chemical and amenity hazards associated with an avian influenza outbreak:

- avian influenza (H5N1), avian influenza (other strains), *Campylobacter spp, Salmonella spp, Yersinia* (*Yersinia enterocolitica, Yersinia fredriksenii, Yersinia pseudotuberculosis and Yersinia kristensenii*) and Q fever and bioaerosols;

- ammonia, disinfectants, veterinary medicines (pesticides, antibacterials, coccidiostats, barbiturates), methane, organic carbon, hydrogen sulphide, carbon monoxide, benzene, toluene, ethylbenzenes and xylenes, wood resins, dioxins/furans and dioxin-like polychlorinated biphenyls (PCBs), polynuclear aromatic hydrocarbons (PAHs), oxides of nitrogen and sulphur (NO_x, SO_x) airborne particles (PM_{10}), heavy metals, hydrogen chloride, metal salts; and

- odour, smoke and noise, as amenity impacts.

A proposed hierarchy of disposal options is presented below. It is intended that, in the event of an outbreak, decision-makers consult the hierarchy and select options from the top of the hierarchy in preference to those appearing lower down the list.

Draft, risk-based carcase disposal hierarchy in the event of an avian influenza H5N1 outbreak

Disposal option*	Statement of preference**
Composting (in vessel), Alkaline hydrolysis, Gasification, Biogas, Atmospheric rendering, Pressure rendering, Controlled incineration, Mobile incineration, Co-combustion in cement kilns.	These are preferred options
Composting (windrow), Air curtain incinerator, Permitted landfill, Mass burial	These are secondary options
Mass pyre, On-farm pyre	These are possible option, but not recommended
Anaerobic digestion (pits), On farm burial, Do nothing	These are generally undesirable options

* Options listed within each of the four categories are not presented in any order of preference
** This study focuses on the risks associated with each process chain. Technological, financial, legal, social and economic factors in (vi) above were excluded from the risk assessment so that a risk-informed hierarchy could be developed. In taking policy and operational decisions on carcase disposal these constraints need to be considered alongside the risks.

Conclusions from this study

(1) The disposal hierarchy presented in the generic contingency plan is supported by this risk assessment. The hierarchy places waste processing (*e.g.* incineration and rendering) above controlled disposal (*e.g.* landfill) which is above uncontrolled disposal (*e.g.* pyres):

commercial fixed plant incineration
↓
rendering
↓
permitted commercial landfill
↓
pyre burning
↓
on farm burial

(2) A number of technologies not mentioned in the generic contingency plan are suitable on risk grounds for use in the event of an outbreak of avian influenza. Some of these (eg, alkaline hydrolysis and gasification) are preferred over options in the existing hierarchy. In selecting waste technologies, practitioners are advised to consider those technologies:

- offering high destruction efficiencies for target pathogens;
- that do not gives rise to significant releases of other pathogenic organisms; and those
- that do not release unacceptable concentrations of toxic chemicals.

(3) Carcase disposal comprises a series of stages (a process chain), with each stage offering opportunities for exposure to hazards. Typically, the process chains for disposal options

offer hundreds of individual exposure pathways for hazards, although the majority are not likely to be of concern.

(4) The range of hazards of concern extends beyond avian influenza H5N1 because of the chemicals used to disinfect carcases, the veterinary products within birds and the byproducts of carcase decomposition and waste processing.

(5) The avian influenza H5N1 virus, as a pathogen in isolation, is not a principal concern in this analysis. Risks to human health, animal health and the environment that are also associated with the other pathogens that may accompany carcases; carcase decomposition products; products of incomplete combustion and the disinfectants used during disposal may be of even greater concern.

(6) This analysis indicates that the early stages of the process chain, on-farm, pose more opportunities for exposure to hazards than the later stages where hazards are generally contained, wastes being treated and residues managed within regulated processes for the most part. This is a key consideration and evidence for this assertion is provided by the semi-quantitative analysis in Chapter 5. The potential risks to front-line workers and the possibility that they could pass on infection must be considered and risk management measures put in place as routine.

(7) For the process chains associated with disposal options, risks are reduced where:
- hazards are contained rather than left in an open environment;
- technologies assure the destruction of hazards rather than partial treatment;
- technologies have engineered process control rather than systems open to the environment;
- residues are minimised;
- process chains are short rather then extended (in time or distance).

Glossary

amenity impact	harm or offence to the senses, including odour, noise, landscape impacts
avian influenza	a disease primarily of birds, of which there are many strains that vary in their ability to cause disease in poultry, wildfowl, man and other animals
barriers	actions, structures or treatment processes that mitigate the likelihood of exposure
carcase	the body of a dead animal
conceptual model	a description of how a system is believed to behave. In this document it is the description of how a receptor may be exposed (via individual pathways) to a hazard
disposal option	possible means of managing carcase disposal from start to finish
exposure	the contact of a receptor with a chemical, biological or physical hazard
harm	the adverse consequence that results at the receptor from significant exposure to a hazard
hazard	a substance or situation with the potential to cause harm
pathogen	micro-organism that can cause disease
pathway	a route for exposure, by which a receptor may become exposed to the source of a hazard
permitted landfill	a landfill that has been authorised to operate under the Pollution, Prevention and Control (PPC) Regulations
process	Physical, chemical or biological means used to treat hazards
process chain	a sequence of stages that comprise, together, a disposal option. The stages include collection and disinfection, transport, pre-processing, processing and dealing with residuals
receptor	in this context, an entity at risk of harm through its exposure to a hazard
risk	the potential realisation of unwanted, adverse consequences to human life, health, property or the environment associated with a hazard
risk analysis	a detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment and how to address them
risk assessment	a logical consideration of the risks identified above in terms of both the probability of the risk occurring and the magnitude of the harm that may ensue
source	the source of a hazard, for example, a dead animal carcase

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Annexes 30
(Only annexes A & G are included as part of the main report. The other documents are working documents used or derived during the workshop and subsequent working group meetings. As such they are not formatted for printing and some of the documents do not include all the background analysis or assumptions made. All the annexes are however available on request).

Annex A: List of contacts

Annex B: Hazard analysis and prioritisation – chemical hazards and pathogenic hazards

Annex C: The assessed effectiveness of microbiological barriers along the process chain

Annex D: Conceptual and exposure model spreadsheet and evaluation

Annex E: Exposure pathways master list

Annex F: Working group methodology

Annex G: Brief overview of disposal options

Annex H: Initial screening of risk management constraints

1. Introduction and rationale

Background

1.1 Previous outbreaks of infectious animal disease have, on occasion, required the disposal of significant numbers of infected or culled stock. Whilst the likelihood of such a need arising in the event of an outbreak of avian influenza is small, it is appropriate to consider it as a contingency measure. This report considers the potential risks to public health, animal health and the environment that may arise from the options used to dispose of carcases in order to develop a hierarchy to inform policy and operational decisions. This study has been undertaken to inform a review of the hierarchy in Defra's generic exotic animal disease contingency plan (Defra 2005). Site-specific assessments will need to be undertaken before any of the options discussed herein are employed to dispose of bird carcases.

1.2 The report draws on the outputs of a working group and facilitated workshop convened to draft an initial risk analysis of disposal options. A list of contacts is provided in Annex A. The approach adopted is outlined below. A key role for SVS has been to collate, summarise and use analyses carried out by others. The study will include the following elements :

- prior work contained within Defra's generic contingency plan (December 2005);
- a draft methodology (Annex F) for reviewing disposal options in the event of an outbreak of a notifiable exotic animal disease that informed this study (February, 2006);
- the methodology within the Department of Health's rapid qualitative assessment of possible risks to public health from current foot and mouth disposal options (June, 2001).
- the specialist knowledge and expertise of a range of professionals delivered through a series of meetings and workshops, including a 2 day workshop at Cranfield University (Feb – August 2006);
- internal consultation of study group members (July/August 2006)
- an independent expert peer review (planned for October 2006); and
- consultation on the approach from a range of stakeholders (planned November 2006).

Carcase removal – operational procedures

1.3 The State Veterinary Service (SVS) is responsible for the culling and disposal of poultry affected by avian influenza. In the event of an outbreak of an exotic animal disease such as avian influenza, a culling and disposal 'cell' will be established in the National Disease Control Centre (NDCC) in Page Street, London. This disposal cell is responsible for arranging the disposal of all carcases resulting from disease control activities. The Local Disease Control Centres (LDCC) are responsible for managing the culling, loading and transport of carcases to disposal facilities and all other local operational aspects.

1.4 Carcase disposal is a multistage process. There are a range of culling methods available for poultry including lethal injection, neck dislocation, percussion killers, electrical stun and kill systems; containerised gassing and whole house gassing (Defra, 2005). Once the birds have been culled, carcases are sprayed with an approved disinfectant and arrangements made for carcase disposal.

1.5 The policy for carcase disposal is that, where possible, this will be by off-site disposal in a recognised permitted disposal facility. The current agreed disposal hierarchy (Defra 2005) for all exotic diseases is:

incineration
↓
rendering
↓
permitted commercial landfill
↓
pyre burning
↓
on farm burial

1.6 Carcases are loaded into specialist leak-proof vehicles whose movements are licensed by the SVS. The vehicles are leak-tested prior to each load and travel to the disposal facility by a pre-determined route. Each load is covered and then escorted to ensure that the vehicle does not develop a leak. In the unlikely event that the vehicle is involved in a road traffic accident or other incident, the escort can manage the situation.

1.7 Carcases are transported in accordance with Animal by-products and other transport Regulations. At the disposal facility, the carcases are disposed of under the supervision of the SVS.

1.8 Following removal of the carcases, all litter, equipment and areas occupied by the affected poultry are sprayed down with an approved disinfectant and left to dry for at least 24 hours. This is termed preliminary cleansing and disinfection (C&D). The owner/keeper of the poultry is then responsible for undertaking a complete cleansing and disinfection of the premises (secondary C&D) under the supervision of the SVS. This involves removing the litter and other organic material, a full wash down followed by degreasing and application of the disinfectant. Restocking can commence 30 days after secondary C&D has been completed.

Study scope

1.9 Defra's exotic animal disease generic contingency plan, covering foot and mouth disease, avian influenza, Newcastle disease and classical swine fever (December 2005) makes provision (paras. 4.34 - 4.50) for the implementation of a disposal hierarchy for culled stock in the event of an exotic animal disease outbreak. [The section on disposal can now be found in *Defra's Overview of Emergency Preparedness for Exotic Animal Diseases* due to be laid before Parliament in mid December 2006]. The selection of disposal options will take account of the assessments of risk and advice from relevant operational partners, Government Departments, regulatory bodies and stakeholders.

1.10 The scope of this work was to focus on avian influenza and undertake a risk-based review of carcase disposal options to inform a review of the hierarchy presented in the generic contingency plan. We considered risks to public health, animal health and the environment. The work was desk-based and informed by an expert panel of cross-Government scientists, academics and policy specialists. In this study, hazards were screened and prioritised. A series of conceptual models for the process chain associated with each disposal option was developed. The number of available pathways and their ready availability was then assessed in a semi-quantitative exposure assessment. Pathways were ranked by the likelihood of the pathway existing (negligible availability of the pathway; low; medium; and high). The data were then analysed in order to identify the number of exposure pathways for each of the options and the proportion of these that could be associated with either a medium or a high likelihood of exposure taking place. This information was used to rank the options from most to least preferred, considering risk only. Constraints such as legality, capacity, practicality and cost have not been taken into account in developing the hierarchy although they need to be taken into account when using it (see Section 6).

1.11 We distinguish between different classes of disposal and within these, 28 individual options. The classes of disposal considered were:

- controlled incineration with co-combustion (within industrial processes or power plant)
- controlled incineration (within waste incinerators)
- controlled thermal (pyrolysis), physical (rendered under pressure), biological (biogas) or chemical processing (hydrolysis)
- uncontrolled burning (pyres)
- controlled landfill
- uncontrolled burial (on farm)
- storage (without further treatment, on- or off-farm)
- do nothing

The full list of disposal options can be found in Annex C. The assumptions made in respect of each are documented in Annex G.

1.12 The risk assessment concentrated on the potential hazards and risks associated with 28 specific options. Importantly, the analysis considered the full 'process chain' from discovery of the carcase, through disinfection and local storage, transport, pre-processing, processing and through to treatment of process residues. This is critical because, while options differ in the process technology applied in the middle of this chain, they have similar features at the beginning and end. It is important to note that other wastes such as manure and bedding were not assessed.

Study limitations

1.13 All risk assessments have limitations.

1.14 This study considered a set of generalised disposal options without reference to specific locations or the timescales within which options could be implemented. For each option we have assumed a set of receptors appropriate to the process chain. No

baseline risk assessment was undertaken. In practice, risks are highly influenced by local conditions, the environmental setting and the elapse of time between the discovery of hazards and their management.

1.15 Adoption of this generalised approach meant that individual source-pathway-receptor relationships were not assessed discretely and that the relative consequences associated with a range of potential impacts on human health, animal health and the environment were not weighted in this analysis.

1.16 For waste treatment facilities, there may be as much variation in risk between individual facilities of the same type (say, between different rendering plants) as between treatment options (say between rendering and incineration). The study therefore assumed the adoption of good operational practice and regulatory compliance for waste processing options and typical permitting arrangements. Disposal options vary greatly in the time available for treatment; between a few seconds within high temperature incinerators to decades within landfills. This generic analysis was unable to account for these distinctions.

1.17 The study did not separately consider options for the mitigation of residual risks from waste residues, which are addressed by the appropriate regulatory framework and its required activities (*e.g.* requisite monitoring, aftercare *etc.*).

Report structure

1.18 The remainder of this document provides an overview of the methodology (Section 2), a description of the hazards screening exercise (Section 3), a qualitative risk assessment of the process chains for a range of disposal options (Section 4), a semi-quantitative exposure assessment (Section 5) for a range of these options, the comparison of options (Section 6) and the report conclusions (Section 7).

1.19 References offer supporting information and a series of Annexes support this summary text:

Annex A: List of contacts.
Annex B: Hazard analysis and prioritisation – chemical hazards and pathogenic hazards.
Annex C: The assessed effectiveness of microbiological barriers along the process chain.
Annex D: Conceptual and exposure model spreadsheet and evaluation.
Annex E: Exposure pathways master list.
Annex F: Working group methodology.
Annex G: Brief overview of disposal options.
Annex H: Initial screening of risk management constraints.

2. Overview of methodology

Approach

2.1 The approach adopted in this study was to identify a number of potential carcase disposal options, consider their process chains and the risks to people, animals and the environment associated with each and then compare options with the aim of constructing a disposal hierarchy on the basis of this analysis.

2.2 The study approach includes the following elements.

- prior work contained within Defra's generic contingency plan (December 2005);
- a draft methodology (Annex F) for reviewing disposal options in the event of an outbreak of a notifiable exotic animal disease that informed this study (February, 2006);
- the methodology within the Department of Health's rapid qualitative assessment of possible risks to public health from current foot and mouth disposal options (June, 2001).
- the specialist knowledge and expertise of a range of professionals delivered through a series of meetings and workshops, including a 2 day workshop at Cranfield University (Feb – August 2006);
- internal consultation of study group members (July/August 2006)
- an independent expert peer review (planned for October 2006); and
- consultation on the approach from a range of stakeholders (planned November 2006).

2.3 This study was concerned with development of a methodology and its application to the disposal of bird carcases during an avian influenza H5N1 outbreak. The analysis is subject to the limitations discussed in Section 1 above.

General principles

2.4 The methodology adopted the general principles of Defra's Guidelines on Environmental Risk Assessment and Management (DETR *et al.*, 2000; Defra, 2002; (Figure 1)

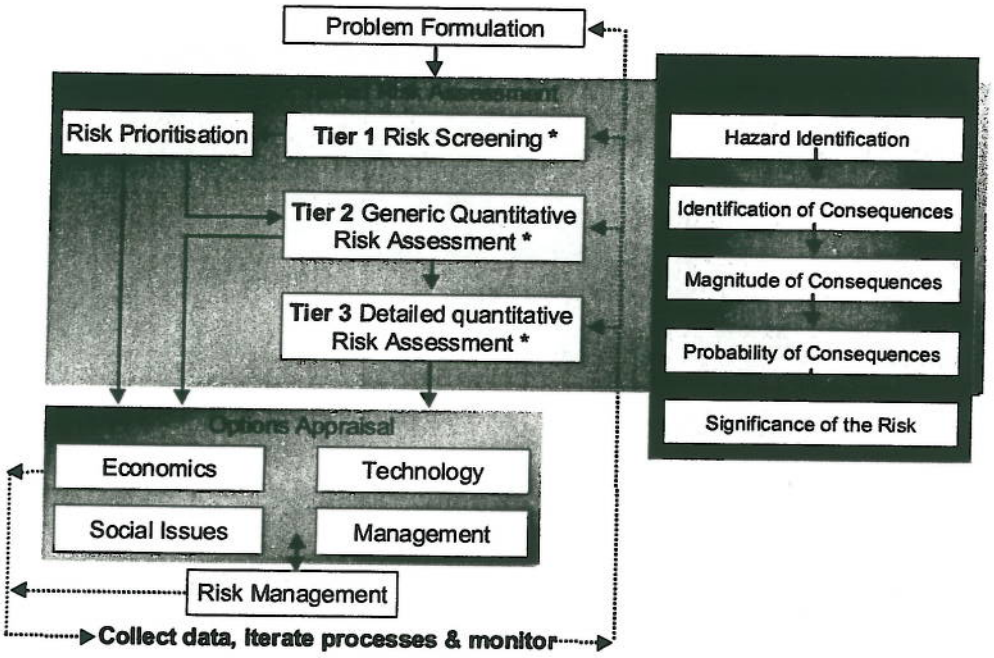


Figure 1. Generalised framework for risk management (after DETR et al., 2000).

2.4 During carcase disposal, the exposure of receptors to hazardous pollutants or pathogens may occur. Managing these potential exposures is central to effective risk management throughout the process chain. In practice, there are critical control points at each stage of the process chain – opportunities to actively manage exposure and reduce risk. Under normal operating conditions with the application of good practice, barriers (management measures) are applied that effectively guard against exposure to hazards. These include technical, managerial and human systems and might include the use of personal protective equipment, the use of leak-proof containers, use of an escort during transportation or the use of secured drainage at rendering plants, for example (see Sections 1.3-1.8).

2.5 A process chain for a carcase disposal option therefore comprises a number of stages with effective barriers in place to guard against exposure.

2.6 Maintaining absolute integrity of these barriers for 100% of the time is not practically achievable even with high degrees of vigilance. Inadvertent failures of these systems may promote the release of pollutants or pathogens or both. A valuable concept describing how failures can occur in systems is the 'Swiss cheese' model (Reason, 1997). It describes how unwanted incidents can occur. Latent factors and active flaws exist in all systems as precursors to the conditions that result in an undesired event – here an exposure event. Most of the time, active risk management measures (layers of the cheese) guard against this. But if unmanaged, these factors and flaws may align and adverse events occur (Figure 2).

2.7 This is a useful analogy because the barrier approach is widely used and familiar to those managing these systems.

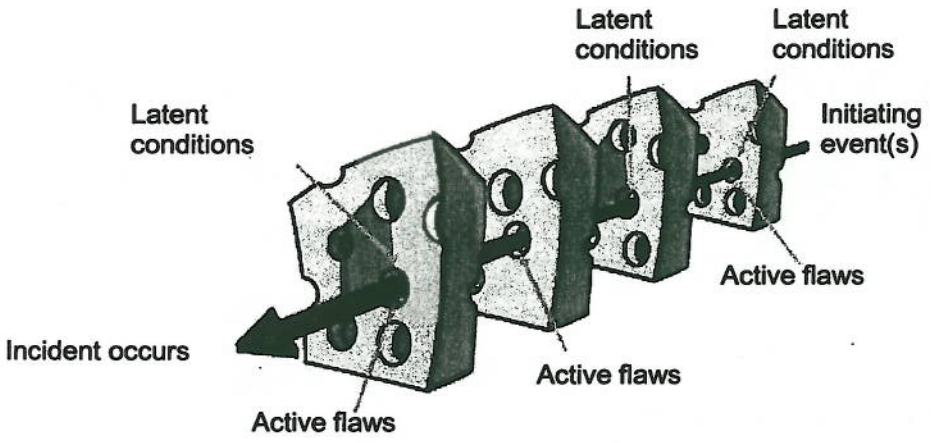


Figure 2 Reason's 'Swiss cheese' model of organisational accidents (after Reason, 1997;2000)

2.8 Applying this general principle to the process of carcase disposal, solid layers of the cheese represent effective risk management measures in place along the process chain that, during routine operation, guard against the release of hazardous agents to humans, animals or the wider environment. The number of holes in each layer can represent the opportunities for exposure at each stage of the process – the relative fallibility of each layer. The more holes, the more fallible that stage of the process chain. The larger the holes, the greater the likelihood of a failure of this stage of the process.

2.9 While engineered processes can be operated with high degrees of safety, other parts of a process chain may be more fallible because less control is available – during storage or on-farm burial, for example. Importantly, the latent conditions and active flaws may represent not just technical failures but deficiencies in training, supervision, communication or of control systems. These must also be managed.

2.10 Exposure pathways that are more available (larger holes in the layers) because there is less control, are more likely to be accessed by hazardous agents. Stages in the process chain that have more exposure pathways associated with them (greater number of holes in a layer) require more active management.

Method

2.11 The method applied in this work comprised six tasks:

(i) hazard identification, screening and prioritisation (Section 3; Annex B);
(ii) representation of the process chain for a series of disposal options and consideration of the efficacy of barriers for risk reduction along each process chain (Section 4, Annex C);
(iii) a review of a master list of potential exposure pathways for hazards from carcases developed previously during the 2001 foot and mouth outbreak (Section 5, Annex E);
(iv) the development of conceptual exposure models for a series of process chains and a semi-quantitative exposure assessment for each option (Section 5, Annex D);

(v) development of a draft disposal hierarchy informed by (i) to (iv) (Section 6); and

(vi) a preliminary screening of operating constraints acting on the disposal options (Annex H).

2.12 The DoH (2001) risk assessment provides a sound rationale for hazard identification, screening and prioritisation. The approach adopted by the working group (Figure 3) followed their lead and identified a set of hazards using expert veterinary, environmental and public health expertise and applied a successive series of filters to a pooled set of hazards, with the aim of focusing on the most significant hazards:

- filter 1 - does the hazard pose potentially serious health effects, animal health effects or environmental impacts?
- filter 2 - for hazards posing potentially serious health effects, animal health effects or environmental impacts, are they likely to evade destruction if not contained?
- filter 3 - for those hazards posing potentially serious effects that may evade destruction, could they be present at a point of exposure in a sufficient quantity to be of concern?

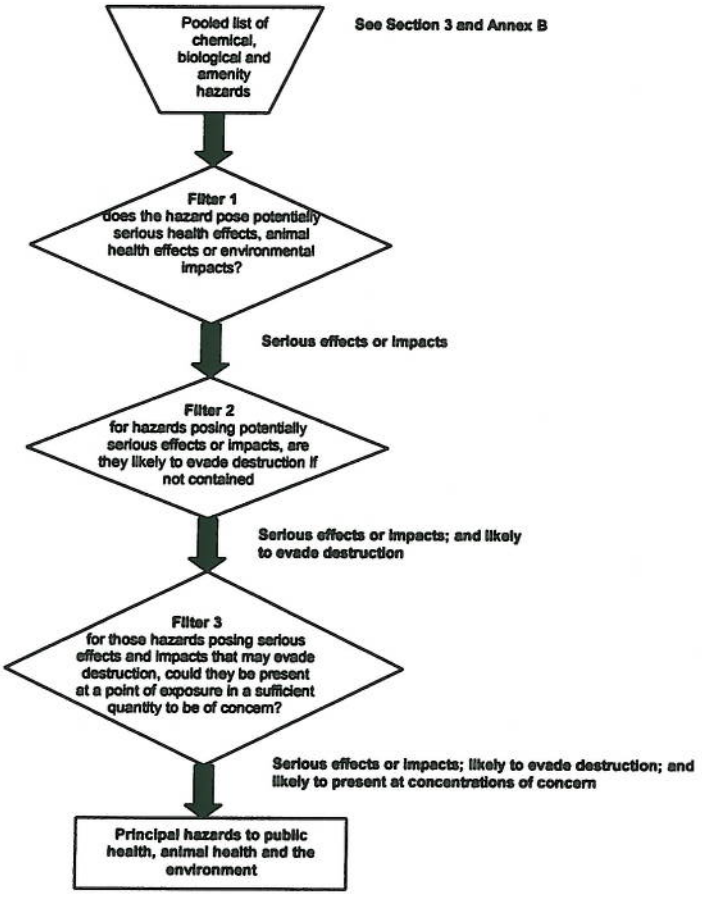


Figure 3. Flow chart for identifying principal hazards from disposal of carcases (after DoH, 2001)

2.13 The process chain for a series of disposal options was represented initially by reference to the discrete stage for each disposal option. The process chain was described by reference to 5 main stages, further broken down into 12 component stages:

- Disinfection and collection:
  - containment *in situ*
  - destruction at source
  - gather carcases to local store
  - contained storage of gathered carcases
  - containment during local processing
  - destruction during local processing
- Transport:
  - transport to facility
- Pre-processing:
  - containment prior to processing
- Processing:
  - containment during off-site processing
  - destruction during processing
- Dealing with residues:
  - residuals containment
  - residuals destruction

2.14 The length of the process chain is option-specific. Options may have very short process chains that terminate early (e.g. do nothing; leave carcase *in situ*) or longer chains in which carcases may be transported some distance to regional facilities, treated and the treatment residues disposed of at some further distance from the treatment facility (e.g., incineration).

2.15 The extent to which each stage in the process chain is susceptible to releases of a hazard was qualitatively assessed, with the expert workshop panel considering the likely efficacy of risk reduction offered by barriers at each stage of the process chain (Section 4, Annex C).

2.16 In general, the early stages of a process chain offer more opportunities for the release of hazards and thus more potential for exposure. Subsequent waste processing, where this is a component, offers differing degrees of effectiveness depending on whether hazard destruction is assured or not. The latter stages of the process chain concern the relative containment of process residues.

2.17 A categorisation of options is then possible by considering the degree of risk mitigation offered across the full process chain. This was completed by reference to four categories of disposal option referred to in the draft methodology document (Annex F):

Table 1: Categories of generic options (after Annex F)

Disposal option	Generic advice
1	This is a preferred option
2	This is a secondary option
3	This is a possible option, but not recommended
4	This is a generally undesirable option

2.18 A semi-quantitative exposure assessment was then completed, first by reference to a master list of potential exposure pathways for hazards from carcases developed during the 2001 foot and mouth outbreak (Section 5, Annex E). Having verified the suitability of this list to the case of avian influenza, a series of conceptual exposure models was developed for a representative sub-set of process chains (Annex D). The analysis included exposure pathways associated with the transport of pathogens and chemicals through the environment and exposure mechanisms such as the ingestion of water, inhalation of volatiles, direct contact with animals and people, human and animal consumption of fish or shellfish, crop irrigation and consumption, the ingestion of irrigation water and the consumption of animals (Annex E).

2.19 The relative availability of potential exposure pathways indicates the likelihood of exposure. Potential exposure pathways were thus described and ranked using a linear scale by the expert panel at the workshop (nominal ranks in brackets) as being:

- not available (0);
- of negligible availability (1);
- of low availability (2);
- of medium availability (3);
- or of high availability (4).

This was achieved by consideration of the environmental and microbiological characteristics of the key hazards, through applying expert knowledge of the principal potential environmental pathways and by consideration of the relative sensitivity of receptors to exposures. The relative consequences of individual impacts at the receptor were not weighted. The analysis represented an assessment of the relative likelihood of exposure to the key hazards identified in Section 3 for humans, animals and the environment across a multistage process chain. It also allowed a semi-quantitative indication of the relative distribution of exposures across the process chain for the options individually assessed.

2.20 Two metrics were developed for comparing options:

(i) the total number of pathways across the full process chain for each option; and

(ii) the percentage of medium to high availability pathways across the full process chain.

2.21 Taken together, these (Annex D) represent the likelihood of a release of hazards for the process chain associated with each option; that is, a potential exposure. Options were categorised as described above in paragraph 2.17. At this generic level of analysis, it is not possible to infer a dose nor identify the specific consequences of exposure to a dose, simply because individual receptors are not considered as they would be in a site-specific analysis. What this analysis does provide however, is insight into the opportunities that exist for releases and thus potential exposures along a process chain. This is critical because risk management needs to be targeted at these critical control points.

2.22 The results of the qualitative analysis and semi-quantitative exposure assessment were synthesised and used to derive a final draft disposal hierarchy (Section 6).

2.23 Finally, a preliminary screening of operating constraints acting on the disposal options was developed using the expert panel at the workshop (Annex H). This considered legal (waste management) constraints and the degree of constraint (4 – fully constraining; 0 – not constrained) that logistics, net relative costs, relative sectoral capacity, time and the public perception of risk might have on selected options.

3. Hazards screening and prioritisation

3.1 Annexes B(i) and B(ii) present the full pool of chemical and biological hazards agreed by the working group. Application of the three filters (Figure 3) produced a subset of hazardous agents posing potentially significant human health effects, animal health effects or environmental impacts, capable of evading destruction and presenting at sufficient doses to be of potential concern. The final list of hazards that is considered further in this report is shown below in Table 2.

Table 2. Hazard screening and prioritisation – hazards passing Filter 3

Agent	Qualifying comment on amount and/or timing of exposure to agent
Avian influenza (H5N1)	For animal health (low dose exposure will cause disease in birds) a small public health risk
Avian influenza (other strains)	For animal health (low dose exposure will cause disease in birds) a small public health risk for H5 and H7 strains
Campylobacter spp	Prevalent pathogen. Several potential pathways. Low dose exposure will cause disease in animals and humans.
Salmonella spp	Present in UK pigs, cattle and sheep. Prevalence falling in recent years but still seen as an important pathogen. (Control of salmonella strains in poultry – very good)
Veterinary medicines (in bird) – pesticides, antibacterials, coccidiostats, barbiturates	If poultry are killed before they would normally have been there is a possibility that veterinary products may be present in the body at elevated levels (within the normal withdrawal period). If killing is by lethal injection there may be barbiturates present – potential impact on the environment
Ammoniacal nitrogen / ammonia gas	Present naturally and in high strength leachate from decaying carcases. Significant potential impact on water bodies, especially groundwaters.
Disinfectants	Used routinely on poultry units for biosecurity but in the event of an outbreak of avian influenza usage will increase. Carcases will be sprayed with disinfectant prior to disposal. Most disinfectants contain List 1 (Groundwater Regulations) substances and should not be discharged to controlled waters.
Detergents	From cleansing and disinfection - potential impact on the aquatic environment through percolation and runoff.
Benzene, toluene, ethylbenzenes, xylenes	Combustion byproducts – potential impact on air quality.
Wood resins and wood preservation products	Poor combustion could release hazards – impact on air quality and ash quality.
Particulates	Combustion products - nuisance and public health impact.
Odour	Amenity and public health impact on local communities.
Smoke	Amenity and public health impact on local communities.
Noise	Amenity and public health impact on local communities.

3.3 Having identified the key hazards, the likelihood of exposures being associated with the process chains of each disposal option were evaluated; qualitatively in the first instance (section 4) and then semi-quantitatively (section 5), so that comparisons between options could be made.

4. Generic, qualitative assessment

Assessment results

4.1 The output of the qualitative analysis (Annex C) is an assessment, across the complete process chain, for each option and an appraisal of the relative effectiveness of each stage to contain hazards.

4.2 The analysis provides a broad overview of each option and considers the potential for exposures across the full process chain for each option (Figure 4).

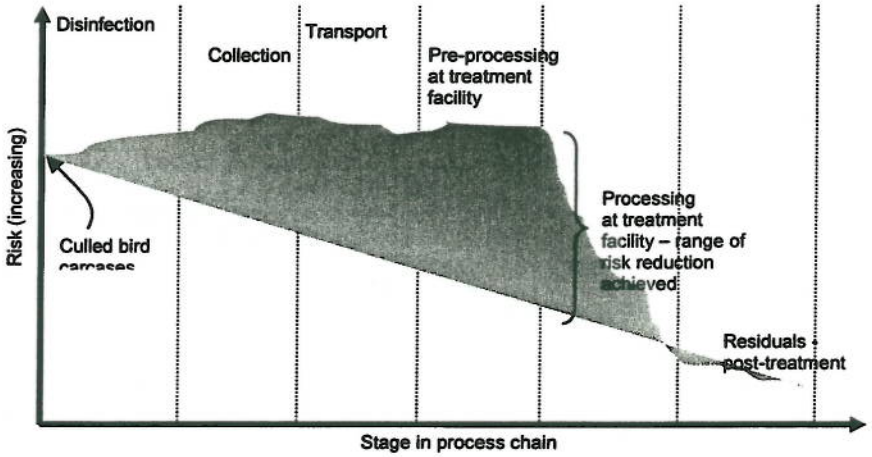


Figure 4. Illustrative risk profile along a process chain for a single carcase disposal option showing range of possible risks and potential distribution along process chain

4.3 Table 3 summarises the analysis and offers a categorisation of options by reference to the draft methodology in Annex F. In interpreting this table, one should note that:

(i) Process chains ending with stages that are effective (or mostly effective) at reducing exposures are preferred options as these indicate no residual risk.

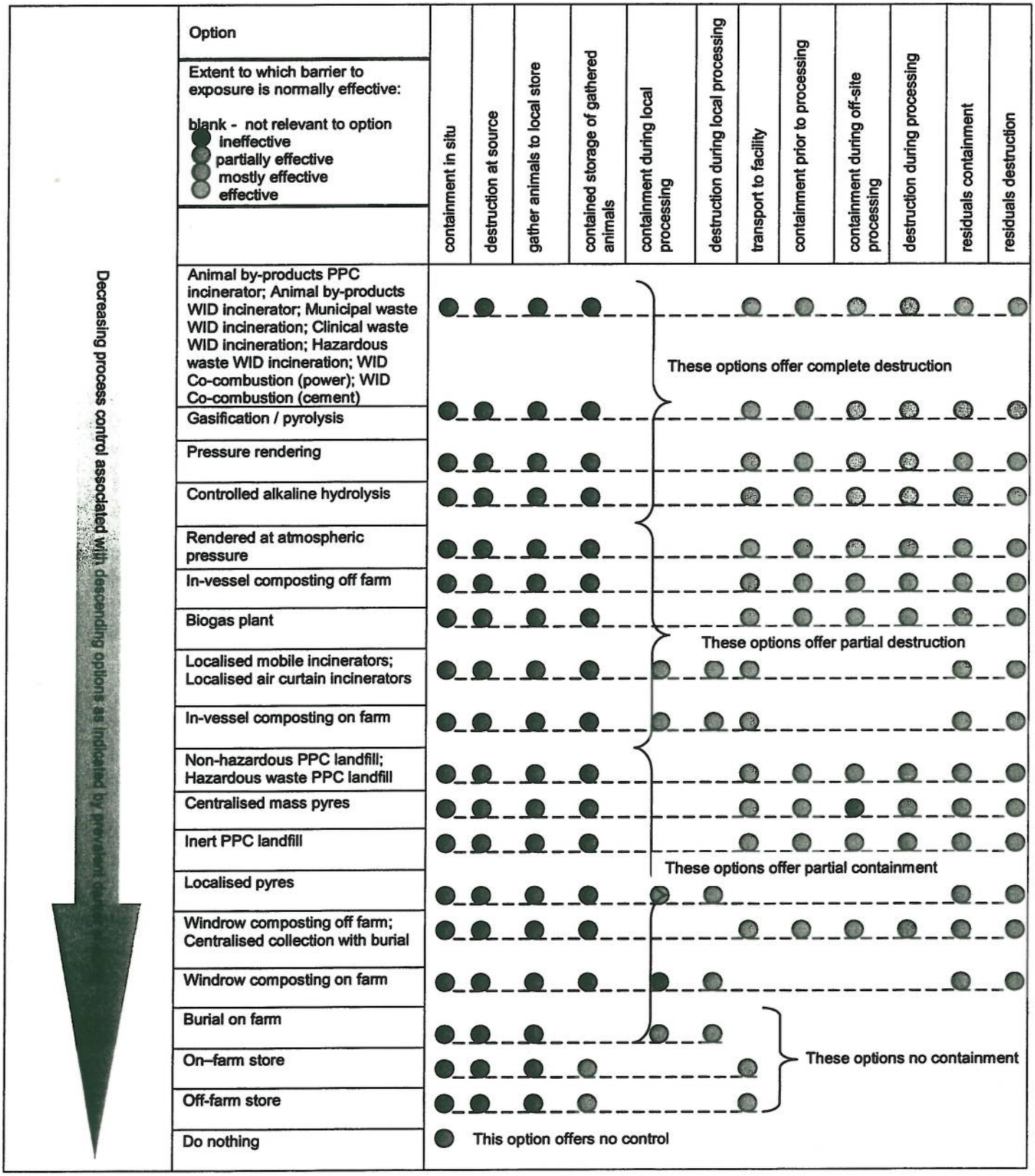
(ii) As one descends the table, there are fewer options terminating with effective barriers for reducing exposure, hence some residual risk remains.

(iii) All options will, if selected and used in practice, be subject to relevant regulatory controls to ensure that actions are taken to mitigate risks. These will need to focus on stages in the process chain where exposures could otherwise take place.

(iv) The analysis in Table 3 does, however, recognise the practicality that during the adoption contingency measures, regulatory and operator controls may not be as completely effective as under normal conditions and so some aspects of the process chains (*e.g.* containment prior to destruction) account for this.

4.4 The central insight of Table 3 is the incremental loss of process control as one descends the Table. In this study, therefore the above appraisal was supplemented by a semi-quantitative assessment of the opportunities for exposure to hazards for a select number of process chains.

Table 3. Assessment of process chain and categorisation of carcase disposal options



5. Generic, semi-quantitative assessment

Assessment results

5.1 The analysis in Annex C (Table 3) does not fully describe the potential exposures associated with each option. A series of conceptual models that expanded the process chains in Annex C was developed. These were formulated in a series of Excel™ spreadsheet layers (Annex D), informed by a master list of exposure pathways (Annex E) developed originally for the foot and mouth outbreak in 2001.

5.2 Disposal options (Table 4) with:

(i) a large proportion of highly available pathways ('leaky' process chains, irrespective of length); and/or

(ii) large numbers of pathways (typically, longer process chains)

are more likely to result in significant exposures. These options may pose a greater potential risk to public health, animal health and to the environment but, whilst this is the case, it is important to note that regulatory frameworks are in place to mitigate these risks. The metrics allow a broad categorisation of these options (Table 4) by reference to the draft methodology (Annex F). The options appear to group into four categories. We propose a distinction where the proportion of medium to high availability exposure pathways exceeds 1/6 of the total number of pathways across all receptors. Undesirable options are those where the proportion of medium to high availability exposure pathways exceeds 1/3 of the total. The categorisation is broadly consistent with the desirability of waste process options, then controlled disposal and finally uncontrolled disposal.

5.3 The semi-quantitative exposure assessment also allows consideration of the distribution of potential exposures across the process chain of the options considered. A selective analysis of this for five options is presented in Table 5. This illustrates that greater opportunities for exposure to hazards occur in the early stages of the process chain, reinforcing the need for protective procedures throughout but particularly at the outset of the management of carcases. The percent contributions are presented in Table 6 for ease. This disaggregation of exposure supports the qualitative analysis in Table 3.

5.4 Care is required in interpreting these data and only generalised trends should be used to infer conclusions for the reasons provided in Section 1. Rankings used in the exposure assessment are on a linear scale (0, 1, 2, 3, 4; footnote to Table 4) and were elicited in the expert workshop.

5.5 This said, the metrics for the semi-quantitative exposure assessment, in terms of (i) the proportion of medium and high availability exposure pathways that exist for public, animal and environmental exposures; and (ii) the total number of medium and high availability pathways appear to provide a sound basis for assessing process chains.

Table 4 Semi-quantitative exposure assessment metrics[1]

	Option and process chain	Metric	Human	Animal	Environment	Total	Medium and high availability pathways across all receptors (n)	Medium and high availability pathways across all receptors (%)
This is a preferred option	Composting (in vessel)	Number of pathways	142	135	17	294	33	11
		Pathway scores [2]	237	220	38	495		
	Alkaline hydrolysis	Number of pathways	149	142	19	310	44	14
		Pathway scores	244	235	44	523		
	Gasification	Number of pathways	149	142	19	310	44	14
		Pathway scores	245	235	44	524		
	Biogas	Number of pathways	157	149	21	327	45	14
		Pathway scores	252	242	50	544		
	Atmospheric rendering	Number of pathways	157	149	21	327	45	14
		Pathway scores	256	242	52	550		
	Pressure rendering	Number of pathways	157	149	21	327	45	14
		Pathway scores	256	242	52	550		
	Incineration (generic)	Number of pathways	149	142	19	310	44	14
		Pathway scores	246	235	45	526		
	Co-combustion (cement)	Number of pathways	122	115	17	254	44	17
		Pathway scores	210	202	44	456		
	Mobile incinerator	Number of pathways	127	120	12	259	44	17
		Pathway scores	198	186	28	412		
This is a secondary option	Composting (windrow)	Number of pathways	163	156	17	336	62	18
		Pathway scores	284	267	40	591		
	Air curtain	Number of pathways	163	154	18	335	62	19
		Pathway scores	323	307	51	681		
	Landfill	Number of pathways	109	103	12	224	46	21
		Pathway scores	169	171	28	368		
	Mass burial	Number of pathways	109	103	12	224	46	21
		Pathway scores	190	192	30	412		
This is a possible option but not recommended	Mass pyre	Number of pathways	164	154	18	336	90	27
		Pathway scores	341	324	57	722		
	On-farm pyre	Number of pathways	164	154	18	336	96	29
		Pathway scores	358	332	58	748		
This is a generally undesirable option	Anaerobic digestion (pits)	Number of pathways	101	95	10	206	73	35
		Pathway scores	214	203	30	447		
	On farm burial	Number of pathways	101	95	10	206	73	35
		Pathway scores	214	203	30	447		
	Do nothing	Number of pathways	36	34	4	74	41	55
		Pathway scores	90	92	14	196		

1 The data presented herein should be interpreted to apply to the relative risks associated with each of the disposal options. They do not indicate that significant risks will actually be associated with these options should they be used in practice. Appropriate regulatory frameworks provide the means for assessing and managing site-specific risks.

2 Pathway scores were generated by summing the probability scores (0 –4, see paragraph 2.19) assigned to each complete pathway for each disposal option

5.6 The analysis reveals little difference between the risks arising from individual waste process technologies when the full process chains are considered. Options that offer engineered process control, containment and high levels of destruction are preferred over open, on-site treatment as they destroy hazards (e.g., avian influenza viruses and other pathogens are sensitive to heat).

5.7 The distribution of opportunities for exposure by process stage is important (Tables 4, 5 and 6) as is the proportion of medium and high availability pathways across the process chain. Even where process chains are short (Table 4; 'Do-nothing'), the observation that they harbour a high proportion of pathways that are readily available to significant hazards (Table 4; on-farm burial; do-nothing) means that they offer significant opportunities for exposure. These data are indicating that the greatest opportunities are where there is poor or no process control (Table 5 and 6). Where this is the case, exposures are not being actively managed. Therefore, the longer carcases remain in this process stage unmanaged, the greater the likelihood for exposure and thus the greater the potential risk. The analysis in this report supports this implicit but hereto unsubstantiated conclusion.

Table 5. Distribution of potential exposure pathways by stage in the process chain

Process stage	1		2		3		4		5	
Description	Disinfection / collection		Transport		Pre-processing		Processing		Residuals	
Disposal option	Number of pathways		Number of pathways		Number of pathways		Number of pathways		Number of pathways	
	Total	Significant[1]	Total	Significant	Total	Significant	Total	Significant	Total	Significant
Incineration	74	38	74	2	89	4	17	3	56	0
Rendering	74	38	74	2	89	4	32	3	58	2
Landfill	74	38	74	2	0	0	76	6	0	0
On-farm pyres	74	38	74	7	75	33	56	13	57	8
Do nothing	74	41	0	0	0	0	0	0	0	0

[1]Pathways assessed to have a medium or high likelihood of being complete

Table 6. Percentage contribution of potential exposures by process stage

Process stage	1	2	3	4	5
Description	Disinfection / collection	Transport	Pre-processing	Processing	Residuals
Incineration	51%	3%	4%	18%	0%
Rendering	51%	3%	4%	9%	3%
Landfill	51%	3%		8%	
On-farm pyres	51%	9%	44%	23%	14%
Do nothing	55%				

6. Comparison of options

6.1 The aim of this study was to undertake a risk-based review of different carcase disposal options. The study involved a qualitative and semi-quantitative analysis of the process chain associated with a range of options (Tables 3 and 4). Consideration of the principles, insights and analyses within this report allowed completion of Table 1, presented below as Table 7.

Table 7 Draft, risk-based carcase hierarchy in the event of an avian influenza H5N1 outbreak

Disposal option*	Statement of preference
Composting (in vessel), Alkaline hydrolysis, Gasification, Biogas, Atmospheric rendering, Pressure rendering, Controlled incineration, Mobile incineration, Co-combustion in cement kilns.	These are preferred options
Composting (windrow), Air curtain incinerator, Permitted landfill, Mass burial	These are secondary options
Mass pyre, On-farm pyre	These are possible option, but not recommended
Anaerobic digestion (pits), On farm burial, Do nothing	These are generally undesirable options

* Options listed within each of the four categories are not presented in any order of preference

6.2 Beyond this are issues of practicality, economics, social implications, public acceptability, industrial capacity and the legality of these options. A preliminary analysis of these constraints was undertaken and is presented in Annex H. Certain waste processing options are constrained because of legality, capacity, for example. These constraints will be considered by SVS and Defra within the context of the generic contingency plan. The composting of carcases killed for disease control purposes, for example, is currently illegal. Similarly. Irrespective of its potential utility, GB has very little biogas and alkaline hydrolysis capacity at present.

7. Conclusions

7.1 This study was undertaken to inform a review of the carcase disposal hierarchy in Defra's generic contingency plan. A screening of chemical and pathogenic hazards and of amenity impacts associated with the disposal of bird carcases (in the event of an outbreak of avian influenza) identified the following key hazards (Section 3):

- avian influenza (H5N1);
- avian influenza (other strains);
- *campylobacter* spp;
- *salmonella* spp;
- veterinary medicines (in bird) – pesticides, antibacterials, coccidiostats, barbiturates;
- ammoniacal nitrogen/ammonia gas;
- disinfectants
- benzene, toluene, ethylbenzene and xylenes;
- wood resins and wood preservation products;
- particles;
- detergents;
- odour;
- smoke; and
- noise.

7.2 The disposal hierarchy presented in the Defra contingency plan is supported by the hierarchy generated in this assessment (Table 8). The hierarchy places waste processing (*e.g.* incineration and rendering) above controlled disposal (*e.g.* landfill) which is above uncontrolled disposal (*e.g.* pyres):

commercial fixed plant incineration
↓
rendering
↓
permitted commercial landfill
↓
pyre burning
↓
on farm burial

7.3 A number of technologies not mentioned in the Defra contingency plan are potentially suitable on risk grounds for use in the event of an outbreak of avian influenza. Some of these (eg, alkaline hydrolysis and gasification) are preferred over options in the existing hierarchy.

7.4 Carcase disposal comprises a series of stages (a process chain), with each stage offering opportunities for exposure to hazards. Typically, the process chains for disposal options offer hundreds of individual exposure pathways for hazards, although the majority are not likely to be of concern.

7.5 The range of hazards of concern extends beyond avian influenza H5N1 because of the chemicals used to disinfect carcases, the veterinary products within birds and the byproducts of carcase decomposition and waste processing.

7.6 The avian influenza H5N1 virus, as a pathogen in isolation, is not a principal concern in this analysis. Risks to human health, animal health and the environment that are also associated with the other pathogens that may accompany carcases; carcase decomposition products; products of incomplete combustion and the disinfectants used during disposal may be of even greater concern.

7.7 This analysis indicates that the early stages of the process chain, on-farm, pose more opportunities for exposure to hazards than the later stages where hazards are generally contained, wastes being treated and residues managed within regulated processes (tables 5 and 6). This is a key consideration and evidence for this assertion is provided by the semi-quantitative analysis in Chapter 5. The potential risks of front-line workers passing on infection must be considered and risk management measures put in place as routine.

7.8 For the process chains associated with disposal options, risks are reduced where:
- hazards are contained rather than left in an open environment;
- technologies assure the destruction of hazards rather than partial treatment;
- technologies have engineered process control rather than systems that are open to the environment;
- residues are minimised;
- process chain are short rather then extended (in time or distance).

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Annexes

(Only annexes A & G are included as part of the main report. The other annexes are working documents used or derived during the workshop and subsequent working group meetings. As such they are not formatted for printing or easy viewing and some of the documents do not include all the background analysis or assumptions made. All the annexes are however available on request).

Annex A List of contacts and constitution of expert panel (e)

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Independent peer review

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Annex G Brief Description of Disposal Routes

(Numbers refer to the list of disposal options considered by the working groups and expert panel, they are also used in annex C)

7,8 & 9 Landfill
Disposal by burial in engineered cells. Landfills are operated in a series of cells, each of which is engineered to include gas and leachate control systems. These systems are integrated within the landfill design which allows management of potential pollutants within the landfill site. As one cell is filled, the next is prepared to receive waste. Waste is added and compacted in consistent, even layers according to strict engineering requirements. Each layer is covered to ensure that the waste is safely contained within the appropriate cell. As each cell is completed, it is capped with a layer of clay that effectively seals the waste in the landfill. Further layers of soil are placed on top of the cap.

12. Localised Mobile Incinerators
Disposal by combustion. Low capacity mobile incinerator.

13. Localised Air Curtain Incinerators
Disposal by combustion. The principle of these machines is that a large fan creates a laminar air flow directed into the fire chamber thus accelerating combustion. Within the containment of the fire chamber the airstream forms a turbulent 'rotary' draft. Waste wood (mainly pallets) and carcases are alternately fed into the combustion chamber and operations are continuous until the fire chamber has to be emptied of ash.

14 & 15 Rendering

Rendering is an industrial process that simultaneously drives off the water contained within the carcase material and separates the fat from the bone and protein. The rendering process yields tallow, and meat & bone meal (MBM) as by-products.

16. Pyrolysis & Gasification
Gasification is the thermal decomposition of organic material at elevated temperatures in an oxygen restricted environment. The process of Pyrolysis is the same, but takes place with the complete absence of oxygen.

Composting
Composting is the controlled aerobic decomposition of organic matter.

17 & 18. In-Vessel Composting
The enclosed composting of waste, allowing a higer degree of process control. In-vessel systems can be broadly catergorised into five types: Containers, silos, agitated bays, enclosed halls and tunnels.

19 & 20. Windrow Composting
Carcase material and a bulky carbon source are heaped into elongated piles called windrows. The windrows are monitored throughout the composting process to ensure

that the optimum temperature, oxygen concentration and moisture content are maintained. The windrows are normally turned periodically, to introduce fresh air, and watered to maintain the ideal conditions for composting.

21. Biogas Plants
A biogas powerplant is a system where biogas is used to generate electricity. The gas, which is produced via anaerobic digestion (the breakdown of organic matter by bacteria in the absence of oxygen), is used to drive an electricty generator.

22. Controlled Alkaline Hydrolysis
Alkaline hydrolysis uses sodium hydroxide or potassium hydroxide to catalyze the breakdown of organic material (through the use of water) into a sterile aqueous solution. Heat is applied to accelerate the process.

Controlled Incineration
The disposal of waste through thermal treatment at very high temperatures.

23. Animal By-Products PPC Incinerator
Industrial Fixed Plant Polution Prevention and Control (PPC) Permitted Incineration Plant.

24. Animal By-Products WID Incinerator
Industrial Fixed Plant Waste Incineration Directive (WID) Approved Incineration Plant.

25. Municipal Waste WID Incineration
Municipal waste incinerators treat all types of municipal waste, burning the waste at high temperatures to reduce the volume of the waste and produce energy.

26. Clinical Waste WID Incineration
These are incinerators which deal solely with clinical waste, mainly in hospitals. Clinical waste includes waste from hospitals, dentists, veterinary surgeries, nursing homes, etc.

27. Hazardous Waste WID Incineration
Hazardous waste incinerators primarily treat dangerous wastes from industrial sources, including the chemical and pharmaceutical industries, paint, food factories and metal processing operations.

28. WID Co-combustion (Power)
Waste is incinerated with other fuels to create electricity.

29. WID Co-combustion (Cement)
Burning waste as part of process of creating cement.

REVIEW OF FUNDING, GOVERNANCE AND RISK MANAGEMENT AT THE INSTITUTE FOR ANIMAL HEALTH

A REPORT FOR BBSRC COUNCIL

APRIL 2008

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REVIEW OF FUNDING, GOVERNANCE AND RISK MANAGEMENT AT THE INSTITUTE FOR ANIMAL HEALTH

A REPORT FOR BBSRC COUNCIL

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EXECUTIVE SUMMARY

This report is from an independent review panel established under the chairmanship of Professor Sir John Beringer in December 2007. The panel's remit was to advise BBSRC[1] Council on the future funding, governance and risk management at the Institute for Animal Health (IAH), which occupies sites at Compton (Berkshire) and Pirbright (Surrey). The review was instigated following the Government's response to the foot and mouth disease outbreak in summer 2007.

Animal health research has high economic and social impact in underpinning the UK livestock industry and food supply and in helping to protect both animal and human health. IAH is at the forefront of UK research in animal health and provides key facilities and expertise to deal with outbreaks of serious animal diseases. If IAH did not exist the facilities and expertise would have to be created elsewhere. However, the institute requires major capital investment and important issues of funding, governance and risk management must be addressed.

Redevelopment at Pirbright

The current plan for redevelopment of the IAH Pirbright site, which is to replace outdated buildings and facilitate the transfer of virology staff from Defra's Veterinary Laboratories Agency (VLA) at Weybridge, is of the utmost importance because it will provide a key component of the nation's ability to respond to outbreaks of serious animal diseases. Funding must be found to complete the project, despite escalating costs.

Recommendation 1: We recommend that the Pirbright Site Redevelopment Programme must be carried through to completion without delay.

The planned redevelopment represents an unprecedented opportunity to establish a new national facility and centre of internationally recognised expertise. As a partnership between BBSRC and Defra it should be based on a jointly agreed science and funding strategy to ensure that it will fulfil its various functions. The joint strategy should be in place before the commissioning of the new facility in 2011.

Recommendation 2: We recommend that the redeveloped Pirbright laboratory should be positioned as a new 'National Centre for Animal Viral Disease' and should be founded upon a joint BBSRC-Defra science strategy for animal health and welfare.

Funding

It is critical that the new National Centre is funded on a sustainable basis and that the funding partners, BBSRC and Defra, resolve issues of uncertainty and short-term funding that have caused instability in the past. To allow proper planning, and to ensure that safety and biosecurity are not compromised, core funding must be secure and sufficiently long-term. It is essential that funding includes adequate provision for running and maintaining the facility, and that it should be administered as a single stream.

Recommendation 3: BBSRC and Defra must jointly provide long-term core funding to ensure the sustainability of the new National Centre at Pirbright. We do not believe it appropriate to fund a national facility with statutory responsibilities primarily through the award of research grants and contracts.

Recommendation 4: We recommend that core funding for the new National Centre at Pirbright should be administered as a single stream with a planning horizon of at least five years. Core funding must include adequate provision for core staff, running

[1] Biotechnology and Biological Sciences Research Council – see Annex 4 for further information.

costs, maintenance and renewal of infrastructure, so that safety and biosecurity needs are satisfied.

Governance

The historical ambiguous governance arrangements at IAH (which previous reports have identified as unsatisfactory) must be resolved more quickly than is currently planned, and the institute should move at once to direct control by BBSRC in line with the wishes of the Governing Body as expressed in October 2006.

Recommendation 5: In line with the previous wishes of the IAH Governing Body, BBSRC should take over direct responsibility for governance of IAH. As an interim measure to resolve the current ambiguity of governance, and in recognition of the scale of change facing IAH, we recommend that the IAH Governing Body should invite BBSRC to become a Corporate Trustee for IAH, in order to accelerate the planned move to bring governance under more direct control.

For effective operation of the new National Centre it will be important to ensure a common scientific 'culture' and that management structures are clear, unambiguous and uniform for all staff, including those relocating from VLA.

Recommendation 6: We recommend that a clear single line of management and reporting is established for all staff within the new Centre at Pirbright, for example through seconding relocated VLA staff to BBSRC or *vice versa*. This will require explicit agreement between BBSRC, IAH and VLA management in advance of the staff moves.

The funding partners must agree longer-term governance arrangements, in recognition of the joint nature and multiple functions of the new National Centre. For simplicity, there must be a single owner, and BBSRC and Defra should agree on ownership over the next year. The issue is of such importance that it must be referred to higher authority in Government if it cannot be resolved within that time.

Recommendation 7: In view of the importance of the new Centre at Pirbright as a national facility, and the potential economic and social impact of serious disease outbreaks, BBSRC and Defra must agree long-term arrangements for its ownership and management. If there is no prospect of agreement by April 2009 the matter should be resolved by referral through DIUS and Defra to the Cabinet Office.

Risk management

Appropriate preventative management of risks is vital to ensure safe and biosecure working. As a joint venture the new National Centre provides an opportunity to bring together the best elements of the existing organisations, and this process should begin forthwith.

Recommendation 8: We recommend that appropriate IAH and VLA staff develop jointly agreed risk management procedures. In order that procedures are in place well in advance of the movement of VLA staff to Pirbright, this process should begin immediately.

Future of IAH Compton

The IAH Compton laboratory requires modernisation and Council will need to take major decisions on investment. Those decisions should be informed by full assessment of scientific and strategic need, given that support from Defra for endemic disease work has declined and is expected to continue to do so. If the case is suitably compelling for large scale investment to provide replacement facilities to house work currently at Compton, we can see advantages in co-locating that work alongside the new Centre at Pirbright.

Recommendation 9: We recommend that BBSRC Council's decisions regarding the future of IAH Compton and investment in endemic disease research should be based on a thorough assessment of scientific and strategic need.

Recommendation 10: We recommend that, provided Council is persuaded by the scientific and strategic case, work should be relocated from Compton to join the new Centre at Pirbright.

Future national context

There is a need for improved coordination across the spectrum of funders of research and associated functions in support of animal health and welfare. A national strategy for the underpinning science is needed to set out the research needs and maximise synergies across the various agencies. A new funders' body, with sufficiently high-level representation, would provide the means to develop such a strategy, and we believe that Defra should lead in setting it up.

Recommendation 11: We recommend that Defra, working closely with BBSRC, should lead in drawing together the main funders and stakeholders of animal health and welfare research to develop a joint national strategy for science and funding to underpin the management of risks from animal diseases, both endemic and exotic.

Recommendation 12: We recommend that Defra, working closely with BBSRC, should lead in setting up a funding body for animal health and welfare research, surveillance and associated functions, as a route to developing a joint national strategy and improving coordination across the relevant funders.

As a longer term bold vision to improve coordination further, we advocate a new national agency, which would integrate the functions of several current bodies and operate at arm's length from Government. Nevertheless we emphasise that it is essential that the longer term vision does not distract from the immediate and urgent issues of IAH funding, governance and risk management that need to be addressed. We envisage that the new agency would take over responsibilities for animal health and welfare from Defra, including ownership of VLA, and also take over ownership and management of IAH.

Recommendation 13: We recommend that a new Animal Health and Welfare agency should be established. Animal health and welfare is simply too important to remain as at present; it must be given clear leadership and be made less vulnerable to budgetary fluctuations and 'border disputes' between organisations.

FOREWORD

1. This report is the output of an independent review panel established under the chairmanship of Professor Sir John Beringer in December 2007. The panel's remit was to advise BBSRC[2] Council on the future funding, governance and risk management at the Institute for Animal Health (IAH).

Origin of this review

2. This is one of several reviews following the outbreak of foot and mouth disease (FMD) in Surrey in summer 2007. Shortly after the outbreak the Government ordered two inquiries, the Health and Safety Executive (HSE) investigation of the Pirbright site[3] and the review led by Professor Brian Spratt: *Independent review of the safety of UK facilities handling foot-and-mouth disease virus*[4].

3. The current review was instigated in response to the Spratt report, where two recommendations were of particular relevance:

Recommendations from the Spratt report:

- ***Recommendation 10**: The plans for future development of the Pirbright site should be reviewed to ensure that all safety critical issues have been addressed. This should be carried out with the help of the full range of relevant experts and regulatory bodies.*

- ***Recommendation 12**: Biosecurity of laboratories that work with FMDV is of paramount importance. Therefore there should be a review of funding, governance and risk management at IAH Pirbright to ensure an appropriate focus on biosafety and biosecurity in the future.*

4. The Government's response[5] to the Spratt report on both recommendations 10 and 12 stated:

"*We agree with both of these recommendations, and at all stages of the design of the new laboratories at Pirbright biosecurity issues have been a priority. The Pirbright Site Redevelopment Programme Board which oversees the project (and which includes members from the IAH, the IAH Governing Body, VLA and the funders), will undertake a review of all aspects of the Pirbright site so as to ensure that all safety critical issues have been addressed* [Recommendation 10]. *It will report its findings to a review body led by BBSRC, an NDPB of the Department for Innovation, Universities and Science* [sic], *in conjunction with the IAH Governing Body and supported by Defra, and with a representative of the farming community. This review body will also assess and report on the funding, governance and risk management at Pirbright* [Recommendation 12]."

This review was therefore established to consider funding, governance and risk management at IAH Pirbright (Recommendation 12), taking into account the conclusions of a separate review group[6] addressing Recommendation 10.

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[2] Biotechnology and Biological Sciences Research Council – see Annex 4 for further information.
[3] HSE report (August 2007): http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf
[4] Spratt report (August 2007): http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt_final.pdf
[5] Government response to the Spratt report: http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/govstatement_fmd2007.pdf

5. BBSRC Council decided that the terms of reference for the review of funding, governance and risk management should be broadened from a narrow focus on Pirbright to include also the IAH Compton site. The two sites are part of the same institute, with close research links, and are covered by the same funding and governance arrangements. They jointly constitute facilities and research capability of national strategic importance in infectious diseases of animals, and provide key components of the UK capacity for emergency response to outbreaks of disease. The review is intended to ensure that the future funding, governance and risk management are appropriate and sustainable for these essential facilities and their associated capability for research, diagnosis and disease surveillance.

Terms of reference

In the context of the report from Professor Brian Spratt on the safety of UK facilities handling FMD virus, and in particular with reference to recommendations 10 and 12, the review group will:

i. Assess the necessary funding, governance and risk management at the Institute for Animal Health, at Pirbright and Compton, to ensure appropriate biosecurity and to sustain a high quality basic and strategic research capability to underpin UK national interests.

ii. Report to BBSRC Council in February 2008.

6. The membership of the review panel is provided at **Annex 1**. Further background on the FMD outbreak and the various follow-up reviews is given in **Annex 2**.

7. It is important to note that it was not the purpose of this review to assess the quality of the research undertaken at IAH; this was last done as part of the BBSRC Institute Assessment Exercise[7] by a Visiting Group of external experts in 2006. Its report confirmed the very high quality and relevance of the research, and stated

"...there is a continued national and international need for the Institute for Animal Health. With its unique expertise and resources, IAH was carrying out internationally competitive research in animal health and welfare as well as fulfilling a vital public safety function in preparedness for disease emergencies."

Structure of the report

8. We begin by setting out in Chapter 1 the context of animal health research and its funding in the UK, with reference to other relevant reports and in the broader context of recent and ongoing changes in the governance of the BBSRC-sponsored institutes.

9. We go on to consider in Chapter 2 options for future arrangements for funding, governance and risk management at IAH, resulting in 13 recommendations. Annexes provide further information including background on BBSRC and its research institutes, the 2007 FMD outbreak and subsequent reports, as well as previous reports on IAH and related topics.

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[6] To address Spratt recommendation 10, BBSRC has established a review group, chaired by Professor Martyn Jeggo (Australian Animal Health Laboratory, Geelong, Australia), working in conjunction with existing bodies overseeing the plans for the IAH Pirbright site redevelopment. See also Annex 2.

[7] Institute Assessment Exercise, 2005-06: http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0606_institute_assessment.html

REVIEW OF FUNDING, GOVERNANCE AND RISK MANAGEMENT AT THE INSTITUTE FOR ANIMAL HEALTH

CHAPTER 1: BACKGROUND

INTRODUCTION

1. In this Chapter we set the context for considering the future funding, governance and risk management at the Institute for Animal Health (IAH). Given the substantial economic and social impact of animal disease, we emphasise that the UK needs to manage the risks and respond appropriately to outbreaks of notifiable diseases. IAH, which is sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC), is a major centre for the scientific research and expertise that are essential in our defence against animal disease, but the institute requires major redevelopment. We go on to summarise the current position, and some of the recent developments, in the funding, governance and risk management relating to IAH and other BBSRC institutes. It is important to understand such background before making recommendations for how to move forward.

ECONOMIC AND SOCIAL IMPACT OF ANIMAL HEALTH

2. Animal health research has significant economic and social benefits in underpinning the UK livestock industry, which is valued at £8.3 billion per year[8], and in helping to protect both animal and human health. The Preston report[9] (2007) stated:

   "*Livestock diseases not only adversely impact animal welfare and performance but may also be transmitted directly to humans or via the food chain. In any year it is estimated that at least one additional animal pathogen is transmitted to man and becomes established as a recognised zoonosis[10]. The increased international movement of people, livestock and their products, compounded by climate change supporting the extended distribution of arthropod vectors, contribute to an ever greater threat of novel or returning exotic diseases. The potential use of biological agents by terrorists adds significantly to this threat.*"

3. The cost of the foot and mouth disease (FMD) outbreak in 2001 was estimated at around £8 billion[11] including major impacts on tourism. The 2007 outbreak, despite its limited geographical spread, is estimated to have cost the Government[12] around £47M not including the costs to the wider economy. As well as the direct economic impact, animal diseases can have severe social consequences, notably on human health (from zoonoses) but also wider societal effects such as the disruption to rural livelihoods and communities.

4. Animal health research provides scientific knowledge and expertise that is extremely important for the UK to manage the risks associated with animal diseases, including the threats from current and emerging diseases that can be transmitted to humans, such as avian influenza. Examples of high impact research include work at IAH Pirbright in understanding the transmission of bluetongue virus, so that the UK was

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[8] Eurostat figures, 2002, cited in *Farm Animal Genomics review* (BBSRC, 2005), p12 http://www.bbsrc.ac.uk/organisation/policies/reviews/scientific_areas/0507_farm_animal_genomics.html

[9] Preston report: *Appraisal of options for the future relationship between the Veterinary Laboratories Agency and the Institute for Animal Health* http://www.bbsrc.ac.uk/media/news/2007/070129_preston_report.html

[10] Zoonosis: any disease and/or infection which is naturally transmissible from vertebrate animals to humans

[11] Economic costs of the foot and mouth disease outbreak in the United Kingdom in 2001. D. Thompson *et al* (2002). Rev. sci. tech. Off. int. Epiz., 21 (3), 675-687

[12] Anderson report: *Foot and Mouth Disease 2007: A Review and Lessons Learned* http://www.cabinetoffice.gov.uk/fmdreview, p117

better prepared for the recent outbreak of this disease; the leading role that IAH has played in the world-wide programme to eradicate rinderpest, with net economic impact estimated[13] at around $1 billion per annum; and the development (based on IAH work) of vaccines for coccidiosis, the most important parasitic infection of poultry world-wide.

5. It is imperative that risks to the livestock industry, and to the UK food supply more widely, are managed effectively. The leading centres for animal health work (including IAH) play essential roles in underpinning the management of those risks, through their important basic research, as well as developing and testing diagnostics, and in surveillance duties to detect new outbreaks of disease.

THE UK FRAMEWORK FOR ANIMAL HEALTH RESEARCH, DIAGNOSTICS AND SURVEILLANCE

6. Research on animal health in the UK, with associated disease diagnostics and surveillance, is undertaken mainly in a small number of specialised publicly funded research institutes, university veterinary schools and some other university departments. Foremost among the UK research centres are Defra's Veterinary Laboratories Agency (VLA) with its main site at Weybridge, and the BBSRC-sponsored Institute for Animal Health (IAH), which occupies sites at Compton (Berkshire) and Pirbright (Surrey). Other centres include the Moredun Research Institute (near Edinburgh) and the Agri-Food & Biosciences Institute (AFBI, in Northern Ireland).

The multiple roles of IAH

7. IAH is one of five research institutes sponsored (i.e., core funded) by BBSRC. It is important to recognise that IAH fulfils multiple functions: not only is it a central component of BBSRC's support for research in animal health, but it provides Defra with essential facilities to enable it to discharge its statutory duties to respond to animal disease threats. The institute has specialist containment facilities, unique facilities in the UK for experimental work on large animals, is an international reference laboratory for various major diseases of livestock, and undertakes internationally recognised basic, strategic and applied research, diagnostics and surveillance for economically important diseases of livestock in their natural hosts. IAH and VLA undertake complementary activities covering different diseases (see **Box 1**).

Box 1: Responsibility for exotic diseases at IAH and VLA

- IAH has international reference laboratory status (at Pirbright) for foot-and-mouth disease, swine vesicular disease, African swine fever, rinderpest, peste des petits ruminants, bluetongue, African horse sickness, vesicular stomatitis, sheep and goat pox and lumpy skin disease.
- Defra's Veterinary Laboratories Agency (VLA) has international reference laboratory status for classical swine fever, Newcastle disease, avian influenza, rabies and .a number of endemic viral and bacterial diseases.

8. The Compton site of IAH works mainly with endemic[14] diseases, including bovine tuberculosis, food-borne zoonoses (such as *Salmonella* and *Campylobacter*), coccidiosis (the most important parasitic infection of poultry). It is the reference laboratory for Marek's disease and also provides underpinning work for scientists at Pirbright. IAH Pirbright undertakes research on exotic diseases (mainly viral)

[13] See http://www-naweb.iaea.org/nafa/aph/stories/2005-rinderpest-eradication.html
[14] See also para 79 for discussion of 'endemic' vs 'exotic'

including foot and mouth, bluetongue and African swine fever (Box 1). The Pirbright site is shared with Merial Animal Health Ltd, a commercial animal health company that operates a large-scale manufacturing facility for animal vaccines (notably for foot and mouth and bluetongue) on part of the Pirbright site separated from the IAH laboratories.

9. IAH has been instrumental in the UK's response to acute disease threats including FMD and bluetongue. Its provision of expertise, as well as rapid testing and diagnosis of samples, have been crucial in supporting the management of outbreaks. For example, in the 2007 FMD outbreak, state-of-the-art genome sequencing promptly identified the order in which farms became infected (techniques developed from fundamental genetic research at IAH). In another example of the translation of basic research through to application, rapid diagnosis was provided through the development of a lateral flow device for the detection of FMD virus particles. Results were delivered to Defra within one hour of the samples being received at Pirbright. By comparison the fastest tests available in 2001 took four to five hours[15].

10. IAH also plays a significant role in the provision of training in exotic diseases of animals. As well as training PhD students in basic research, the institute runs practical courses in diagnostics which benefit, among others, field staff from Defra's Animal Health agency (incorporating the former State Veterinary Service).

FUNDING

Funding of public sector research institutes

11. The funding of UK research institutes is complex, partly as a result of historical factors. Various previous reviews have examined the issues.

12. Notable among previous reviews, the 'RIPSS' report[16] (2004) considered the funding and organisation of not only research council institutes but also a wide range of public sector research establishments (PSREs) and concluded that the long-term sustainability of many PSREs was under threat. The report put forward a framework of principles and preferred models, and recommended that research councils and government departments should join up their thinking about what research capacity the country needs in the public sector and how to work together to sustain it. The report argued that PSREs should increase their level of annual investment in asset maintenance, renewal and replacement towards norms accepted for the university sector (approx 4.7% pa of replacement cost).

13. The RIPSS report also recommended that it should be government policy that the fitness for purpose and sustainability of the wider science and engineering base is a matter of joint responsibility of the principal public funding stakeholders (the research councils, government departments and their agencies). It further recommended that research council Chief Executives and Permanent Secretaries of government departments, working through Chief Scientific Advisors, should be jointly accountable for developing joint scientific and investment strategies for their cross-boundary research interests. As a minimum, such an interest exists if the government department procures 15% or more of a research council institute's turnover. This policy has not yet been implemented for IAH by Defra.

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[15] Anderson report (see footnote 12), p86

[16] Research Council Institute and PSRE Sustainability Study ('RIPSS') (DTI, 2004): http://www.berr.gov.uk/dius/science/science-funding/ripss/page22675.html and http://www.berr.gov.uk/files/file14578.pdf

14. Funding for animal health research and related functions in the UK is provided mainly by BBSRC and Defra, with further support from the devolved administrations. BBSRC is the UK's principal funder of research and training across the biosciences, and animal health research represents around 10% of BBSRC's total research funding.

Funding at IAH

15. Despite the central role and importance of IAH Pirbright in the UK's emergency responsiveness to outbreaks of animal disease, the provision of funding (for both Pirbright and Compton laboratories) has been complex – from multiple sources – and prone to uncertainty over many years.

16. Work at both the Compton and Pirbright sites is supported by core funding from BBSRC (£14M in 2007-08), allocated by Council following each institute assessment exercise (but see also para 21 for forthcoming changes). Core funding is supplemented by the institute obtaining further competitive grants from BBSRC; IAH receives by far the largest component of BBSRC's overall animal health research funding. Other funding sources include industry and notably the EU through its Framework programmes.

17. In addition, IAH obtains significant amounts of funding from Defra (£7.7M in 2007-08), both for research projects and (especially at Pirbright) as contracts to provide international reference laboratory services (diagnostics and surveillance). Almost half the funding for the IAH Pirbright laboratory derives from Defra[17].

18. With the move of some VLA staff to the Pirbright site as part of the planned redevelopment (para 29), the funding (and potentially governance) of IAH will become still more complex, with an added component of Defra funding for VLA staff on a predominantly BBSRC site.

GOVERNANCE AND OTHER CHANGES IN BBSRC INSTITUTES

19. Pertinent recent developments are changes in the governance and associated restructuring of several of the BBSRC-sponsored institutes. During 2006, BBSRC established an independent review, chaired by Sir Brian Follett, of the governance of its seven (at that time) sponsored institutes[18]. The Follett review concluded that the current arrangements for institute governance should be modernised. It set out four basic governance models, but did not make specific recommendations for each institute, recognising that different solutions may be appropriate for different institutes.

20. In light of the Follett report, BBSRC Council agreed to consider each institute separately to maximise its opportunities depending on the local circumstances. The governance of IAH (Compton and Pirbright sites) is currently planned to change from 2009. BBSRC owns the IAH sites and employs the staff, but the institute is a company with charitable status, and the Director is responsible to a governing body and the BBSRC Chief Executive. Under the new governance arrangements proposed by Follett, IAH would "move in" (in Follett terminology) to come under the direct control of BBSRC. The institute Director would then report directly and solely to the BBSRC Chief Executive. The move would thus alter the role of the current governing body, but it is expected that a body of external experts would be retained

[17] For further detail of IAH funding see also Anderson report (see footnote 12), p96

[18] Follett report: *Report of an independent review of governance of BBSRC-sponsored Institutes* (BBSRC, 2006): http://www.bbsrc.ac.uk/media/releases/2006/061024_follett_review.html

to provide scientific and strategic advice. The current members of the governing body agreed to serve on the basis that this change in governance arrangements would take place during their term of office.

21. A further significant forthcoming change across the BBSRC institutes will be in the way that BBSRC provides core funding. The core strategic grants (CSG) by which most BBSRC support has been provided in recent years will be replaced in 2008 principally by Institute Strategic Programme Grants (ISPG). These will be large five-year grants, fewer in number than the current CSG projects, and will be assessed by external peer review.

22. In addition to ISPGs, each institute will receive a single Institute Integration Award (IIA), to be held by the institute Director and intended to cover the range of the institute's non-programme, institute-wide activities. One such activity could be to sustain national facilities of key strategic importance: we consider this further in Chapter 2. Institutes will also continue to be able to apply for competitive funding through BBSRC responsive mode committees, as well as seeking funding from other sources including Defra.

RISK MANAGEMENT

23. The assessment and management of risk in government departments and institutes is described within their individual departmental and institutional risk management frameworks. With respect to business risk and its oversight by internal audit, BBSRC has 'risk management assurance statements' agreed with its institutes[19] . Defra published its Departmental risk management strategy[20] in 2002. We understand that IAH has its own business risk register and below this, individual risk registers pertaining to biosecurity, the project risk (relating to redevelopment plans) and other functional risk registers.

24. The assessment, management and communication of business risk has an important role in any organisation. The Follett report[21] recognised that the BBSRC Chief Executive has a legitimate interest in the whole of the finances, business systems and managerial capabilities of the institutes, including the management of risk. Clearly, with respect to this review the management of biosecurity in a regulatory context is a key risk to manage with utmost vigilance.

25. Following the FMD outbreak in 2007 the Government ordered a review of the regulatory framework for the containment of animal pathogens in laboratories. The Callaghan report[22] (published December 2007) recommended a single regulatory framework to govern work with both human and animal pathogens and that the HSE should become the regulatory, inspection and enforcement body. The Government accepted this and the animal disease licensing arrangements are in the process of revision and transfer from Defra to HSE. The licensing of work at IAH will therefore change in future in line with the revised regulatory framework.

26. IAH has had in place risk management processes to cover its work with animal pathogens. Licences were obtained through Defra as the relevant regulatory

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[19] BBSRC Annual Report: http://www.bbsrc.ac.uk/publications/accounts/bbsrc_annual_04_05.pdf#search=%22risk%22

[20] Defra risk management strategy: http://www.defra.gov.uk/science/documents/papers/2004/SAC%20_04_%2029_Risk_Management.pdf

[21] Follett report (see footnote 17), p.1 executive summary; p.7, paras. 21-22

[22] Callaghan report: *A Review of the Regulatory Framework for Handling Animal Pathogens* http://www.defra.gov.uk/news/2007/071213b.htm

authority, including those under the Specified Animal Pathogens Order (SAPO). In the future this will change under the new framework, as above. However, the arrangements to date have been complicated by the co-location on the Pirbright site of not only the IAH laboratory but also the vaccine manufacturing facility operated by Merial Animal Health Ltd. We set out further details and recommendations in Chapter 2.

IAH REDEVELOPMENT

27. Against this background of the importance of animal health research and the key role that IAH plays, there are nonetheless major issues to be addressed. The Gull review[23] of IAH Pirbright (2002) found the condition of much of the Pirbright site infrastructure was unsatisfactory and identified a clear need for urgent investment in new laboratories and facilities. BBSRC Council and Defra took forward recommendations from the report, as well as those of the Cawthorne report[24] (for BBSRC and Defra, 2003), leading to the current major Pirbright Site Redevelopment Programme (PSRP).

28. To date, new high containment animal facilities, access roads and an insectary have been completed. The next phase involves a major new state-of-the-art laboratory complex with high level containment facilities, to replace the current buildings that date from the 1950s and 1960s. It had been agreed that the original estimate of £121M would be jointly funded by BBSRC, the DIUS Large Facilities Capital Fund and Defra. However, costs have recently increased substantially (currently more than £165M) due partly to new regulatory requirements but also to other factors including high inflation for laboratory building work. Nonetheless we concur with the Spratt and Anderson reports that the facility is of such national importance that funds must be found to carry through the redevelopment to completion (see Chapter 2, Recommendation 1).

29. As of part of the redevelopment, the intention is to move the virology work at the Defra Veterinary Laboratories Agency (VLA) from its current location at Weybridge to the Pirbright site, to join IAH virology research in the new laboratory. VLA has facilities and responsibility for research, surveillance and emergency responsiveness on viruses other than those currently covered by IAH Pirbright (see **Box 1**). Bringing the two groups together will provide the UK with a new, expanded and strengthened capability in animal virology. Once the new development is operational (scheduled for 2011/12) it will be one of the foremost facilities of its kind in Europe and probably the world. The plans for this redevelopment are being reviewed in relation to biosecurity requirements, in accordance with Recommendation 10 of the Spratt report (see also **Annex 2**).

30. The IAH Compton site also requires major work to bring it to modern standards; some of the buildings are no longer usable and most of the rest are barely fit for purpose. An estates strategy is being developed to modernise or replace the Compton research facilities and meet regulatory needs. The replacement of facilities (on a site yet to be decided) may require investment of up to £220M over the next 6-7 years. BBSRC is planning to meet 50% of the costs and is seeking the other 50% from DIUS via the Large Facilities Capital Fund. Because of the state of the Compton facilities, some capital expenditure may be needed in the short-medium

[23] Gull report: *Review of the Institute for Animal Health - Pirbright Laboratory*: http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0207_iah_pirbright.html

[24] Cawthorne report: *Review of the UK's national facilities for infectious animal disease research, surveillance and diagnosis: A report for the Defra and the BBSRC* (September 2003)

term to enable the research programmes at Compton to continue whilst the longer term investment strategy is resolved.

31. Given the extremely high cost of replacing the existing IAH facilities, it is timely for this review to reconsider future options for IAH as a whole and in the wider context of the UK's overall needs for research facilities in animal health.

CHAPTER 2: A FRAMEWORK FOR FUTURE FUNDING, GOVERNANCE AND RISK MANAGEMENT OF IAH

INTRODUCTION

32. Against the background set out in Chapter 1, we now turn to recommendations for the future of IAH. We have formulated our recommendations predicated on the basis that the planned redevelopment of the IAH Pirbright site, including the transfer of some staff from VLA at Weybridge, (see para 27) will go ahead, given the national importance of the facility.

33. We structure this section around three broad considerations:

- The future of IAH Pirbright: the need for a new National Centre
- The future of IAH Compton
- The future national context for IAH: coordination of national science strategy, funding and risk management for animal health.

For clarity we attempt to deal with issues of funding, governance and risk management in distinct sections (and initially for Pirbright), but it is important to recognise that many aspects are interdependent, and must therefore be considered as related parts of an integrated package of measures.

34. At the end of this Chapter we propose a way forward that includes an ambitious vision for a new agency that would be responsible for both developing and delivering a coherent national strategy for research and associated functions (surveillance, diagnostics, etc) in animal health and welfare. The new agency would provide a framework within which the work undertaken by IAH and other relevant research establishments would be supported in a more stable and sustainable way than at present. Nevertheless, **we emphasise that it is essential** that the longer-term vision does not distract from the immediate and urgent issues of IAH funding, governance and risk management that need to be addressed.

THE FUTURE OF IAH PIRBRIGHT: THE CASE FOR A NATIONAL CENTRE

35. With the ever-present risk of new diseases emerging or entering the UK and having the potential to cause emergencies, in our view there remains a clear need for a modern, integrated animal health research institute that can sustain coherent programmes of basic, strategic and applied research as well as providing essential diagnostic and surveillance services. If IAH did not exist, the UK would need to set up a national facility (as many other countries have done around the world) to perform its functions in providing the knowledge and expertise, as well as facilities needed for the UK to manage disease risks appropriately.

36. Based on the high strategic relevance of the work at IAH, coupled with high scientific quality, several previous reports (**Box 2**) concluded that there is a clear strategic need for the institute. We fully endorse these findings.

37. There is a strong case for animal health research being based in an institute setting rather than in one or more universities. Mission-driven research institutes such as IAH are able to provide specialised (sometimes unique) facilities and expertise, and to sustain integrated research programmes over longer time scales than are typically seen in the university sector. There is particular merit in co-location of basic work with more applied research, promoting synergistic interactions across research teams. Findings from fundamental work can then be readily applied, for example in

the development of diagnostic tools and vaccines. Equally, basic and strategic research benefits from access to resources arising from more applied work, such as unique collections (within the world reference labs at IAH Pirbright) of viruses from around the world.

Box 2: Previous reports that supported strongly the need for an institute such as IAH

- In 2001-02, Professor Keith Gull chaired a review of IAH Pirbright[25]
- In 2003, Dr Richard Cawthorne (then Deputy Chief Veterinary Officer) chaired a review for BBSRC and Defra of UK facilities for handling infectious animal disease[26]
- In 2006, a Visiting Group of external experts chaired by Professor Chris Gilligan reviewed the IAH science programmes as part of the BBSRC Institute Assessment Exercise[27]
- In 2006-07, Professor John Preston chaired a review of options for the future relationship between IAH and VLA[28]
- In 2007-08, Dr Iain Anderson led a review of lessons learned from the 2007 FMD outbreak[29]

Further background information on these reports is provided at **Annex 2**.

38. The remit of IAH covers both endemic and exotic diseases (endemic primarily at Compton, exotic at Pirbright) and there are clear benefits and synergies in undertaking work on both types of disease within a single organisation, since both endemic and exotic viral diseases (for example) may share common biological mechanisms and host animal responses.

The new laboratory at IAH-Pirbright: a National Centre

39. We strongly welcome the agreement between BBSRC and Defra on major joint investment in the redevelopment of the Pirbright laboratory (see 'IAH Redevelopment' in Chapter 1): the Pirbright Site Redevelopment Programme (PSRP) is a commendable long-term commitment of capital funding. We concur with both the Spratt report and Iain Anderson in his recently published report[29] that it is essential for the national capability to respond to animal disease threats that the redevelopment is completed as soon as practicable, and we urge both parties to resolve rapidly the problem of resourcing the redevelopment and to see it through to completion with due speed.

Recommendation 1: We recommend that the Pirbright Site Redevelopment Programme must be carried through to completion without delay.

40. The new laboratory building that is being established under the redevelopment programme provides an unprecedented opportunity to create a nationally important facility in animal virology, which should be established and positioned as a new world-class national centre of excellence.

41. The VLA staff moving from Weybridge to Pirbright will bring expertise and reference laboratories in viral diseases complementary to those currently worked on at Pirbright (see **Box 1** on page 8). The new grouping (expected to be around 70 staff from VLA added to around 150 from IAH) will create a concentration of international

[25] Gull report: see footnote 23
[26] Cawthorne report: see footnote 24
[27] Institute Assessment Exercise: see footnote 7
[28] Preston report: see footnote 9
[29] Anderson report: see footnote 12

quality work on exotic diseases of animals. It will include an expanded set of world and EU reference laboratories, underpinned by excellent basic and strategic research coupled with more applied diagnostics and surveillance work. While the main focus will be on viral diseases, the facility would provide scope for work on other types of pathogen that have the potential to cause emergencies. The new integrated facility will be on the front line of response in any UK outbreak of a wide range of exotic animal diseases, with capability to expand effort for diagnostics as required. In addition it will constitute an enlarged and cohesive centre of expertise and advice for Government.

42. The Anderson report[30] acknowledged the importance of the redeveloped Pirbright laboratory, commenting that the research conducted at IAH is world class and needs to be positioned at the centre of a national strategy for animal health. Dr Anderson made a personal recommendation (in the foreword of the report) that IAH should be repositioned as a 'National Institute of Infectious Diseases'. We agree with its national positioning but suggest the working title should more explicitly reflect its focus on animal infectious diseases.

43. For effective operation of the new National Centre, it will be essential that BBSRC (Swindon Office and IAH) and Defra (all relevant arms of the Department and VLA) agree a joint science and funding strategy in animal health and welfare as a focus for the Centre's various functions. The joint strategy should be in place before the commissioning of the new facility in 2011. We will return later to the broader issue of coordination across different funders.

Recommendation 2: We recommend that the redeveloped Pirbright laboratory should be positioned as a new 'National Centre for Animal Viral Disease' and should be founded upon a joint BBSRC-Defra science strategy for animal health and welfare.

The status of the redeveloped laboratory as a National Centre would emphasise its importance, its nature as a shared venture between BBSRC and Defra, and the step change it represents in bringing together the internationally recognised expertise in virology from IAH and VLA in new state-of-the-art facilities.

Funding of the new National Centre

44. It is critical that the new Centre is funded on a sustainable basis. One of the main difficulties faced by IAH has been the duality of its principal funding income via BBSRC and Defra. Not only is the institute constantly juggling the different research aims of the two organisations but they also, in large part, work to different funding time scales, where BBSRC typically funds in 3-5 year grants but Defra typically over 1-3 years. This makes financial planning difficult, particularly in relation to maintaining the continuity of the science and facilities.

45. Of particular note is Defra's surveillance contract to IAH-Pirbright, worth around £1.7M per annum. The expertise and facilities at Pirbright are crucial if the department is to fulfil its statutory obligations regarding due vigilance for exotic agents such as foot and mouth disease, yet the surveillance contract is renewed only on an annual basis. It is difficult to see why a longer term planning horizon for this work is not possible.

[30] Anderson report: see footnote 12

46. A substantial proportion of funding for an institute (running costs of the facilities and research, as well as capital investment) must be sufficiently long-term to allow proper financial planning and provide stability. This would include allowing for timely renewal of infrastructure and necessary provision for biosecurity, which must be a paramount consideration. As numerous previous reports have highlighted, IAH has historically not been properly funded for long-term sustainability of the infrastructure, leading to increasingly dilapidated facilities at both Pirbright and Compton. We note that inadequate provision for maintenance and renewal has been widespread also in the university sector, but nonetheless both BBSRC and Defra, as principal funders, must carry some of the responsibility for past neglect of IAH. We do acknowledge that BBSRC has increased funding in recent years but further investment is needed. Future funding (however it is to be organised – see below) must include adequate provision for running costs, and for maintenance and renewal of infrastructure, as well as research, so that safety and biosecurity needs are satisfied.

47. It cannot be acceptable for more than £165M of public money to be allocated to the redevelopment of IAH Pirbright without a binding agreement by BBSRC and Defra to provide core funding to ensure its sustainability.

Recommendation 3: BBSRC and Defra must jointly provide long-term core funding to ensure the sustainability of the new National Centre at Pirbright. We do not believe it appropriate to fund a national facility with statutory responsibilities primarily through the award of research grants and contracts.

One stream of core funding

48. For clarity of operation there should ideally be one single stream of core funding, rather than the mixed model of principally BBSRC and Defra sources that has been problematic to date.

Recommendation 4: We recommend that core funding for the new National Centre at Pirbright should be administered as a single stream with a planning horizon of at least five years. Core funding must include adequate provision for core staff, running costs, maintenance and renewal of infrastructure, so that safety and biosecurity needs are satisfied.

Longer term funding commitments

49. If a single stream of funding proved to be not realistically achievable, then stability of funding and sustainability must be achieved via an alternative route. We can envisage a model where there would continue to be two main streams of funding but with both on similar 5-year terms and administered seamlessly as far as possible:

- In the case of BBSRC, the funding for research and recurrent costs would be provided at full economic cost through 5-year Institute Strategic Programme Grants and an Institute Integration Award (see para 21-22).
- In the case of Defra, the fixed costs of fully serviced accommodation, including cost of capital would derive principally from agreement around a 20-year accommodation lease with respect to the new Pirbright laboratories.

50. Regarding the BBSRC funding, it will be important that the running of the national facility is not put at risk by one or more ISPG not being renewed. Animal disease work in containment facilities is intrinsically expensive. Therefore core funding through the Institute Integration Award (IIA – see para 22) must be on a sufficiently large scale to ensure sustainability. In recognition of the role of Pirbright as a

national facility, Council should not be constrained by preconceptions about the proportion of total funding for IAH that should be allocated through the IIA, and should give consideration to ring fencing if necessary.

51. We heard from Defra about the Department's budgetary position which makes it difficult to commit funds for periods longer than the current 3-year spending review cycle. Whilst we appreciate this position, we note that the research councils and other government departments also have to operate within the spending review framework and yet they manage to commit research funding over longer periods.

Governance

52. We are aware that, following the Follett review[31] in 2006, the governance of BBSRC-sponsored institutes is being modernised (see para 19). There is little value in rehearsing again here the features of good governance set out in the 2006 report; Council is well aware of these. We do, however, make some further recommendations relating to the overarching governance of IAH and specifically the future management of the new National Centre at Pirbright.

Resolve IAH governance now

53. Governance of the IAH has long been recognised as being unsatisfactory and specific comments to this effect were made to BBSRC, Defra and the Governing Body in the Gull report[32] (2002).

54. In October 2006 the Governing Body responded to the Follett report with unanimous agreement that BBSRC direct control was the preferred option for governance of the institute. The then Chair of the Governing Body made clear the willingness of the Governing Body to surrender its autonomy to BBSRC direct control. Further, the Governing Body suggested that BBSRC should establish an External Advisory Committee with skills including financial, estates, livestock and veterinary expertise as well as scientific research expertise. In early 2007 new member expertise was added and existing members agreed to extend their tenure to facilitate the transfer process.

55. BBSRC Council discussed governance of IAH with the IAH Director and Governing Body Chair at the February 2007 meeting. Council agreed that IAH should come under direct BBSRC control but, due to phasing of the governance changes across its sponsored institutes, the IAH changes would not be effective until April 2009. The Governing Body Chair pressed for priority and speed in development of a route for this transfer.

56. In our view April 2009 is too long a time scale and the remaining ambiguity surrounding IAH governance must be resolved immediately by bringing the institute under direct BBSRC control. This is not a reflection on the current Governing Body, which has performed well under extremely difficult circumstances. Rather it is in accord with their previously expressed opinion and reflects the requirement to make governance, reporting and lines of responsibility at this institute as simple as possible, as quickly as possible.

57. We have been advised that a mechanism to bring IAH under direct BBSRC control quickly is that of Corporate Trusteeship. It is incumbent on the Governing Body to

[31] Follett report: see footnote 18
[32] Gull report: see footnote 23

invite BBSRC to become a Corporate Trustee, having satisfied itself that its charitable aims will be protected. It could be a temporary measure to resolve and simplify governance, giving Council much greater control, until the new Centre is commissioned and longer-term governance/management arrangements can be put in place.

Recommendation 5: In line with the previous wishes of the IAH Governing Body, BBSRC should take over direct responsibility for governance of IAH. As an interim measure to resolve the current ambiguity of governance, and in recognition of the scale of change facing IAH, we recommend that the IAH Governing Body should invite BBSRC to become a Corporate Trustee for IAH, in order to accelerate the planned move to bring governance under more direct control.

A single line of management for the new National Centre

58. Whilst the transfer of around 70 VLA staff to the new national centre at Pirbright is a great opportunity for the science it will inevitably cause local governance challenges. It is essential for effective operation and risk management that all staff in the institute report through a single line of management to the Director. It is not acceptable for a large cohort of ex-VLA staff to report through a different line, perhaps even off-site. All staff should understand and share the same institute mission, strategy etc in a single scientific 'culture'. In the next section we turn to the question of overall ownership of the new Centre, but under the current arrangement with BBSRC owning the site and employing the staff, a simple solution to address the need for a single line of management would be to second the relocated VLA staff to BBSRC.

Recommendation 6: We recommend that a clear single line of management and reporting is established for all staff within the new Centre at Pirbright, for example through seconding relocated VLA staff to BBSRC or *vice versa*. This will require explicit agreement between BBSRC, IAH and VLA management in advance of the staff moves.

A matter of ownership

59. If the new Pirbright facility is to be positioned as a national centre of excellence it is essential first and foremost that the main funders regard the venture as a true partnership with clear joint responsibility for its sustainability, in accordance with the RIPSS principles (para 12-13). There remains, however, the issue of overall ownership, which includes the question of who employs the Director. Should the facility remain essentially as a BBSRC institute into which Defra places funding for the research and services it requires, or should it transfer to become a mainly Defra-owned institute into which BBSRC is a principal funding partner supporting the basic science?

60. Iain Anderson in the foreword to his report[33] stated (in the context of funding and governance):

"*...the old arrangements at Pirbright must now be discarded. My hope is that a new consensus can be formed to move forward swiftly on a firm, sustainable basis, and I believe that Defra is best placed to take the lead in making this happen.*"

Although Anderson did not stipulate that Pirbright should move to be under Defra management he expressed the personal opinion that Defra should at least lead in

[33]Anderson report: see footnote 12

driving forward and championing the new arrangements. As the government department with overall policy responsibility for animal health, we agree that Defra should reflect its responsibilities by taking more of a leading role.

61. The Anderson report was also critical of the way BBSRC has managed IAH Pirbright, and implied that this necessitated a change of management in the future. We agree that IAH has not been managed in a way that has ensured sustainability. This is in part the result of failures by BBSRC, previous IAH management and previous Governing Bodies, but in practice has been a result of difficulties arising from the arm's length relationship BBSRC has had with its institutes, the stresses from reductions in Defra funding, the inability of BBSRC and Defra to agree the implementation of RIPSS, and the invidious position of the Governing Body, which neither employs the staff nor owns the institute.

62. We are aware that BBSRC's approach to its institutes has changed, particularly with the modernisation of governance, formal business planning and the establishment of an Estates and Equipment Board. However, our confidence that BBSRC was the obvious partner to manage the new Centre would have been enhanced if the governance and sustainability issues had been addressed and resolved long ago.

63. It is also important when considering the future management to take into account the distinct missions of both funding partners and their support for different aspects of animal health. BBSRC's mission is to support research; it has no remit to ensure that the public and animals are protected from harm arising from animal diseases. This is the responsibility of Defra and the VLA, who do this through their own laboratories and jointly with BBSRC through IAH. Over the last couple of decades BBSRC has maintained an increasing level of funding for research in IAH, while budget cuts (and the lack of extra resource to Defra to enable it to finance Full Economic Costing) have resulted in a steady decline in Defra funding. The present outlook is for continued BBSRC funding, at about the same level as the last few years, but further cuts from Defra at both the VLA and IAH.

64. We conclude that there is no clear and obvious answer as to whether BBSRC or Defra should manage IAH Pirbright in the future. In large part it depends on the balance of its dual function; is it primarily a centre for basic research or primarily a centre for the management of animal diseases, including diagnostics and surveillance roles? It may be that the simple solution is to continue with BBSRC ownership and management, given that the Council owns the land and will employ around two thirds of the staff. If research currently at IAH Compton were to be relocated to Pirbright (see below – para 78), that proportion would be higher and the argument for continued BBSRC management could be stronger. If Defra were to take over management, a further issue to be resolved would be how to ensure continued eligibility for BBSRC funding of the more basic research[34]. But whatever the outcome, BBSRC and Defra must decide between themselves, and decide quickly. We concur with Anderson that if the issue cannot be resolved at departmental level it should be referred further within Government.

Recommendation 7: In view of the importance of the new Centre at Pirbright as a national facility, and the potential economic and social impact of serious disease outbreaks, BBSRC and Defra must agree long-term arrangements for its ownership and management. If there is no prospect of agreement by April

[34] Government laboratories (including VLA) are in general not eligible for funding from the Research Councils – see http://www.rcuk.ac.uk/research/eligibility.htm

2009 the matter should be resolved by referral through DIUS and Defra to the Cabinet Office.

Risk management

65. IAH already has in place a risk management system, and detailed procedures are being reviewed by other groups in line with recommendations of the Spratt review (see also **Annex 2**). Proper funding and governance arrangements that ensure sustainability and renewal of infrastructure, including the considerations set out above, will lead naturally to better risk management. Nevertheless, we consider the following points to be the most salient.

Culture and accountability

66. Considering the nature of the work at IAH there must be a strongly embedded culture of risk management, safety and biosecurity throughout the institute. This must start with an explicit leadership commitment from senior management. The risk management culture should reflect a unity of purpose and of action throughout the organisation. In addition the organisation will likely need specific culture change to work with the expected new HSE-based regulations.

67. The Spratt report commented[35]:

"*There was evidence of a lack of urgency and ownership of risk at all levels, resulting in the failure to take appropriate decisions on the funding for essential improvements in safety critical infrastructure.*"

We believe a step improvement in the institutional management of risk is warranted, both in the interim and in the future new Centre. We would expect the new Centre to develop quickly a refreshed, compelling vision, and to enact a substantive shift towards the proactive and preventative management of (residual) risk. We are encouraged by recent reappraisals of IAH's corporate risk register and by its inclusion as a standing item at IAH Executive meetings.

68. We endorse IAH's intent to appoint a dedicated risk manager, this signalling one step towards an improved commitment to embedding risk management more firmly within the organisation. The bringing together of VLA and BBSRC staff on one site provides an excellent opportunity to establish a risk management culture encapsulating the best elements of the existing cultures of both groups of scientists.

Recommendation 8: We recommend that appropriate IAH and VLA staff develop jointly agreed risk management procedures. In order that procedures are in place well in advance of the movement of VLA staff to Pirbright, this process should begin immediately.

69. Risk management at the institute should be implemented in line with current codes of good practice in risk management[36],[37] and the code of good corporate governance (revised Turnbull code[38]). The institute should maintain, actively manage and review

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[35] Spratt report (see footnote 4), p57

[36] HM Treasury (2004). *The orange book. Management of risk – principles and concepts*, HM Treasury London, 50pp

[37] Office of Government Commerce (2007) *Management of risk: guidance for practitioners*, TSO, 170pp

[38] Financial Reporting Council (2005) *Internal control: revised guidance for Directors on the Combined code*, 15pp

at least quarterly a regularly updated business risk register[39], with clear accountabilities for risk management. There must be Director-level accountability for risk management and consideration given to publishing the key business risks in the Institute's annual report.

70. Specifically, there must be unambiguous responsibility and accountability for safety and biosecurity, the appropriate training of staff and contractors, record keeping, risk assessment and agreed procedures, including those for visitors. An organisational culture of vigilance will ensure that staff see preventative risk management, safety and biosecurity as integral to their everyday work and to the success of the Institute. Safety and biosecurity should be addressed in individuals' annual objectives and appraisal processes.

One 'controlling mind'

71. IAH has a dedicated biosafety officer who reports to the institute Director. The BSO must be part of the institute's executive and act as the lead individual on all aspects of biosafety and biosecurity. We also advocate a clear route to refer above the Director if necessary.

72. The presence of the Merial vaccine production facility on the Pirbright site creates some special risk management considerations, as have been highlighted in other reports following the 2007 foot and mouth outbreak. We fully endorse the findings of the Callaghan review regarding reform of the regulatory framework for animal pathogens (para 25), but also, in particular, the need for a clearly identified 'controlling mind' for safety and biosecurity. Ideally we would advocate a single overarching Biological Safety Officer (BSO) with responsibility and an appropriate degree of authority for biological safety and biosecurity across the whole Pirbright site, including Merial (and any other organisations operating on the site). But we accept that this may not be realistically achievable, given that the organisations are of very different types (research laboratories vs. vaccine manufacturing plant).

73. We are aware of, and strongly welcome, the plans for Merial to develop its own service and waste disposal infrastructure, thus becoming more independent of IAH. We would advocate that it should become entirely independent. We also welcome the agreement to improve sharing of information between Merial and IAH. Nevertheless, for the purposes of biosecurity the company and the institute must be considered as a single entity unless and until Merial becomes entirely self-contained. Until that time, in accordance with the recommendations of the Callaghan report, a single BSO should have appropriate jurisdiction over the whole site.

Regulation and licensing

74. Clearly, biosecurity procedures at the institute must conform to regulatory requirements and current best practice. Biosecurity procedures should be proportionate to the risks they seek to manage, and not unduly complicated. Buildings, services and infrastructure developments must, by design, support the risk management requirements of the institute. Buildings, services and infrastructure needs must be reviewed and actively accounted for within investment plans for the institute. We are pleased that the Jeggo report (see footnote 6) will inform BBSRC, IAH and Defra on biosafety and biosecurity aspects of the design requirements for

[39] General guidance on managing risk in Government is available on the Government's risk portal at www.hm-treasury.gov.uk/documents/public_spending_reporting/governance_risk/psr_governance_risk_riskguidance.cfm

the redevelopment of the Pirbright site. We are aware of the emerging recommendations of the Jeggo review and we endorse, in particular, the view that:

- Best practice in biosafety and biosecurity should be a primary consideration in the design of the site redevelopment. Any changes to the design intended to control increases in capital costs should be focused where the impact on biosafety and biosecurity would be minimal.

- The process for tendering and issuing contracts for the construction work should not be allowed to compromise the biosafety and biosecurity aspects of the design: proper control of the design must be retained.

- Management of biosafety and biosecurity must not be over-complicated, and should be as simple as possible while consistent with best practice. An external advisory group for biosafety and biosecurity could be valuable to support the ongoing management of risk.

It is clear that the redevelopment plans are still evolving and some aspects will need to be reconsidered once the new regulatory framework has been put in place. We urge Council to continue the process of evaluating risk management at every step.

75. We share the concerns (raised in other reports following the 2007 FMD outbreak) that separate SAPO licences were issued to Merial and IAH, and that even though they shared the same site there was no joint risk management. IAH was not made aware of the details of the Merial licence (because of commercial confidentiality) despite it allowing the release of potentially large quantities of live virus into drains on the site. Another concern is that it appears that the granting of a SAPO licence to IAH (renewed in 2007 for a further 5 years) was deemed to be endorsement that the facilities were appropriate for the level of risk. We assume that this is one reason why redevelopment has not progressed further, six years after it was first recognised that much of the Pirbright site was unsuitable for the work being done (Gull review, 2002).

76. We fully endorse the progress to achieve better communication and more open sharing of information between IAH and Merial. Under the future revised regulatory framework to be implemented following the Callaghan report, we would hope that greater transparency can be maintained, perhaps to the extent of a joint site licence to cover all animal pathogen work.

77. Council may wish to consider the risks, costs and benefits accruing from the current arrangement with Merial leasing part of the Pirbright site (with a lease until 2015).

THE FUTURE OF IAH COMPTON

78. IAH Compton requires modernisation (see para 30) and Council will shortly need to decide whether and how to do that. In our view, decisions on the best way forward for Compton must be made on the basis of future need for research in endemic diseases. That question of science need is outside the scope of the current review, but we make the following observations and recommendations to Council.

79. We referred earlier (para 38) to the benefits of working on both endemic and exotic diseases within a single institute. It is important to note that the definition of what constitutes 'endemic' or 'exotic' is liable to change over time, as new diseases emerge, spread or are introduced (e.g., bluetongue). We will use the term 'endemic' here as a convenient shorthand, but acknowledge its shortcomings. It is also

important to understand that there is at present no simple divide of IAH staff. Much exotic disease research includes Compton-based staff: for instance, the FMD and bluetongue immunology groups are located at Compton.

80. Both types of disease may share common biological mechanisms, and research on one type will often inform work on the other. It will often be easier to work on endemic diseases (e.g., with fewer requirements for high containment) and then apply that knowledge to exotic diseases.

81. Defra funding has declined particularly for endemic disease research and this trend is expected to continue, possibly to the extent of Defra withdrawing support entirely, other than for food-borne zoonoses and bovine tuberculosis. The question then arises as to what extent research on other endemic diseases should continue and how it should be funded.

82. In its recent consultation on Responsibility and Cost Sharing[40], Defra sets out proposals that more responsibility for funding of animal health and welfare should transfer to the 'user' sector, i.e. the farming and associated industries. While we entirely support the concept of engaging with users (for example, in helping to set research priorities), BBSRC Council needs to consider the possible impact of the changed mode of funding for longer-term basic research.

83. If the industry does not step in to pick up funding for endemic disease research as Defra withdraws its support, then it could be argued that its priority for BBSRC should also reduce. BBSRC could be seen as having a duty as a main public funder of research on endemic diseases to maintain a core national capability but we would question whether BBSRC could or should substitute for the entirety of Defra's historical funding in this area.

84. Given the necessity to balance competing priorities for finite funds, a crucial immediate question for Council is to what level and in what areas should BBSRC continue to fund research on endemic diseases of livestock, beyond that supported through responsive mode?

85. The outcome of that decision is crucial to the next steps for Compton. If BBSRC Council judges that research on endemic disease will be less of a priority then it follows that the redevelopment of the facilities currently at IAH-Compton could be more modest.

86. We are aware that IAH management has expressed preference to co-locate the Compton research on the Pirbright site, entailing further new building in addition to that already planned. Providing the 'need' and 'scale' criteria (para 81) are met, then we can see advantages in such a move, in bringing together the full range of IAH expertise on a single site, with benefits of improved synergies across complementary lines of research, as well as efficiencies in the provision of shared facilities.

87. Nonetheless, Council should consider the full range of available options, which could range from large-scale redevelopment at Pirbright or on another site, to relocation of parts of the Compton portfolio to other sites (which might include other institutes, vet schools or leading university departments), to retention of a reduced scale of activities within IAH on a site to be agreed. The over-riding consideration should be to deliver the science that is required in the most appropriate and cost-effective manner.

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[40] Defra consultation: http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/index.htm

Recommendation 9: We recommend that BBSRC Council's decisions regarding the future of IAH Compton and investment in endemic disease research should be based on a thorough assessment of scientific and strategic need.

Recommendation 10: We recommend that, provided Council is persuaded by the scientific and strategic case, work should be relocated from Compton to join the new Centre at Pirbright.

Implications of IAH on a single site at Pirbright

88. If all or part of the research currently at Compton were to be relocated to the Pirbright site then we would envisage this being most likely accommodated in an additional new laboratory adjacent to the current new build. Given the broader scientific remit under those circumstances, it would be appropriate to reconsider the name of the expanded Centre and to broaden the working title we proposed above to (for example) 'National Centre for Animal Health'.

89. While the considerations for funding, governance and risk management set out above would still apply, additional challenges or requirements would come into play for IAH consolidated onto one site.

Funding of IAH on a single site

90. With regard to funding, the challenge is to ensure that the institute as a whole is sustainable. We discussed above the funding of the new National Centre already under development at Pirbright and many of the same considerations would apply to an expanded Pirbright that included work relocated from Compton. However, with declining funding from Defra for endemic disease research currently at Compton, we would anticipate that research transferred from Compton would be funded largely by BBSRC through ISPGs and an IIA, supplemented by further grant funding won competitively from BBSRC and other sources.

Governance of IAH on a single site

91. It would be important that all work within the institute was under a single cohesive management structure, and that the full range of activities should be integrated as far as possible, to avoid the risk of some aspects becoming isolated and in particular avoiding any artificial polarisation into 'exotic' and 'endemic' silos. We anticipate that at least some of the BBSRC core funding through ISPGs should operate across different research areas, with the aim of promoting multidisciplinary approaches and maximising the opportunities for cross-fertilisation. Similarly, supplementary funding through responsive mode grants should be cross-IAH wherever appropriate. IAH already operates in this fashion in numerous respects, and we would wish this to continue.

92. One model for management on a single site could be to appoint Deputy Directors, for example with one for research and a second covering surveillance and associated functions (including reference laboratory services). The Deputies would free the Director from some of the burden of day-to-day management, allowing more time for strategic issues. This is a model used at some other BBSRC institutes, although we recognise there would be financial implications. It would also be important to avoid imposing artificial barriers and to ensure effective integration of research with surveillance and other activities.

Risk management at IAH on a single site

93. There may be risk management issues associated with working with exotic diseases alongside endemics on a single site, including practical complications with different levels of containment required for different types of work. In addition, valuable resources such as specially developed lines of livestock could in principle be put at risk in the event of accidental release of exotic pathogens if held on the same site. Such considerations have sometimes been raised in the past as a reason not to consolidate the two types of research. But we note that other countries successfully operate research institutes in this way and in our view the scientific benefits of consolidation would outweigh the risks – provided those risks are properly assessed and managed.

THE FUTURE NATIONAL CONTEXT FOR IAH

Coordination of national strategy, funding and risk management for animal health

94. We could not conclude our report on the future governance, funding and risk management at IAH without considering briefly the wider UK context in which the institute or new National Centre should sit and operate.

The need for a national research strategy

95. The UK currently lacks a coherent overarching national strategy for animal health research. Considering the social and economic importance of animal disease (see Chapter 1), we find it surprising that there is no common agreement between policy makers and funders on the key facilities, science and skills that are needed in this crucial area.

96. In 2004, the Government produced the '*Animal Health and Welfare Strategy for Great Britain*'[41] which sets a broad policy framework for England, Wales and Scotland. But it barely mentions the importance of research in informing policy and decision making, and provides no views on underpinning science requirements and priorities.

97. There are a number of funders of animal health research in the UK including Defra, DfID, the devolved administrations, research councils (principally BBSRC) and certain larger charities, e.g. Animal Health Trust, Wellcome Trust. It seems self-evident that there would be overall benefit for these funders to be party to a national strategy for research that at the very least sets out common science needs, maximises synergy and minimises duplication. Such a strategy would also benefit the research community which, whilst maintaining its flexibility to respond to emerging issues, would have a clear steer on the funders' key priorities, something that is currently lacking. We envisage that the new National Centre at Pirbright should be central in helping to deliver the overarching strategy.

98. Ideally Council should be making its decisions regarding the future funding and governance of IAH (especially the future of IAH-Compton) against the background of an agreed national strategy for research. Unfortunately Council will need to take key decisions in its absence. Nonetheless, if future disease risks are to be managed properly, with policy-making underpinned by high quality scientific evidence, it remains an important goal to achieve such a national strategy as a central plank on which to build more joined-up UK responsiveness to animal disease threats.

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[41] *Animal Health and Welfare Strategy for Great Britain*: http://www.defra.gov.uk/animalh/ahws/strategy/ahws.pdf

Recommendation 11: We recommend that Defra, working closely with BBSRC, should lead in drawing together the main funders and stakeholders of animal health and welfare research to develop a joint national strategy for science and funding to underpin the management of risks from animal diseases, both endemic and exotic.

Overarching coordination: a new funding body for animal health and welfare

99. In order to improve coordination across the full spectrum of relevant funders of research and associated activities in animal health and welfare (AHW), we propose that a new funders' body should be established. This could be set up relatively quickly, requiring only that the relevant funders agree to participate actively and that a secretariat is made available.

100. We do not envisage that the new body would, in itself, hold a central research budget, but by bringing together the relevant funders and stakeholders, particularly Defra, BBSRC and the devolved administrations it will:

- Provide national strategic oversight of the AHW research area, ensuring that the funding activities of its members are coordinated to maximise synergy, value for money and impact
- Develop, and then ensure delivery of, the national AHW strategy (above)
- Horizon scan for emerging threats and needs or gaps in terms of research, facilities and skills.

101. For the funders' body to be effective, its members must be very senior in their organisations and be able to take the necessary funding and strategic decisions. Consequently it should be chaired by the Defra Chief Veterinary Officer (CVO) or Deputy CVO and include the BBSRC Chief Executive, with equivalent status individuals from the other organisations.

Recommendation 12: We recommend that Defra, working closely with BBSRC, should lead in setting up a funding body for animal health and welfare research, surveillance and associated functions, as a route to developing a joint national strategy and improving coordination across the relevant funders.

102. Iain Anderson proposed[42] establishing a new 'Independent Advisory Committee on Animal and Emerging Infectious Diseases' to provide independent high-level expert advice to government. We can see merit in such a committee, and its advice could helpfully inform the new funders' body, in particular for the formulation of the national AHW strategy, scientific priorities and identifying research needs.

A new agency for Animal Health and Welfare

103. The measures described above to develop a more joined-up and coordinated approach to science underpinning AHW across the UK would undoubtedly be an improvement on the current situation where major funders are working broadly in similar directions but largely in isolation. The funders' body would, however, by its nature as a non-statutory body, be limited in its capacity for implementing and taking forward a joint strategy, since responsibility for funding would remain with the individual funding bodies, each with their own remit, changeable budgets, strategic goals and specific scientific priorities. This is precisely the lack of overall clarity and divided 'ownership' that has bedevilled the field of AHW.

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[42] Anderson report (see footnote 12): personal recommendation in the Foreword

104. An admittedly radical and longer-term solution would be to create a new 'national agency' for AHW. We are under no illusion that such a bold move would face considerable policy and legislative hurdles, and it is certainly not a 'quick fix'. Nevertheless there are clear precedents – for example the Food Standards Agency – where important areas of policy been removed from one or more government departments and made the responsibility of a new independent body. And along with the shift in policy responsibility goes the necessary statutory enforcement lead.

105. Without getting mired here in the constitutional details and whether or not the FSA is wholly the right model, we see the underlying principles for a new animal health and welfare agency as follows:

- We envisage a transfer from Defra of responsibility for AHW including research and also emergency response, diagnostics, surveillance and reference laboratories. The agency would take responsibility for VLA as well as the Animal Health agency (incorporating the former State Veterinary Service). It would become the British competent authority in Europe, and coordinate with sister agencies across Europe through ERA-NET[43] and other mechanisms as appropriate.

- The Agency would manage the laboratories at Pirbright, ensuring adequate facilities for research – basic, strategic and applied. BBSRC would fund research in that environment on the basis of its excellence and strategic relevance.

- The agency would operate on the principles of openness and transparency, and regarding as paramount the protection of human and animal health and the environment from infectious diseases of animals.

- While Defra's current responsibilities cover England and Wales, the new agency should operate with counterparts across Great Britain. Animal disease does not recognise borders. The new agency would set a science strategy for AHW, taking into account the advice and priorities of BBSRC, industry and the devolved administrations.

- It would be important for the new agency to have its own central budget set in government spending reviews either as a ring-fenced element of a departmental budget or wholly independent. Part of its funding could derive from the 'cost sharing' principles being consulted upon by Defra (para 82).

106. We believe there would be clear advantages in bringing responsibility for AHW under one independent and properly constituted body that would embrace functions currently undertaken by several disparate bodies. Not only would a new agency provide better integration and coordination at a national level, but it would also provide a ring-fenced budget arguably less sensitive to the ebb and flow of departmental priorities and financial constraints.

107. A new independent agency would, importantly, place the management, response and preparedness for serious animal disease outbreaks at arm's length from government ministers, reducing the potential for accusations of political interference. Similar arguments supported the case for an independent Food Standards Agency in the late 1990s.

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[43] ERA-NET (EU scheme for coordination of national research programmes): see http://cordis.europa.eu/coordination/era-net.htm

Recommendation 13: We recommend that a new Animal Health and Welfare agency should be established. Animal health and welfare is simply too important to remain as at present; it must be given clear leadership and be made less vulnerable to budgetary fluctuations and 'border disputes' between organisations.

ANNEX 1

PANEL MEMBERSHIP

Name	Affiliation	Position / notes
Professor Sir John Beringer CBE (chair)	independent	Formerly University of Bristol; member of Council for Science and Technology; Chair, John Innes Centre Governing Council
Professor Keith Gull CBE FRS FMEdSci	University of Oxford	Wellcome Trust Principal Research Fellow; Professor of Molecular Microbiology; Chair, IAH Governing Body
Professor Tony Minson	University of Cambridge	Professor of Virology and Pro Vice chancellor for Planning and Resources
Dr Alistair Penman	independent	Formerly Unilever; Former member of BBSRC Council
Professor Simon Pollard	Cranfield University	Head of Department, Sustainable Systems; Professor of Waste and Environmental Risk Management
Mr Meurig Raymond MBE	National Farmers' Union	farmer; deputy president, NFU
Mr Alick Simmons	Defra	Deputy Chief Veterinary Officer

Secretariat: Strategic Planning Unit, BBSRC Swindon Office

Dr Paul Burrows
Dr Huw Tyson
Dr Adrian Pugh

Acknowledgements

The Chairman and panel wish to thank the Director and staff of IAH for their cooperation during the review; also senior staff at Defra for helpful discussions. Thanks are also due to the BBSRC secretariat for their efficient support during the review and their hard work in drafting this report.

ANNEX 2

FURTHER BACKGROUND: THE 2007 FOOT AND MOUTH OUTBREAK AND FOLLOW-UP REVIEWS

The 2007 foot and mouth disease outbreak

1. On 3 August 2007 Defra announced there was a suspected foot and mouth disease (FMD) outbreak at a farm in Normandy, Surrey, located less than 5 miles from the IAH Pirbright site. Genome sequencing showed that this and the subsequent cases identified following the original outbreak were all related.

2. The virus strain causing FMD in the first infected herd of cattle was a laboratory strain not naturally found in the environment and was one upon which work was being carried out by all three occupants of the Pirbright site ahead of the first outbreak - IAH and two private companies, Merial Animal Health Ltd and Stabilitech Ltd. During the most likely period of infection, 14 and 25 July 2007, Merial were engaged in large-scale FMD vaccine production (10 000 litres). The quantities involved were much larger than those for IAH and Stabilitech (less than 10 millilitres in each of the latter cases), but at a level permitted by Defra.

Two main inquiries following the FMD outbreak

3. Following the outbreak of FMD in Surrey in August 2007, the Government ordered two inquiries, the Health and Safety Executive (HSE) investigation of the Pirbright site[44] and the review led by Professor Brian Spratt: *Independent review of the safety of UK facilities handling foot-and-mouth disease virus*[45].

The HSE report

4. The final HSE report, published on 7 September 2007, indicated that the cause of the outbreak was almost certainly the escape of live virus from Pirbright, most probably in the period immediately following 20 July. However, due to very small differences in the strains used at all three organisations at Pirbright, it had not been possible to pinpoint the exact origin of the virus.

5. It was likely that waste water containing the live virus, having entered the drainage pipe work, then leaked out and contaminated the surrounding soil. Excessive rainfall in July may have increased the potential for virus release from the drains. HSE found that during the period of the investigation both human and vehicle movements at Pirbright were not adequately controlled. HSE established that some of the vehicles, probably contaminated, drove from the site along a road that passes the first infected farm. The HSE concluded that this combination of events was the likely link between the release of the live virus from Pirbright and the first outbreak of FMD.

The Spratt report

6. The review group led by Professor Spratt was asked to look at biosafety at the Pirbright site and whether a breakdown in biosafety led to the FMD outbreak. It was also unable to determine with confidence which of the two facilities, IAH or Merial, was the source of the outbreak virus. However, it did find several areas where biosafety and biosecurity at the site must be improved.

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[44] HSE report (August 2007): http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf
[45] Spratt report (August 2007): http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt_final.pdf

7. The recommendations covered four main areas:

- Immediate action on containment (*Recommendations 2, 5, 8, 9*)
- Further action on biosecurity and biosafety (*Recommendations 4,6,7,13*)
- Funding, design and governance (*Recommendations 10, 11, 12, 13*)
- Regulatory and inspection framework (*Recommendations 14*)

Follow-up reviews

8. Following the two main FMD inquires, five reviews were set up to take forward various recommendations from the Spratt and HSE reports. BBSRC was responsible for convening three of these review groups to respond to recommendations 5, 10, and 12 (this review) in the Spratt report:

- ***Recommendation 5**: IAH should have a thorough review of the safety of all laboratory activities to ensure that procedures which could release infectious FMDV into the containment laboratories are eliminated.*

- ***Recommendation 10**: The plans for future development of the Pirbright site should be reviewed to ensure that all safety critical issues have been addressed. This should be carried out with the help of the full of relevant experts and regulatory bodies.*

- ***Recommendation 12**: Biosecurity of laboratories that work with FMDV is of paramount importance. Therefore there should be a review of funding, governance and risk management at IAH Pirbright to ensure an appropriate focus on biosafety and biosecurity in the future.*

9. The Government's response[46] to the Spratt report on Recommendation 5 stated:

"We agree, and believe that IAH should carry out a more far-reaching review of the safety of management procedures for all pathogens. IAH will appoint an independent person to lead the review. The Biotechnology and Biological Sciences Research Council will work with IAH to assist in undertaking the review and applying any findings from it."

10. Accordingly, BBSRC has established an external group to make an independent assessment of the process and outcome of an internal review by IAH of arrangements for the risk assessment and safe management of its pathogen-handling procedures. The group, chaired by Professor Willie Donachie of the Moredun Research Institute, will report to the Institute's Governing Body and to BBSRC. The review, which is being undertaken in two phases, will cover activities involving all pathogens at both the Pirbright and Compton laboratories of IAH.

11. The Government's response on both Recommendations 10 and 12 of the Spratt report stated:

"We agree with both of these recommendations, and at all stages of the design of the new laboratories at Pirbright biosecurity issues have been a priority. The Pirbright Site Redevelopment Programme Board which oversees the project (and which includes members from the IAH, the IAH Governing Body, VLA and the funders), will undertake a review of all aspects of the Pirbright site so as to ensure

[46] Government response to Spratt report:
http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/govstatement_fmd2007.pdf

that all safety critical issues have been addressed [Recommendation 10]. *It will report its findings to a review body led by BBSRC, an NDPB of the Department for Innovation, Universities and Science* [sic], *in conjunction with the IAH Governing Body and supported by Defra, and with a representative of the farming community. This review body will also assess and report on the funding, governance and risk management at Pirbright* [Recommendation 12]."

12. The review group chaired by Professor Sir John Beringer was therefore set up to consider funding, governance and risk management at IAH Pirbright (Recommendation 12). A separate review group, chaired by Professor Martyn Jeggo (Australian Animal Health Laboratory, Geelong, Australia) and working in conjunction with existing bodies overseeing the plans for the Pirbright site redevelopment, will address primarily Recommendation 10.

Other Government reviews

13. The fourth and fifth of the reviews were instigated by the Government and have been recently completed:

- Sir Bill Callaghan was asked by the Government to chair a review of the regulatory framework for animal pathogens, as recommended by the HSE in its report on the Pirbright outbreak 2007. The report from the Callaghan review was published[47] in December 2007. Among its recommendations were that there should be a single regulatory framework to govern work with both human and animal pathogens and that the HSE should become the regulatory, inspection and enforcement body. The Government accepted all the recommendations and is taking them forward.

- Dr Iain Anderson was asked to chair a review of the Government's reaction to the 2007 foot and mouth disease outbreak. Dr Anderson previously conducted an inquiry into the 2001 outbreak, and was asked to review his lessons drawn from the 2001 outbreak and identify any others arising from the 2007 outbreak. The report from the 2007 outbreak was published[48] in March 2008. Among its recommendations were a personal proposal (in the Foreword) to reposition Pirbright as a new 'National Institute for Infectious Diseases'.

[47] Callaghan review: *A Review of the Regulatory Framework for Handling Animal Pathogens* http://www.defra.gov.uk/news/2007/071213b.htm

[48] Anderson review: *Foot and Mouth Disease 2007: A Review and Lessons Learned* http://www.cabinetoffice.gov.uk/fmdreview

ANNEX 3

PREVIOUS REPORTS ON IAH AND THE FUNDING AND GOVERNANCE OF INSTITUTES

Previous reports on IAH

1. There have been several previous reports into various aspects of IAH in recent years.

Gull report

2. Professor Keith Gull (a member of the Beringer review panel) chaired a review of IAH Pirbright[49], published in 2002. It concluded that there was a continuing danger to the UK of known and novel exotic diseases of large farm animals, and that Pirbright's role would continue to be highly relevant. The group recognised that investment was required in the laboratories and considered whether to rebuild or relocate, but could only support the relocation of Pirbright's research activities elsewhere if that plan were part of a single, major new infectious disease facility, as the costs involved would be substantial.

3. BBSRC Council took forward recommendations from the review, leading to the current major redevelopment plans for the Pirbright site (original estimate £121M, to be jointly funded by BBSRC and Defra). The plans include the relocation of the virology work at the Veterinary Laboratories Agency (VLA) from its current location at Weybridge to the Pirbright site (Pirbright and Weybridge are about 15 miles apart).

Cawthorne report

4. In 2003, Dr Richard Cawthorne (then Deputy Chief Veterinary Officer at Defra) chaired a working group to consider the UK's national facilities for infectious animal disease research, surveillance and diagnosis. Its remit was to advise Defra and BBSRC on present and future needs for laboratory and animal containment facilities to undertake work on exotic diseases, particularly those with a zoonotic potential. The report[50] reaffirmed the continuing need for work on exotic animal disease and included recommendations that the facilities at IAH Pirbright (including the high containment facilities) should be updated urgently, and that relocation of the VLA virology work to Pirbright should be pursued.

Institute Assessment Exercise

5. In 2006, a Visiting Group of external experts chaired by Professor Chris Gilligan reviewed the IAH science programmes as part of the BBSRC Institute Assessment Exercise[51]. Its report confirmed that:

> *"...there is a continued national and international need for the Institute for Animal Health. With its unique expertise and resources, IAH was carrying out internationally competitive research in animal health and welfare as well as fulfilling a vital public safety function in preparedness for disease emergencies."*

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[49] Gull report: http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0207_iah_pirbright.html

[50] Cawthorne report: *Review of the UK's national facilities for infectious animal disease research, surveillance and diagnosis: A report for the Defra and the BBSRC* (2003)

[51] Institute Assessment Exercise, 2005-06: http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0606_institute_assessment.html

Preston report

6. This study[52] was commissioned by BBSRC and Defra in 2006 to evaluate the future relationship between IAH and VLA. The options considered ranged from closer collaboration and the retention of two institutes to total integration into a new organisation which would embrace the totality of VLA and IAH. The review criteria were captured under the headings of:

   - Sustain the delivery of world class science to support evidence-based policy development and decision making that can adapt to changing requirements
   - Support the UK to respond effectively to a national emergency
   - Protect the UK taxpayer - ensure financial sustainability over the medium term

7. The report recommended Option D from the following four options presented:

   Option A: Both organisations remaining autonomous but working with increasing collaboration.
   Option B: Merger of the VLA and selected activities from Pirbright
   Option C: Merger of the VLA , Pirbright and some additional activities
   Option D: Both VLA and IAH in a single structure.

8. In December 2006, BBSRC Council discussed the Preston report and decided to support Option A - closer working between independent organisations, rather than the merger favoured in the report. The Council also considered at that time that it would be inappropriate to consider the relationship any further for at least the next two years.

IAH and other Public Sector Research Establishments (PRSEs)

9. In addition to reports specifically relating to IAH, other recent reports on public sector research establishments and institute governance arrangements are pertinent.

Research Council Institute and Public Sector Research Establishment Sustainability (RIPSS) report

10. The 'RIPSS' report[53] (2004) considered the funding and organisation of not only research council institutes but also a wide range of public sector research establishments (PSREs) and concluded that the long-term sustainability of many PSREs was under threat. The report put forward a framework of principles and preferred models, stating that the Government should take a holistic view of the need for strategic PSRE capacity and the contribution it makes to the science and engineering base, and that research councils and government departments should join up their thinking about what capacity it is that the country needs in the public sector and how to work together to sustain it. It recommended that PSREs should increase their level of annual investment in asset maintenance, renewal and replacement towards norms accepted for the university sector.

11. The report also recommended that it should be government policy that the fitness for purpose and sustainability of the wider science and engineering base is a matter of joint responsibility of the principal public funding stakeholders (the research councils,

[52] Preston report: http://www.bbsrc.ac.uk/media/news/2007/070129_preston_report.html
[53] *Research Council Institute and PSRE Sustainability Study* ('RIPSS') (DTI, 2004) http://www.berr.gov.uk/dius/science/science-funding/ripss/page22675.html and http://www.berr.gov.uk/files/file14578.pdf

government departments and their agencies). Also, that research council Chief Executives and Permanent Secretaries of government departments, working through Chief Scientific Advisors, should be jointly accountable for developing joint scientific and investment strategies for their cross-boundary research interests. As a minimum, such an interest exists if the government department procures 15% or more of a research council institute's turnover.

Institute governance – Costigan and Follett reports

12. In 2005, the Costigan report[54] examined the governance of research council institutes, centres, etc and recommended improvements in the arrangements for the BBSRC-sponsored institutes in order to make them compatible with best practice.

13. The report concluded that BBSRC Council needed to consider the relationship between itself, the institutes, and their governing boards, and achieve clarity on the different roles. It suggested a number of options for changing the governance model, and also noted that the then current lack of clarity about Defra's future needs and budgets presented real challenges to BBSRC.

14. In response to the Costigan report, BBSRC Council asked Sir Brian Follett to advise on governance of the BBSRC-sponsored institutes. The Follett report[55] (2006) summarised the situation as follows:

At the heart of the governance issue is the tension between the levels of responsibility and risk held by the BBSRC, and the independent status of the institutes as companies limited by guarantee and registered charities. The BBSRC's requirement to exert influence and control the institutes, stemming from the Chief Executive's Parliamentary accountability, is incompatible with their constitutional autonomy. This weakness is systemic. It becomes acute when institutes are under strain, particularly when they experience financial difficulties.

Without contesting the importance of effective governance, a wider perspective was needed for the review. Governance cannot be isolated from fundamental questions about the purpose and role of the institutes in the 21st Century and the distinctive contribution they should make to the BBSRC's mission and to the government's Science and Innovation Framework. Clarity about the purpose of the institutes must precede, then shape, options for good governance. Scientific excellence and effective knowledge transfer are the primary requirements of any research council institute.

Sustainability is a recurring problem for the institutes, exacerbated in some by continuing reductions in Defra funding. The task of leading a BBSRC institute with its emphasis upon operational management and raising research income makes senior posts unattractive to many leading scientists and the institutes are not always attracting outstanding young scientists.

15. The Follett report concluded that governance arrangements should be modernised, and this has led to significant changes among several of the institutes, with further changes planned or under discussion.

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[54] Costigan report: *Research Council Institutes, Centres, Surveys and Units: a Review of Governance Issues* http://www.berr.gov.uk/files/file27331.pdf

[55] Follett review: *Report of an independent review of governance of BBSRC-sponsored Institutes* http://www.bbsrc.ac.uk/media/releases/2006/061024_follett_review.html

16. Among these have been changes to the composition of IAH, which now comprises just two sites, at Compton and Pirbright. The Neuropathogenesis Unit (NPU, in Edinburgh), which formerly carried out most of the IAH research in transmissible spongiform encephalopathies (e.g., BSE and scrapie), transferred in 2007 from IAH to join the BBSRC-sponsored Roslin Institute. The merged institute (now named The Roslin Institute) is to transfer to the University of Edinburgh to form part of a new centre for animal sciences being established from 2008, in a consortium that also includes the University of Edinburgh's veterinary school and the animal science researchers of the Scottish Agricultural College and the Moredun Research Institute.

ANNEX 4

BACKGROUND INFORMATION ON BBSRC, INSTITUTES, IAH AND VLA

BBSRC

1. The Biotechnology and Biological Sciences Research Council (BBSRC[56]) is a non-departmental public body (NDPB) constituted by Royal Charter. BBSRC is one of seven UK research councils funded through the Government's Office for Science within the Department for Innovation, Universities and Skills, and forms part of Research Councils UK (RCUK[57]).

2. BBSRC's mission, defined by Government and embodied in the Council's charter, is:

   - to promote and support high-quality basic, strategic and applied research, and related postgraduate training, relating to the understanding and exploitation of biological systems;
   - to advance knowledge and technology, and provide trained scientists and engineers, which meet the needs of users and beneficiaries, thereby contributing to the economic competitiveness of the United Kingdom and the quality of life;
   - to provide advice, disseminate knowledge and promote public understanding in the fields of biotechnology and the biological sciences.

3. Users and beneficiaries of the Council's research and training include the agricultural, bioprocessing, chemical, food, healthcare, pharmaceutical and other biotechnological related industries, together with universities, government departments and other public-sector organisations.

4. BBSRC's overall goal is to support science of international quality, relevant to its mission. The Council has a responsibility to sustain a broad base of interdisciplinary research and training in the non-medical life sciences which will help to create prosperity, improve the quality of life, inform policy-making or contribute in other ways to the public good. It seeks to develop research capabilities relevant to the needs of industrial and other users and beneficiaries to enhance the management and utilisation of biological resources.

BBSRC-sponsored institutes

5. BBSRC supports science in over 100 universities and other research institutions, mainly through the award of fixed-term grants for specific projects. The Council also funds work on a rolling, longer-term basis in a number of research institutes and other centres. In particular, five institutes are currently "sponsored" by the Council and receive, on average, between one third and a half of their income from BBSRC.

6. As of April 2008, the BBSRC-sponsored institutes[58] are:

Babraham Institute (BI)	Cambridge
Institute for Animal Health (IAH)	Compton, Berkshire; Pirbright, Surrey

[56] BBSRC: http://www.bbsrc.ac.uk/
[57] RCUK: http://www.rcuk.ac.uk/
[58] BBSRC institutes: http://www.bbsrc.ac.uk/organisation/institutes/sponsored_institutes.html

Rothamsted Research (RRes)	Harpenden; Broom's Barn, Suffolk; North Wyke, Devon
Institute of Food Research (IFR)	Norwich
John Innes Centre (JIC)	Norwich

7. These institutes receive core funding from the Council in the form of a Core Strategic Grant (CSG) awarded over a period of 4-5 years after each round of the Institute Assessment Exercise. From 2008, CSG funding will be replaced by Institute Strategic Programme Grants (ISPG) and an Institute Integration Award – see para 21 in the main report. The balance of institute funding comes from a number of other sources, including competitive research grants from BBSRC and other UK government sources, industry and the EU.

Institute for Animal Health (http://www.iah.bbsrc.ac.uk/)

8. The Institute for Animal Health (IAH) was formed in 1987 through the merger of previously distinct bodies and operates at sites in Compton (Berkshire) and Pirbright (Surrey). It is a major centre for research on infectious diseases of livestock, including many that transmit to man. The institute is a registered charity and sponsored by the BBSRC.

9. The IAH has an annual income of over £29M and employs around 400 staff. The institute receives core and competitive funding from BBSRC, for fundamental and strategic research. Substantial funding is also secured from Defra, mainly in support of applied research and capacity to respond to an outbreak of a notifiable disease, such as foot and mouth disease. The IAH has International Reference Laboratory status for many diseases on the OIE list.

10. The focus of work at Pirbright is on exotic viral diseases of livestock, whilst the research at Compton centres primarily on endemic diseases and underpinning approaches to studies on infectious disease. However, this separation is not exclusive, with a programme, in collaboration with VLA, on avian influenza based at Compton.

11. The principal diseases studied at IAH include food-borne zoonoses, avian influenza, bovine tuberculosis, coccidiosis and Marek's disease at Compton, with foot and mouth disease, African swine fever, rinderpest, bluetongue and other orbiviruses at Pirbright.

12. The institute published its science strategy in 2005, outlining its 10 year strategic objectives. The focus is on cattle and poultry with fundamental programmes on the immunology and genomics of both species.

13. The IAH Governing Body provides support on scientific and fiscal issues to the management team; members of the body are trustees and directors. The BBSRC Council determines BBSRC policies and strategies and receives reports, recommendations and advice from several boards and committees which cover a range of BBSRC's activities, including those relating to the IAH.

Veterinary Laboratories Agency (www.defra.gov.uk/corporate/vla/)

(Reproduced from Preston report (January 2007), Chapter 3)

14. The Veterinary Laboratories Agency (VLA) is an Executive Agency of Defra established in 1995, and comprises a main site at Weybridge supported by a nationwide network of 15 regional laboratories. The mission of the VLA is "*to safeguard public and animal health through world class veterinary research and surveillance*".

15. The VLA currently employs just over 1400 staff with an income of £107M, 90% of which is provided by Defra. The science, surveillance and commercial programmes deliver a range of services to its customer base. A comprehensive surveillance network, multi-disciplinary research programme and the provision of an effective national emergency response enable the VLA to meet these requirements.

16. To provide this service, there are six main customer-focused programmes which are supported by discipline-based groups including pathology, epidemiology, risk analysis, applied immunology, microbiology and chemistry.

17. The six programmes are:

- Statutory and exotic viruses
- Statutory and exotic bacteria
- International trade
- Emerging diseases and welfare
- Food and Environmental Safety
- TSEs

18. A seventh programme is focused on commercial work, the aim of which is to generate surpluses for reinvestment in the business.

19. In terms of governance, the VLA Ownership Board, chaired by a non-executive, provides advice on strategic direction to Defra while the VLA Strategy Management Group, chaired by the CEO, retains oversight and management of operational delivery, and provides strategic direction to the CEO.

ANNEX 5

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http://www.hm-treasury.gov.uk/documents/public_spending_reporting/governance_risk/psr_governance_risk_riskguidance.cfm

Defra reports and strategy documents

Defra consultation on responsibility and cost sharing for animal health and welfare
http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/index.htm

Animal Health and Welfare Strategy for Great Britain
http://www.defra.gov.uk/animalh/ahws/strategy/ahws.pdf

ANNEX 6

ABBREVIATIONS

AFBI	Agri-Food & Biosciences Institute
AHW	animal health and welfare
BBSRC	Biotechnology and Biological Sciences Research Council
CSG	Core Strategic Grant (BBSRC core funding to a sponsored institute)
CSR	Comprehensive Spending Review
CVO	Chief Veterinary Officer
DARD	Department of Agriculture and Rural Development (Northern Ireland)
Defra	Department for Environment, Food and Rural Affairs
DIUS	Department for Innovation, Universities and Skills
FEC	full economic cost
FMD	foot and mouth disease
FSA	Food Standards Agency
HSE	Health and Safety Executive
IAA	Institute Integration Award (component of BBSRC institute funding from 2008)
IAH	Institute for Animal Health
ISPG	Institute Strategic Programme Grants (replacing CSG from 2008)
NDPB	non-departmental public body
PSRP	Pirbright Site Redevelopment Programme
RIPSS	Research Council Institute and PSRE Sustainability Study
SAPO	Specified Animal Pathogens Order 1998
VLA	Veterinary Laboratories Agency

Final Report - March 2008

A generalised exposure assessment of anaerobic digestion products in various end-use settings

WRAP and Environment Agency
Project OFW002

Cranfield UNIVERSITY
/ UNIVERSITY

School of Applied Sciences
Centre for Resource Management and Efficiency

Cranfield UNIVERSITY

Document summary

Final Report - March 2008.

A generalised exposure assessment of anaerobic digestion products in various end-use settings

WRAP and Environment Agency Project OFW002

The waste protocols project is a joint Environment Agency and Waste Resources and Action Programme (WRAP) initiative, funded by the Department for the Environment, Food and Rural Affairs (Defra) Business Resource Efficiency and Waste (BREW) Programme.

This document has been prepared by the Centre for Resource Management and Efficiency, Cranfield University.

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ISBN:
Release date:
Reviewed by:
WRAP Project manager: Dr Nina Sweet, Technical Specialist

"WRAP and Centre for Resource Management Efficiency, Cranfield University believe the content of this report to be correct as at the date of writing. This report describes an exposure assessment undertaken specifically to inform the development of a Quality Protocol for Anaerobic Digestate. In this context, and to generate the output required of this assessment, important assumptions and generalisations have been made. Care should be taken in using elsewhere any of the information provided as it is based upon numerous project-specific assumptions.

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Executive summary

Background & purpose

This research is concerned with providing confidence to the market on the safe and responsible use of the products of anaerobic digestion (AD). It has been stimulated, in part, by the commitment to future investments in waste technology infrastructure set out in the Waste Strategy for England, 2007 and specifically, with reference to the Government commitment to encourage a variety of energy recovery technologies (including AD).

Through the BREW Waste Protocols Project, WRAP are developing a technical report, recognised by (and produced with the support of) Industry, that defines when the outputs from an anaerobic digester (AD), that treats biodegradable waste, have been reprocessed to such a level that they can be considered to be fully recovered and no longer subject to the requirements of the regulatory waste regime.

This report describes an exposure assessment undertaken to inform the development of a Quality Protocol for Anaerobic Digestate. This exposure assessment describes the relative likelihood of exposure to a range of significant hazards from AD residues in a variety of end uses. Without exposure there can be no risk. When the likelihood of exposure to a significant hazard is judged as a result of exposure assessment to be high, controls need to be put in place to avoid, mitigate, or manage that exposure.

In this work, we are concerned with how hazardous agents in wastes might survive an anaerobic treatment process and, through the use of the AD residue in a specific end use, be transported to a receptor of concern (a river, a plant species, human, animal stock). In practice, there are several barriers that act to prevent exposures occurring:

- the initial exclusion of unsuitable wastes from treatment;
- the effective treatment of suitable wastes in an AD plant;
- the appropriate use of the residue in its final end use, adopting accepted codes of good practice;
- the attenuation of residual, post-treatment hazards in the environment prior to reaching a receptor of concern, including the processes of dilution, dispersion, sorption and biotransformation.

By exploring the capacity of these barriers to reduce exposure and thereby reduce risk, it is possible to identify the most significant hazardous agents (chemical, biological, physical), wastes, exposure pathways and end uses. The combinations of these factors that offer the greatest potential for exposure of a receptor of concern have been identified and are key features that can be addressed by the AD quality protocol, which is designed as a risk management tool.

Methodology

The method applied in this work is an adaptation of the exposure assessment methodology that was recently developed for the State Veterinary Service (Defra) for the risk assessment of carcass disposal options in the event of an avian influenza outbreak

and which is currently being further developed by Defra for use with other exotic diseases. In summary the method comprised the following nine stages:

(i) an initial pre-screening of European Waste Catalogue (EWC) waste categories, process technologies and end uses to identify feasible input-treatment-output-end use groupings;
(ii) the development of a hazard master list, incorporating evidence for key hazards (physical, chemical, biological) within *ca.* 70 EWC waste categories;
(iii) the screening and prioritisation of hazardous agents using a four filter system to deliver a set of principal hazards of concern;
(iv) a profiling and grouping of EWC waste categories by reference to their key hazardous constituents;
(v) consideration of the treatment efficacy for hazards in input waste streams, with subsequent assumptions for the hazards that remain, post-treatment;
(vi) the development of a master list of potential exposure pathways for residual hazards posed by the output materials by reference to seven selected end uses;
(vii) subsequent development of conceptual exposure models for a series of end uses
(viii) a (semi)quantitative exposure assessment for each end use; and
(ix) the development of a matrix for AD outputs in their end use, with the key exposure pathways for significant residual hazards identified and ranked according to an aggregate measure of potential exposure.

To inform this assessment, we referred to studies from the open and grey literature and have used a number of experts to inform the work. Critically, we have used both AD Quality Protocol Technical Advisory Group (AD QP TAG), chaired by Dr Nina Sweet of WRAP and a working group of technical specialists, AD operators, regulators and the project team to inform the assessment.

Assumptions

A generic exposure assessment of this nature requires a large number of working assumptions for it to be both pragmatic and meaningful. This is particularly true of this project where the heterogeneity of waste, the variety of AD processes; and the complexity of environmental pathways and processes necessitated the development of methodological approaches that enabled the assessment to be handled in a manageable way. The following assumptions were recorded and agreed with the AD QP TAG prior to completion of the analysis. The analysis has assumed:

- comprehensive coverage of key EWC waste categories as inputs to AD processes, as informed by the AD QP TAG and risk assessment working group;
- comprehensive collation of key hazardous constituents in these waste categories, as informed by the AD QP TAG risk assessment working group and independent experts;

- the assignment of a single hazard profile to all of the wastes represented within each EWC waste category; allowing the number of waste categories to be collapsed to a manageable subset of profiles;
- AD process technologies were grouped into two types for this assessment: mesophilic anaerobic digestion and thermophilic anaerobic digestion (see the definition of the AD Process for the purposes of this exposure assessment)
- thermophilic digestion is operated at temperatures above 45°C, thus substantially reducing pathogen loads (see screening of the pathogens);
- EWC waste categories requiring pasteurisation under EU Animal By-Products Regulation 1774/2002 were assumed to have been processed to the required standard and therefore to represent a substantially reduced hazard load.
- AD processes are operated competently and in accordance with their design and operating standards;
- All applicable regulations currently in force are assumed to be met;
- AD residues are applied, within their end use, in accordance with accepted codes of good practice;
- as a conservative assumption in the first instance, the combined characteristics of liquid and fibre residues are considered so allowing a reasonable worst case assessment of hazards within AD residues;
- environmental processes act to attenuate hazardous constituents in their final end use setting in accordance with the fate and transport characteristics of the constituents;
- environmental pathways are either not available, or available to various degrees, thus allowing a semi-quantitative assessment of the relative likelihood of exposure for accessible pathways.

Results

We have generated several metrics from the exposure assessment. The metrics that we believe to be of most value in identifying the wastes, exposure pathways and end uses of greatest concern are:

I. Hazard profile – end use – exposure pathway scores

The value represents the score for an individual pathway and is derived from exposure availabilities ranked 3 or 4. The value is a surrogate for probable exposure to the hazards in that waste and end use and it represents those pathways of:

- medium availability (scored 3), that are plausible, known to have occurred but that still harbour barriers, even though some hazards can overcome them; and
- highly availability (scored 4), that are direct exposure pathways like inhalation of odours, direct application to plants, that is short pathways without barriers.

II. Total pathways (3-4)

This is the total number, as opposed to a score, of the available pathways above, that is those pathways that have received a score of 3 and 4. This metric represents the number of opportunities for exposure of medium or high availability.

III. Total pathway score (3-4)

This is the grand total of the scores for a particular hazard profile – end use couple. It is an aggregate measure of pathway availability. It excludes pathways scoring 1 and 2 (very low and low availability). We believe that this is the principal metric to be used for ranking the table and it represents, for each hazard profile end-use couple, the total availability for exposure.

Conclusions

We conclude from our analysis that:

1. The hazard profile (i.e. the characteristics of different wastes) is the principal variable that governs the exposure ranking. That is, the more hazardous the input stream, the greater the concern. Hazard profiles 207 and 199 (both EWC 020106 pre- and post- AD) that represent wastes with a high proportion of animal faeces have high rankings in the matrix. This happens due to the fact that the material has not been pasteurised. Hazard profiles representing wastes derived from the leather industry EWC 040101, 040105 and 040107 (hazard profiles 229 & 197) also appear towards the top of the matrix. It should be noted that although ABPR wastes are hazardous they have a relatively low exposure ranking because we have assumed pasteurisation to be an effective treatment.

2. It is possible to identify exposure pathways of greatest concern. Those pathways judged to be the most direct pathways of highest availability were pathways 23 (direct ingestion of AD residues) and pathway 13 (ingestion of soil contaminated with AD residues). Other highly available pathways were 2 & 4 (contamination of private water supplies by surface and subsurface routes) and 11 (ingestion of contaminated crops).

3. The influence of end use is subsidiary to that of waste hazard profile in the overall ranking. However, at the level of an individual hazard profile, end uses are consistently ranked by this exposure assessment technique. The end uses presenting the highest number of highly available pathways were ready to eat crops (end use 4), grazing and animal feed (end use 2), and non ready to eat crops (end use 1). These are the end uses most closely linked to the human food chain and would, intuitively, be expected to present additional potential for human exposure.

The exposure assessment offer insights into where control might be most effective; through the exclusion of certain EWC waste categories, through the application of

codes of practice or national standards, backed up by the quality protocol for specific exposure routes and through specific attention being given to certain end uses.

The analysis presented in this report is a generic one. We have made assumptions about the hazards present in broad EWC waste categories. Hazards within these generic categories were characterised according to simplified hazard groupings. AD processes were categorised and applied to the hazard profiles to generate post-treatment profiles. The likelihood of transport of potent hazards from a source to a receptor via an available pathway was scored on a 1-4 scale according to generalised (rather than site-specific) judgements of environmental mobility, persistence and barriers affecting availability. These generalisations were necessary to ensure that the exposure assessment was manageable and fit for purpose. Through this methodology we have linked and codified expert understanding on waste categories, AD processes and the environmental fate of contaminants in the context of AD product end use. This has highlighted the key drivers of potential exposure and provides a basis for control through the AD Quality Protocol. Any wider application of the findings of this research should bear in mind the the assumptions made. It is assumed that site-specific assessment will be undertaken before any of the options discussed herein are used in practise. In undertaking the generic assessment presented here, it is not possible to take site-specific factors into account. These can only be considered within a specific environmental setting.

Glossary

AD end-products	products resulting from the anaerobic digestion of organic material without successive post-maturation in solid (solid digestate) or liquid form (liquid digestate).
Anaerobic digestion	is a biological process that produces biogas, principally methane (CH_4) and carbon dioxide (CO_2), from organic materials including wastes such as livestock manure, food processing waste, etc.
Availability	Refers to the extent to which there are barriers to the transport of a potent hazard(s) from a source to a receptor via an available pathway. Pathways of high availability have no significant barriers to exposure. A pathway of high availability has a high capacity to carry a potent hazard from source to receptor. Transport of a potent hazard is highly likely where there is a pathway of high availability. Whereas, a pathway with low availability has significant barriers in place that are likely to prevent exposure of a receptor to a hazard.
Available pathway	an available pathway is defined here as the means by which it is at least theoretically possible to connect the source of a hazard(s) to a receptor(s).
Conceptual model	description of how a system is believed to behave. In this document it is the description of how a receptor may be exposed (via individual pathways) to a hazard.
Decimation reduction time (T90)	the time required for a 90% reduction of viable counts of population of microorganisms or a decrease by one log unit (log10).
Exposure	the contact of a receptor with a chemical, biological or physical hazard.
Exposure assessment	the qualitative and/or quantitative evaluation of the likelihood of contact of a receptor with a biological, chemical or physical agent.
Hazard	a biological, chemical or physical agent with the potential to cause an adverse effects on human, animal or environmental receptors.
Hazard characterization	the qualitative and/or quantitative evaluation of the nature of the adverse effects on human, animal or environmental receptors associated with the hazard.
Hazard identification	the identification of biological, chemical, and physical agents capable of causing adverse effects on human, animal or environmental receptors.

Mesophilic AD Process	process which employes mesophilic bacteria, working at temperatures between 30°C and 45°C.
Pathogen	microorganism that can cause disease.
Pathway	a route for exposure, by which a receptor may become exposed to the source of a hazard.
Quantitative risk assessment	a risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis).
Qualitative risk assessment	a risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.
Receptor	an entity at risk of harm through its exposure to a hazard.
Risk	the potential realisation of unwanted, adverse consequences to human life, health, property or the environment associated with a hazard.
Risk analysis	a detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment and how to address them.
Risk assessment	a logical consideration of risk in terms of both the probability of the risk occurring and the magnitude of the harm that may ensue.
Risk management	the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.
Source	the source of a hazard i.e. digestate.
Thermophilic AD process	process which employes methanogenic thermophilic bacteria, working at temperatures between 45°C and 60°C.

1. Introduction and study rationale

Background

This research is concerned with providing confidence to the market on the safe and responsible use of the products of anaerobic digestion (AD). It has been stimulated, in part, by the commitment to future investments in waste technology infrastructure set out in the Waste Strategy for England, 2007 and specifically, with reference to the Government commitment to encourage a variety of energy recovery technologies (including AD).

The waste protocols project is a joint Environment Agency and Waste Resources and Action Programme (WRAP) initiative, funded by the Department for the Environment, Food and Rural Affairs (Defra) Business Resource Efficiency and Waste (BREW) Programme. Through the BREW Waste Protocols Project, WRAP are developing a technical report, recognised by (and produced with the support of) Industry, that defines when the outputs from an anaerobic digester, that treats biodegradable waste, have been reprocessed to such a level that they can be considered to be fully recovered and no longer subject to the requirements of the waste regulatory regime.

WRAP and the Environment Agency have established the AD Quality Protocol Technical Advisory Group (AD QP TAG) to take forward the issues of product specifications and use. Without safe routes for the onward utilisation of AD residues, there is a risk of market failure; hence the need to assess, and secure consensus on, the potential for exposure of human, animal and environmental receptors to hazards associated with AD residues through a credible, independent assessment.

Study scope

This document reports on a generic, semi-quantitative exposure assessment of AD products in their end use settings. It uses a hazard screening methodology, a 'source-pathway-receptor' analysis of exposure and a ranking of critical exposure pathways to identify the most significant hazardous agents (chemical, biological, physical), wastes, exposure pathways and end uses. The combinations of these factors that offer the greatest potential for exposure of a receptor of concern have been identified and are key features that can be addressed by the AD quality protocol, which is designed as a risk management tool. The report's findings can be used to determine policy and inform operational decisions on the AD products in their end use.

Study limitations

The analysis presented in this report is a generic one – that is, it adopts a broad consideration of the hazards in generic waste categories. Wastes are assumed to be treated by AD processes and the residues used within a suite of generalised end uses. When applied to their end uses, it is assumed residual hazards in residues can access

various environmental pathways and be transported to receptors. A number of working assumptions were made to ensure that the exposure assessment was manageable. The methodological approach taken is appropriate in the context of informing the AD Quality Protocol but wider application of the findings should bear in mind the assumptions made.

It is assumed that site-specific assessment will be undertaken before any of the options discussed herein are used in practise. In undertaking the generic assessment presented here, it is not possible to take site-specific factors into account. These can only be considered within a specific environmental setting. The study therefore has its limitations.

Report structure

The remainder of this document provides an overview of the methodology (Section 2), a description of the hazards identification and AD processing (Section 3), the conceptual model development (Section 3), a semi-quantitative exposure assessment (Section 3), the exposure ranking (Section 3) and the report results and conclusions (Section 4).

References offer supporting information and a series of Annexes support this report.

Brief overview of anaerobic digestion

Anaerobic digestion is a natural microbial process through which organic materials decompose in the absence of air within an in-vessel or controlled environment. Anaerobic digestion is a technology frequently employed to treat organic waste materials e.g. manure /slurries and food processing / municipal waste, however, potential feed stocks for AD are not only limited to waste materials. A prime example of a feed stock which is not a waste is energy crops (e.g. maize, ryegrass and wheat), which is widely used in anaerobic digestion in other European countries. Solid waste, such as agricultural and municipal waste, is a relatively new feedstock for the UK plants. The AD process can stabilise the high organic content of this type of waste, reduce odours and pathogens and control physical and chemical contamination.

This assessment aims to identify the likelihood of exposure that might arise from the use of the digestate produced during this process. The full list of waste feedstocks is detailed in Appendix 2.

Co- digestion plants - AD plants for agricultural and other 'wastes' frequently include three distinctive stages:

* Pre-treatment

* Anaerobic digestion

* Post treatment

There are 4 stages in the digestion process

- Hydrolysis or liquefaction (hydrolysis of polymers such as carbohydrates, lipids and proteins)

- Acidogenesis (fermentation of aminoacids and sugars to short chain fatty acids)

- Acetogenesis (oxidation of volatile faty acids and alcholos to acetate)

- Methanogenesis (methane production from acetate and/or from carbon dioxide and hydrogen).

An extensive description of the four stages can be found in many textbooks or in Monson K.D. *et al.*, 2007.

There are four main ways in which AD systems can be configured. These are as follows:

1. wet or dry
2. mesophilic or thermophilic
3. single stage or multistage
4. batch or continuous

The digester design will be a combination of the above and will operate in many different modes.

Dry AD processes usually treat high solid content waste (15-40%) and are suited to high solids feed materials such as energy crops and farm residues. Wet systems treat low solid content wastes (<15% dry solids) like manures and sludges. It is often the case that two or more waste streams are mixed prior to digestion to obtain a suitable consistency.

Mesophilic AD processes work between 30°C and 45°C (optimum 35°C – 37°C). The advantage of the mesophilic process is that the bacteria are more robust and more adaptable to changing environmental conditions. Thermophilic AD processes operate in the range from 45 to 60°C (optimum 55°C).

In comparison with mesophilic, thermophilic digestion offers the advantages of a faster reaction rate, therefore faster waste throughput and potential for a higher loading rate. Thermophilic digestion also offers superior pathogen kill due to the higher temperatures, and thus a more sanitised output. Thermophilic systems will require additional energy input and show greater sensitivity to operating and environmental conditions, therefore tighter control is required to avoid instability (Monson K.D. *et al.*, 2007).

In single stage AD processes the two stages of the digestion take place in the same reactor, whereas in multistage AD two or more vessels are used for the different stages of the digestion. The two phases have different optimum conditions and multi-stage processes allow the optimisation of each stage independently with higher methane production yields (BioREGen, 2007).

Batch processes are relatively simple systems but because there is no continuous solid input or output, the biogas yield reaches a maximum and then decreases as the waste in the digester is consumed. In continuous AD systems, the waste is continually fed to

the process and digestate and biogas discharged and, hence, more relevant to biomass projects for biogas production (BioREGen, 2007).

2. Overview of methodology

Approach

In this work, we are concerned with how hazardous agents in wastes might survive an anaerobic treatment process and, through the use of the AD residue in a specific end use, be transported to a receptor of concern (a river, a plant species, human or animal stock). In practice, there are several barriers that act to prevent exposures occurring:

- the initial exclusion of unsuitable wastes from treatment;
- the effective treatment of suitable wastes in an AD plant;
- the appropriate use of the residue in its final end use, adopting accepted codes of good practice; and
- the attenuation of residual, post-treatment hazards in the environment prior to reaching a receptor of concern, including the processes of dilution, dispersion, sorption and biotransformation.

By exploring the capacity of these barriers to reduce exposure and thereby reduce risk, we have been able to identify the most significant hazardous agents (chemical, biological, physical), wastes, exposure pathways and end uses. The combinations of these factors that present the greatest opportunity for the exposure of human, animal and environmental receptors to significant hazards have been identified and are key features that can be addressed by the AD quality protocol, which is designed as a risk management tool.

General principles

The methodology adopts the general principles of Defra's Guidelines on Environmental Risk Assessment and Management (DETR , 2000; Figure 1)

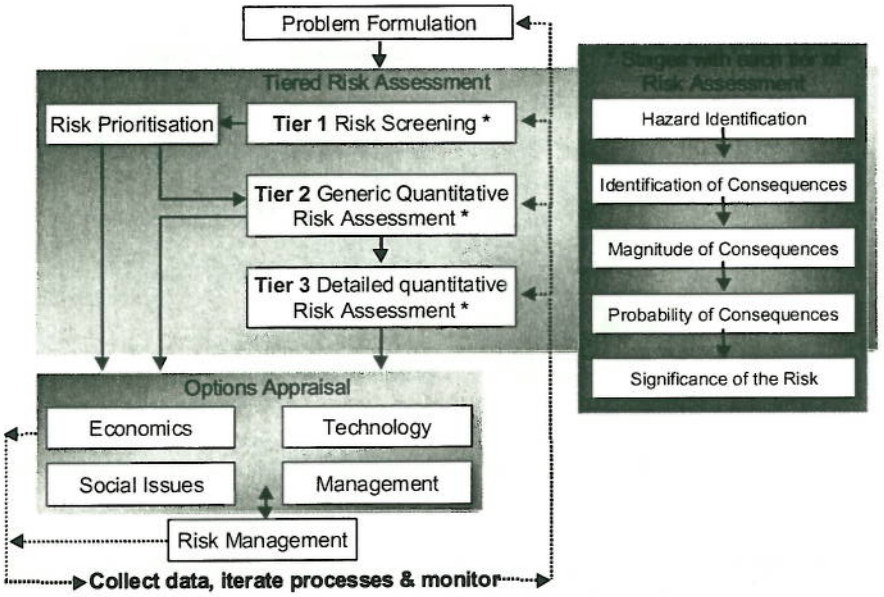

Figure 1 Generalised framework for risk management (after DETR, 2000).

The guidelines were developed to inform environmental risk management decisions in Government. Managing exposure pathways is central to effective risk management, throughout the process chain from waste input to end use of the AD residue. In practice, there are critical control points at each stage of the process chain – opportunities to actively reduce risk. Under normal operating conditions with the application of good practice, barriers (management measures) can be applied that will effectively guard against exposure to hazards.

One good example for AD is the maintenance of temperatures and minimum residence times during treatment. This said, maintaining the absolute integrity of these barriers for 100% of the time is not practically achievable, even with high degrees of vigilance. If the integrity of these systems is compromised, this may promote the release of pollutants or pathogens or both to the wider environment, hence the need for additional control.

A valuable concept describing how releases can occur in systems is the 'Swiss cheese' model (Reason, 1997). It describes how unwanted incidents can occur. Latent factors and active flaws exist in all systems as precursors to the conditions that result in an undesired event – here an exposure event. Most of the time, active risk management (layers of the cheese) guards against this. However, if unmanaged, these factors and flaws may align (represented by aligned holes in the cheese) and adverse events, or exposures, occur (Figure 2). This becomes a useful analogy for this research because it is widely familiar to those managing waste systems as the 'multi-barrier' approach.

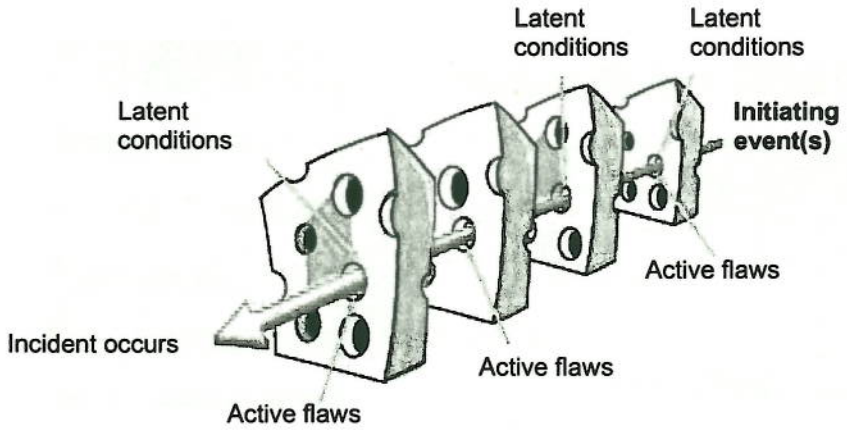

Figure 2 Reason's 'Swiss cheese' model of organisational accidents (after Reason, 1997; 2000).

Applying this general principle to the process of AD residues, solid layers of the cheese represent effective risk management measures in place along the process chain that, during routine operation, guard against the release of hazardous agents to humans, animals or the wider environment. The number of holes in each layer can represent the opportunities for exposure at each stage of the process – the relative fallibility of each layer. The more holes, the more fallible that stage of the process chain and thus the greater opportunity for exposures. The larger the holes, the greater the likelihood of a failure of this stage of the process and thus the greater opportunity for exposures.

While engineered processes can be operated with high degrees of safety, other parts of a process chain may be more fallible because less control is available. Importantly, the latent conditions and active flaws may represent not just technical failures but deficiencies in training, supervision, communication or of control systems. These must also be managed.

In summary, exposure pathways that are more available (larger holes in the layers), because there is less control, are more likely to be accessed by hazardous agents. Stages in the process chain that have more exposure pathways associated with them (greater number of holes in a layer) require more active management. The method described below has the overall objective of assessing both the number and extent of available exposure pathways for each residue-end use couple.

Exposure assessment methodology

The method applied in this work comprised the following nine stages:

(i) an initial pre-screening of European Waste Catalogue (EWC) waste categories, process technologies and end uses to identify feasible input-treatment-output-end use groupings;

(ii) the development of a hazard master list, incorporating evidence for key hazards (physical, chemical, biological) within *ca.* 70 EWC waste categories;

(iii) the screening and prioritisation of hazardous agents using a four filter system to deliver a set of principal hazards of concern;

(iv) a profiling and grouping of EWC waste categories by reference to their key hazardous constituents;

(v) consideration of the effect of process on hazards in input waste streams, with subsequent assumptions for the hazards that remain, post-treatment;

(vi) the development of a master list of potential exposure pathways for residual hazards posed by the output materials by reference to seven selected end uses;

(vii) subsequent development of conceptual exposure models for a series of end uses;

(viii) a (semi)quantitative exposure assessment for each hazard profile-end-use couple; and

(ix) development of a matrix for AD outputs in their end use, with the key exposure pathways for significant residual hazards identified and ranked according to an aggregate measure of potential exposure.

A generic exposure assessment of this nature requires substantive evidence and a large number of working assumptions for it to be both pragmatic and meaningful. For this assessment, we refer to studies from the open and grey literature and have used a number of expert groups to inform the work. Critically, we have used both AD Quality Protocol Technical Advisory Group (AD QP TAG), chaired by Dr Nina Sweet of WRAP and a working group of technical specialists, AD operators, regulators and the project team to inform the exposure assessment.

Assumptions and limitations

All risk assessments embody working assumptions and limitations. This is especially the case for environmental exposure assessment, because the environment is complex and not fully characterised. Wastes are also heterogeneous, complex materials and the AD processes require careful process control. The following assumptions were recorded and agreed with the AD QP TAG prior to completion of the analysis. The analysis has assumed:

- comprehensive coverage of key EWC waste categories as inputs to AD processes, as informed by the AD QP TAG and risk assessment working group;
- comprehensive collation of key hazardous constituents in these waste categories, as informed by the AD QP TAG risk assessment working group and independent experts;
- the assignment of a single hazard profile to all of the wastes represented within each EWC waste category; allowing the number of waste categories to be collapsed to a manageable subset of profiles;
- AD process technologies were grouped into two types for this assessment: mesophilic anaerobic digestion and thermophilic anaerobic digestion (see the definition of the AD Process for the purposes of this exposure assessment)

- thermophilic digestion is operated at temperatures above 45°C, thus substantially reducing pathogen loads (see screening of the pathogens);
- EWC waste categories requiring pasteurisation under EU Animal By-Products Regulation 1774/2002 were assumed to have been processed to the required standard and therefore to represent a substantially reduced hazard load.
- AD processes are operated competently and in accordance with their design and operating standards;
- All applicable regulations currently in force are assumed to be met;
- AD residues are applied, within their end use, in accordance with accepted codes of good practice;
- as a conservative assumption in the first instance, the combined characteristics of liquid and fibre residues are considered so allowing a reasonable worst case assessment of hazards within AD residues;
- environmental processes act to attenuate hazardous constituents in their final end use setting in accordance with the fate and transport characteristics of the constituents;
- environmental pathways are either not available, or available to various degrees, thus allowing a semi-quantitative assessment of the relative likelihood of exposure for accessible pathways.

Definition of the AD Processes for the purpose of this assessment

The assessment includes two categories of AD namely:

1) A mesophilic AD process

2) A thermophilic AD process (not necessarily achieving pasteurisation)

The term thermophilic is used in this exposure assessment to define any process that will use methanogenic thermophilic bacteria, running at an optimum temperature between 45°C and 60°C.

In this exposure assessment, the term mesophilic is used to define processes which employ mesophilic bacteria, running at temperatures between 30°C and 45°C.

Assuming the ABPR (Animal By Products Regulation) treatment is performed effectively, the post treatment waste should comply with regulatory conditions and, therefore, have a level of hazards similar to non-ABPR waste and should be treated as such. In this report we use the word pasteurisation for any effective treatment achieving ABP regulatory conditions.

In this assessment, we have assumed that temperatures between 45°C and 60°C (thermophilic) will kill many, but not all, pathogens and parasites within a few hours, whereas at mesophilic temperatures a similar pathogens reductions may take several days.

Temperatures of 53°C are reported to achieve good pathogen reduction (Al Seadi, 2001 and Lukehurst, 2006). However, 55°C is often used as the optimum temperature for pathogen destruction (Sahlstrom, 2003; Bagge, 2005; Aitken, 2005: See Appendix 10).

It has proven difficult to define a standard reference temperature because many operating thermophilic plants will work within the given temperature range, using different residence times, depending on the waste being treated and the particular features of the plant design. Hence the need for the more generic definition given above.

3. Description of exposure assessment

The exposure assessment is presented in a series of appendices to this main report and constructed in a series of Excel™ spreadsheets that link the stages of analysis and allow the carry over of assumptions between stages of the analysis. Described below is a summary of each stage and brief description of the rationale for the analysis.

Stage (i) Problem formulation

Stage (i) involved problem formulation and an initial pre-screening of EWC waste categories, process technologies and end uses to identify feasible input-treatment-AD output-end use groupings for analysis. These features were assembled by the AD QP TAG and presented to the project team for analysis. They represent the context in which the AD Quality Protocol may be applied. The intent is to allow this analysis to inform the AD Protocol. In doing so, the wastes, processes, residues and exposure pathways that present the greatest potential for exposure of receptors are then identified for further management control.

Stages (ii) - (iv) Hazard identification and waste profiling

Environmental risk is routinely driven by the potency of the hazard, the availability of exposure pathways and the sensitivity of receptors. With respect to the multitude of hazards present in the wastes being treated by AD, this analysis sought to reduce this multitude down to a number of key hazards and then further screen these down to a small number of hazards of significance.

In the assessment, a hazard master list was first developed, grouping individual hazardous constituents potentially present within the wastes into categories (potentially toxic elements, nutrients, persistent organic compounds etc.). This resulted in the development of a hazard master list, incorporating cited evidence for key hazards (physical, chemical, biological) within *ca.* 70 EWC waste categories (See Figure 3 and Appendix 4).

MASTER HAZARD LIST	References
Potentially toxic elements (PTEs) Cd, Cr, Pb, Hg, Ni, As, Ba, Zn, Cu	Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste Amlinger F., Pollak M. and Favoino E., Heavy metals and organic compunds from wastes used as organic fertilisers. Final report .2004, TEND/AML/2001/07/20 Fuchs J., Galli U., Schleiss K. and Wellinger A., ASCP Guidelines 2001 Quality criteria for composts and digestates from biodegradable waste management, Published by the Association of Swiss Compost Plants (ASCP) in collaboration with the Swiss Biogas Forum. http://www.vks-asic.ch/acrobatreader/vks_richtlinie_english.pdf
Nutrients / Organic pollutants N03, NH4, P, K, Micronutrients, BOD	Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste Amlinger F., Pollak M. and Favoino E., Heavy metals and organic compunds from wastes used as organic fertilisers. Final report .2004, TEND/AML/2001/07/20 Brändli R., Kupper T., Bucheli T., Mayer J., Stadelmann F.X., Tarradellas J., Occurrence and relevance of organic pollutants in compost, digestate and organic residues, EPF Lausanne – ENAC – ISTE – CECOTOX / Agroscope FAL Reckenholz Brändli, R.C. et al., Organic Pollutants in Source Separated Compost, Organohalogen Compounds 2006, 68
Animal and human pathogens Salmonella sp., Streptococcus sp., E. coli sp., E. coli O157:H, Enteric viruses, Bacillus sp., Cryptosporidium sp., BSE, Q-Fever (Coxiella burnetii), Ringworm, Leptospirosis (Leptospira sp.), M. bovis (Tuberculosis), Psittacosis (Chlamydia sp.), Giarda entamoeba, Staphylococcus aureus, Campylobacter, Mycobacterium paratuberculosis, Clostridium perfringens/botulinum, Ascaris suum, Foot and Mouth Disease, Swine Fever, Pasteurellosis, Tapeworm, Toxocariasis, Toxoplasmosis, Trichinosis, Yersiniosis, Listeriosis, Brucella abortus (Brucellosis)	"Common zoonoses in agriculture", 2000, HSE information sheet, Health and Safety Executive http://www.hse.gov.uk/pubns/ais2.pdf Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants, 2003, Biores. Technol. 87, 161–166. Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180 Termorshuizen A.J.; Volker D.; Blok W.J.; Brummeler E. ten; Hartog B.J.; Janse J.D.; Knol W.; Wenneker M., Survival of Human and Plant Pathogens during Anaerobic Mesophilic Digestion of Vegetable, Fruit, and Garden Waste. European Journal of Soil Biology, 2003, 39, 165-171.
Invasive weeds and exotic species and plant toxins Ragwort Yew	Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste TAG consultation

Figure 3 Hazards master list and key references.

MASTER HAZARD LIST	References
Plant pathogens Fusarium oxysporum spp, Phytophtora spp., Pythium spp., Plasmodiophora brassicae, Rhizoctonia solani, Thielaviopsos basicola, Verticillium dahliae, Xanthomonas spp., Microdochium nivale, Armillaria mellia, Pepino Mosaic Virus, Tobacco Mosaic Virus, Tobacco rattle Virus, Sclerotium cepivorum, Nematodes (Globodera), Streptomyces spp., Pseudomonas spp.	Mikkelsen L., Elphinstone J., Funck Jensen D., 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660. http://www.ecn.nl/docs/society/horizontal/Hor_30_plant_pathogens_critical%20_review%20D5.2.pdf Noble R. and Roberts S. J., Eradication of plant pathogens and nematodes during composting: a review, 2004, Plant Pathology, 53, 548–568 Ryckeboer J., Cops S., Coosemans J., "The fate of plant pathogens and seeds during anaerobic digestion and aerobic composting of source separated household wastes" 2002, Compost science and utilisation 10 (3): 204-216
Physical contaminants Glass, Stones, Plastics, Metal	Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste
Odorous chemicals / bioaerosols Methane, SOx, Ammonia, NOx, Bioaerosols	TAG + experts consultation

Figure 3 Hazards master list and key references.

Each hazards class contained individual hazards selected using the same method. This list was sent to the TAG prior to the workshop for amendments and additions. The complete hazard list was used during the workshop where some of the hazards were screened out by the experts. Having assembled a hazard master list, the risk assessment working group filtered these for significance using a rationale presented in Figure 4 below. The screening and prioritisation of hazardous agents using the four filter system was incorporated into a spreadsheet model constructed for the purpose of this exposure assessment and resulted in a subset of principal hazards of concern, irrespective of the waste in which they may be present.

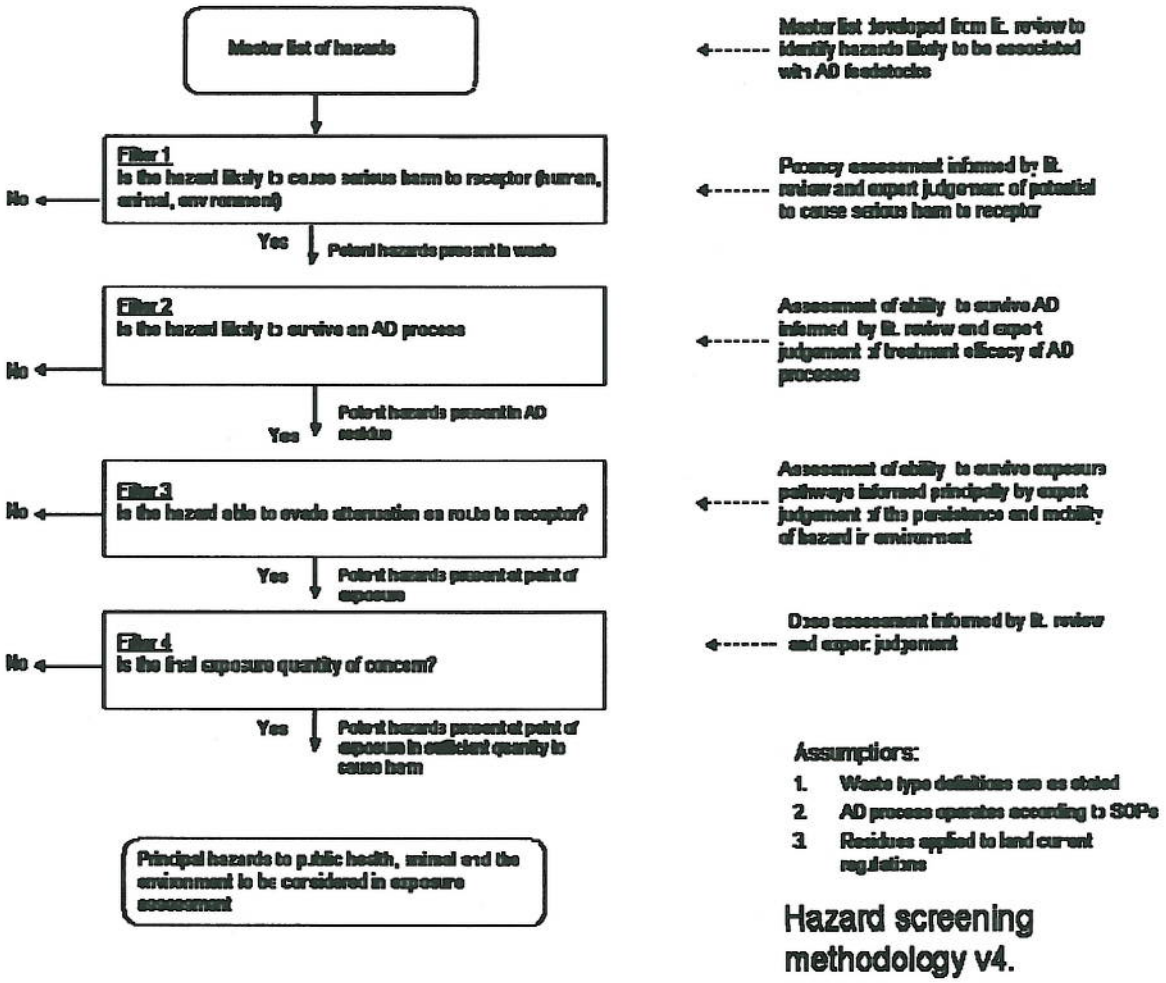

Figure 4 Flow chart for identifying principal hazards from disposal of carcases (adapted from DoH, 2001; Defra, 2007)

The spreadsheet was constructed to allow an automated carryover of those hazards that 'survived' each successive filter. At the end of this stage, only those hazards that were deemed potent (filter 1); and able to survive AD (filter 2); and able to evade attenuation in the environment (filter 3); and able to reach receptors in a sufficient quantity to be of concern (filter 4) remained (see Appendix 5). These were then captured in the spreadsheet under the hazards groupings of PTE's, nutrients, POPs, plant pathogens, weeds, animal and human pathogens, physical contaminants and odorous chemicals for subsequent analysis. Few hazards were screened out by the filters. The TAG and the risk assessment team agreed that at this stage it was prudent to allow the majority of the hazards identified to be considered in the exposure assessment process.

Following this, the analysis considered the extent to which the hazard categories were represented in each of the input waste categories. It is not possible within a generic analysis to consider the composition of each individual waste consignment or the

variability in composition that might be expected within wastes from a particular source. Hence the analysis profiled each waste, with its European Waste Category code, according to the principal categories of hazard within it. The profile of hazards was done by expert judgment of the project team and not by analysis of the wastes. To assess the comparative risk of differing hazards from each waste classification, waste categories [EWCs] were attributed a hazard profile of high [1] or low [0] probability for each category of hazard (see Fig 5). The 0 or 1 scaling is not used to represent the absence or presence of a hazard. Within the model 0s or 1s are used to represent the comparative probability of the presence of groups of hazards at a significant level.

EWC code	Binary score	Decimal	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals
02 01 01	01000111	71	0	1	0	0	0	1	1	1
02 01 02	01000011	67	0	1	0	0	0	0	1	1
02 01 03	01011001	89	0	1	0	1	1	0	0	1
02 01 06	11001111	207	1	1	0	0	1	1	1	1

Figure 5. Extract from Appendix 7 - Hazard combinations and waste profiles. Each EWC code was given a binary score which summarises the hazards posed by that waste type. The code was then transformed into a decimal number which grouped waste with the same binary code and represent the waste profile.

The 0 or 1 coding for each EWC was allocated by expert judgment by the research team. These codes were then presented to the TAG and subsequently were subjected to further independent scrutiny by an expert member of the AD QP TAG. At this stage a small number of minor profile changes were made. It is relevant to note that hazards within these EWC classifications can vary greatly. Such a qualitative approach to determining comparative hazards was inevitable as to provide a more refined coding would have required extensive resources to develop and interpret a normative evidence base of research literature for each hazard category for every EWC waste category code.

The output of this stage of the analysis was a profiling and subsequent grouping of EWC waste categories by reference to their key hazardous constituents (Appendix 7 and 8).

Stage (v) AD waste processing

This research is concerned with the risks posed by the use of AD residues (digestate, liquid or fibre) after treatment. AD renders certain hazards in incoming wastes less harmful, but this does not apply to all of them. A requirement of this research was to consider the extent to which hazards in input waste streams were reduced by AD and then develop subsequent assumptions for the hazards that remain in the residues, post-treatment. The views of the working group and project team informed this assessment, the central question being 'what credit could defensibly be allowed for the reduction of hazards by the AD process'.

Securing consensus on this issue is difficult because there is a range of operational processes and competencies in place and because AD is recognised as a possible waste treatment technology requiring careful process control. In essence, the technologies considered in this analysis (wet/dry, mesophilic/thermophilic, single stage/multistage, batch/continuous), differed only in the extent to which they adopt the optimum temperature profiles of differing microbial communities – mesophiles or thermophiles - and so different operating temperatures. The analysis adopted two sets of conditions – mesophilic conditions (30-45°C) under which, as a reasonable worst case, it was assumed that no hazard categories could be switched from 1 to 0 (despite the fact that individual hazards within a hazard category may be eliminated) reduction occurs; and thermophilic conditions (45-60°C), under which it was assumed that the pathogen hazard category could be removed for some wastes.

For thermophilic conditions, the baseline (mesophilic) hazard profiles generated above were amended by removing all pathogens from the profiles, so presenting a set of lower hazard residues, with exception of some wastes where we judged the concentration of the biological agent to be particularly high.

This approach clearly has limitations as it gives no apparent credit to treatment conducted under mesophilic conditions. The judgement was that unless all of the hazards in a hazard category could be reduced to a level at which there was no significant risk to a sensitive receptor, then that category could not be switched from 1 to 0. To that extent, the assessment was precautionary.

Stage (vi) and (vii) Conceptual model development

Unless the exposure of a receptor to a hazard occurs there can be no risk. The dose received by a receptor is the key determinant of risk. Having developed a subset of significant post treatment hazards above, the next stage was to consider how exposures might occur within the end uses that AD residues are put to. A number of decisions are required:

- what is the full range of exposure pathways associated with all of these end uses – the global set of pathways;
- which of these pathways are relevant for human, animal and environmental (including plant) exposures?
- which pathways are just relevant for certain hazards, because of their specific physico-chemical or biological characteristics?

Firstly, the working group and project team developed a master list of plausible, potential exposure pathways for the residual hazards posed by the AD residues by reference to seven selected end uses:

- Non-ready to eat crops e.g. cereals for human food chain – end use 1
- Grazing & animal feed – end use 2

- Industrial crops (e.g. biomass and silviculture) – end use 3
- Ready to eat crops – end use 4
- Bulbs, cut flowers, garden centre plants – end use 5
- Land restoration and soft landscape applications – end use 6
- Technical uses. e.g. biofilters – end use 7

This resulted in 23 key exposure pathways (e.g. subsurface transport to aquifer, surface transport to surface water ect., see appendix 9). Then, for each end use, a conceptual model of exposure was constructed within the spreadsheet (e.g. subsurface transport to aquifer - public water supply – ingestion of drinking water, see appendix 9). The question is posed 'for a specific end use, are these exposure pathways available, or not, to residual hazards in the AD residue'. Where not, the exposure pathway was switched off in the spreadsheet, indicating the inaccessibility of that individual pathway in that specific end use. For example, the contamination of animal meat and human food chain through the uptake of contaminants of crops they eat is not an available pathway for non-ready to eat crops being grown exclusively for the human food chain (e.g. wheat).

This product of this stage is the Exposure Availability Matrix presented in Appendix 9. The Exposure Pathway Availability Matrix is linked to and provides key information for the semi-quantitative exposure assessment (Stage viiii).

Stage (viii) Semi-quantitative exposure assessment

By this stage, the analysis has developed a suite of significant, residual hazards from feasible waste inputs to AD, considered the impact of treatment on these hazards and developed a suite of exposure pathways for selected end uses. The question remains, 'for exposure pathways that remain available for significant hazards within the AD residues, how likely is exposure to occur?' Returning to the Swiss cheese analogy in Figure 2, that is, how much exposure can pass the layers of the cheese? Two features of the problem are important – how many exposure pathways can be accessed by the hazards and how available is each pathway? This is the critical part of the analysis because it codifies the likelihood of exposure.

The requirement here is, for each waste profile (comprising wastes of a similar hazard makeup) in each of the seven end uses, to rank the relative availability of accessible exposure pathways. Direct pathways of exposure that are readily available pose most risk. The sum of all the pathways across each hazard profile-end use couple provides an indication of the total amount of available exposure for residual hazards of significance. This is a surrogate for risk and can be used subsequently to rank the end uses and identify additional controls in the AD quality protocol.

The project team considered each hazard profile-end use couple in turn and, for the available pathways, ranked the relative availability of the pathway for each hazard category. Pathways were scored 1-4, where a score of:

- 1 indicates a plausible pathways but one of negligible to very low availability;

- 2 represents a plausible pathway of low availability;
- 3 represents a plausible pathway for which there is known evidence and medium availability – it is possible; and
- 4 represents a direct pathway of high availability.

So, for example, the inhalation of odours from the direct use of AD residues is highly likely and ranked as 4 on a scale of 1-4 (see Figure 6).

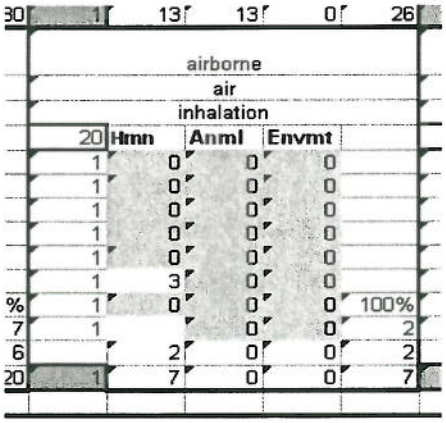

Figure 6. Extract from Appendix 11 Exposure assessment for one hazard profile - end-use couple. Example of ranking matrix table of one of the available pathways (e.g. airbone – air – inhalation) for a hazard profile-end use spreadsheet.

The exposure assessment required the ranking of each available pathway using the 1-4 scale above. In the spreadsheet model, the results sheet shown in Appendix 11 was used as the the basis for doing this. The spreadsheet model facilitated the completion of such an exposure assessment for each of 161 hazard profile – end-use permutations.

These spreadsheets represent the likely availability of various exposure pathways (ingestion, leaching, inhalation, direct contact) to receptors (animals, people, plants, groundwater). By considering the number of exposure routes in total, their availability as represented by a ranked score and the percent contribution of routes that are likely to be available, an assessment of the probability of exposure can be made. Taken together, this allows an assessment of the likelihood of exposure to receptors from the significant hazards remaining after AD treatment of input materials. This then acts as a surrogate for harm.

Stage (ix) Summary metrics and ranking of combinations

The product of each of the 161 hazard profile – end-use specific exposure assessments described above was a series of summary metrics:

- the total number of available pathways, representing the number of opportunities for exposure to occur;
- the total number of medium to high availability pathways, representing the number of opportunities for **significant** exposures to occur;

- the total pathway score for all pathways; a surrogate for the overall likelihood of exposure and accounting for the relative likelihood of all pathways.

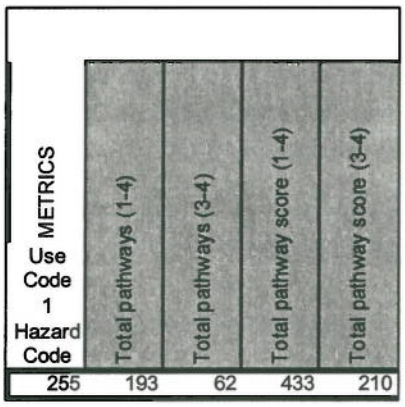

Figure 7. Extract from Appendix 11 Exposure assessment for one hazard profile - end-use couple. Example of the summary matrix of all the available pathways for a hazard profile-end use spreadsheet.

These summary metrics are fundamental components which when assembled and ranked, allow the final ranked risk matrix to be generated for AD outputs in their end use, with the key exposure pathways for the significant residual hazards identified.

4. Results and discussion

Figure 9 sets out a subset of the metrics generated by the exposure assessment. Each row in the table contains the data for one combination of hazard profile and end use. On the right hand-side of the table we present the the total pathway scores (for pathways ranked 3 or 4) for each of the 23 individual exposure. On the left hand side of the table we present a number of summary metrics. The summary metrics are used to rank the matrix and they represent different ways of viewing the potential for exposure. To help readers, we present an extract from the table (see Figure 8) and re-iterate the meaning of the metrics below.

	End use	Total pathway score only 3-4s	Pathways count 3-4	Total available pathways (1-4)	Total pathway score	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
255	4	216	64	193	435	0	12	0	12	0	6	0	0	0	0	24	0	30	8	0	16	4	4	18	7	3	16	56
255	2	210	62	202	441	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	1	210	62	193	433	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	6	192	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
255	3	192	56	181	405	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
207	4	180	53	153	347	0	12	0	12	0	6	0	0	0	0	18	0	24	8	0	10	4	4	12	7	3	12	48
255	5	174	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	0	7	3	16	56

Figure 8. Extract from the Ranked Risk Matrix (Figure 9).

Metrics used in the table

Hazard profile – end use – exposure pathway scores

On the right-hand side of the table and under each of the 23 exposure pathway column headings is a value derived from the exposure assessment. The value represents the score for an individual pathway and is derived from exposure availabilities ranked 3 or 4. The value is a surrogate for probable exposure to the hazards in that waste and end use and it represents those pathways of:

- medium availability (scored 3), that are plausible, known to have occurred but that still harbour barriers, even though some hazards can overcome them; and
- highly availability (scored 4), that are direct exposure pathways like inhalation of odours, direct application to plants, that is short pathways without barriers.

Total pathways (3-4)

This is the total number, as opposed to a score, of the available pathways above, that is those pathways that have received a score of 3 and 4. In terms of the 'Swiss cheese' model this metric simply represents the number of "big" holes in the cheese – the number of opportunities for exposure of medium or high availability.

Total pathway score only 3-4's

This is the grand total of the scores on the right hand side (Figure 9) across all the 23 exposure pathways for a particular hazard profile – end use couple. It is an aggregate measure of pathway availability. It excludes pathways scoring 1 and 2 (very low and low availability). In terms of the Swiss cheese model this metric represents the aggregated area of "big" holes in the cheese. We believe that this is the principal metric to be used for ranking the table and it represents, for each hazard profile end-use couple, the total availability for exposure – the total area of the larger holes, by analogy.

Total available pathways (1-4)

This is the total number of available pathways i.e. those pathways that have received a score of 1 and above. In terms of the Swiss cheese model this metric represents the total number of holes in the cheese (including those that we consider to be relatively insignificant). This metric may not be the best surrogate for likelihood of exposure because it does not capture the significance of the exposure posed by highly available exposure pathways.

Total pathway score (1-4)

This is the sum of the ranked scores for the 23 exposure pathways for a particular hazard profile – end use couple. It is an aggregate measure of total pathway availability. It includes pathways scoring 1 and 2 (very low and low availability) as well as the medium to high availability pathways. As with the total available pathways (1-4), the inclusion of low scoring pathways gives too much weight to relatively unimportant exposure routes and therefore we believe that this is not the best metric to use to rank the table.

Hazard profile – end use – exposure pathway scores

Hazard profile	End use	Total pathway score (3-4)	Total pathways (3-4)	Total pathways (1-4)	Total pathway score (1-4)	Total score for individual pathways (scoring only 3-4)																					
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
255	4	216	64	193	435	0	12	0	12	0	6	0	0	0	0	24	0	30	8	0	16	4	4	18	7	3	16	56
255	2	210	62	202	441	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	1	210	62	193	433	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	6	192	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
255	3	192	56	181	405	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
207	4	180	53	153	347	0	12	0	12	0	6	0	0	0	0	18	0	24	8	0	10	4	4	12	7	3	12	48
255	5	174	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	0	7	3	16	56
207	2	174	51	159	350	0	12	0	12	0	6	0	0	0	0	12	0	24	8	0	10	4	4	12	7	3	12	48
207	1	174	51	153	345	0	12	0	12	0	6	0	0	0	0	12	0	24	8	0	10	4	4	12	7	3	12	48
229	4	165	50	160	348	0	12	0	12	0	6	0	0	0	0	24	0	24	0	0	9	0	0	12	7	3	16	40
207	3	162	47	143	323	0	12	0	12	0	6	0	0	0	0	0	0	24	8	0	10	4	4	12	7	3	12	48
207	6	162	47	143	323	0	12	0	12	0	6	0	0	0	0	0	0	24	8	0	10	4	4	12	7	3	12	48
229	2	159	48	166	351	0	12	0	12	0	6	0	0	0	0	18	0	24	0	0	9	0	0	12	7	3	16	40
229	1	159	48	160	346	0	12	0	12	0	6	0	0	0	0	18	0	24	0	0	9	0	0	12	7	3	16	40
199	4	151	45	131	290	0	12	0	12	0	6	0	0	0	0	18	0	18	8	0	6	0	0	9	7	3	12	40
207	5	150	47	143	323	0	12	0	12	0	6	0	0	0	0	0	0	24	8	0	10	4	4	0	7	3	12	48
79	4	150	44	117	280	0	12	0	12	0	6	0	0	0	0	12	0	18	8	0	7	4	4	9	7	3	8	40
199	2	145	43	135	291	0	12	0	12	0	6	0	0	0	0	12	0	18	8	0	6	0	0	9	7	3	12	40
199	1	145	43	131	288	0	12	0	12	0	6	0	0	0	0	12	0	18	8	0	6	0	0	9	7	3	12	40
79	2	144	42	121	281	0	12	0	12	0	6	0	0	0	0	6	0	18	8	0	7	4	4	9	7	3	8	40
229	3	141	42	152	324	0	12	0	12	0	6	0	0	0	0	0	0	24	0	0	9	0	0	12	7	3	16	40
229	6	141	42	152	324	0	12	0	12	0	6	0	0	0	0	0	0	24	0	0	9	0	0	12	7	3	16	40
93	4	140	42	114	270	0	12	0	12	0	6	0	0	0	0	12	0	18	0	0	10	4	4	12	7	3	8	32
79	3	138	40	109	262	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	7	4	4	9	7	3	8	40
79	6	138	40	109	262	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	7	4	4	9	7	3	8	40
197	4	135	41	124	270	0	12	0	12	0	6	0	0	0	0	18	0	18	0	0	6	0	0	9	7	3	12	32
93	2	134	40	119	272	0	12	0	12	0	6	0	0	0	0	6	0	18	0	0	10	4	4	12	7	3	8	32
93	1	134	40	114	268	0	12	0	12	0	6	0	0	0	0	6	0	18	0	0	10	4	4	12	7	3	8	32
77	4	134	40	110	260	0	12	0	12	0	6	0	0	0	0	12	0	18	0	0	7	4	4	9	7	3	8	32
227	2	133	39	137	287	0	6	0	6	0	0	0	0	0	0	18	0	18	8	0	9	0	0	9	4	3	12	40
227	1	133	39	133	283	0	6	0	6	0	0	0	0	0	0	18	0	18	8	0	9	0	0	9	4	3	12	40
227	4	133	39	133	283	0	6	0	6	0	0	0	0	0	0	18	0	18	8	0	9	0	0	9	4	3	12	40
199	3	133	39	123	270	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	6	0	0	9	7	3	12	40
199	6	133	39	123	270	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	6	0	0	9	7	3	12	40
229	5	129	42	152	324	0	12	0	12	0	6	0	0	0	0	0	0	24	0	0	9	0	0	0	7	3	16	40
79	5	129	40	109	262	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	7	4	4	0	7	3	8	40
197	1	129	39	124	268	0	12	0	12	0	6	0	0	0	0	12	0	18	0	0	6	0	0	9	7	3	12	32
77	2	128	38	114	261	0	12	0	12	0	6	0	0	0	0	6	0	18	0	0	7	4	4	9	7	3	8	32
197	2	129	39	128	271	0	12	0	12	0	6	0	0	0	0	12	0	18	0	0	6	0	0	9	7	3	12	32
93	6	128	38	110	258	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	10	4	4	12	7	3	8	32
77	1	128	38	110	258	0	12	0	12	0	6	0	0	0	0	6	0	18	0	0	7	4	4	9	7	3	8	32
93	3	128	38	108	254	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	10	4	4	12	7	3	8	32
199	5	124	39	123	270	0	12	0	12	0	6	0	0	0	0	0	0	18	8	0	6	0	0	0	7	3	12	40
77	3	122	36	104	244	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	7	4	4	9	7	3	8	32
77	6	122	36	104	244	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	7	4	4	9	7	3	8	32
71	4	121	36	95	223	0	12	0	12	0	6	0	0	0	0	12	0	12	8	0	3	0	0	6	7	3	8	32
165	4	120	36	126	265	0	6	0	6	0	6	0	0	0	0	18	0	18	0	0	6	0	0	9	7	0	12	32
225	2	117	35	130	267	0	6	0	6	0	0	0	0	0	0	18	0	18	0	0	9	0	0	9	4	3	12	32
225	1	117	35	126	263	0	6	0	6	0	0	0	0	0	0	18	0	18	0	0	9	0	0	9	4	3	12	32

Figure 9 Ranked Risk Matrix (ranked according to the summary metric: Total pathway score only 3-4s).

Key: **Hazard profiles coloured**: blue = MAD, orange = TAD and yellow = unchanged waste profiles after TAD.
Hazard profile – end use – exposure pathway scores shading is done using arbitrary ranges for visual effect. Black shading = values >30; dark grey shading = values>20; light grey shading = values>10; no shading = values <10.

Hazard profile	End use	Total pathway score (3-4)	Total pathways (3-4)	Total pathways (1-4)	Total pathway score (1-4)	Total score for individual pathways (scoring only 3-4)																					
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
225	4	117	35	126	263	0	6	0	6	0	0	0	0	0	0	18	0	18	0	0	9	0	0	9	4	3	12	32
79	1	144	42	117	278	0	12	0	12	0	6	0	0	0	0	6	0	18	8	0	7	4	4	9	7	3	8	40
197	3	117	35	118	252	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	6	0	0	9	7	3	12	32
197	6	117	35	118	252	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	6	0	0	9	7	3	12	32
93	5	116	38	110	258	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	10	4	4	0	7	3	8	32
71	2	115	34	97	222	0	12	0	12	0	6	0	0	0	0	6	0	12	8	0	3	0	0	6	7	3	8	32
71	1	115	34	95	221	0	12	0	12	0	6	0	0	0	0	6	0	12	8	0	3	0	0	6	7	3	8	32
227	3	115	33	125	263	0	6	0	6	0	0	0	0	0	0	0	0	18	8	0	9	0	0	9	4	3	12	40
227	6	115	33	125	263	0	6	0	6	0	0	0	0	0	0	0	0	18	8	0	9	0	0	9	4	3	12	40
165	2	114	34	132	268	0	6	0	6	0	6	0	0	0	0	12	0	18	0	0	6	0	0	9	7	0	12	32
165	1	114	34	126	263	0	6	0	6	0	6	0	0	0	0	12	0	18	0	0	6	0	0	9	7	0	12	32
77	5	113	36	104	244	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	7	4	4	0	7	3	8	32
85	4	111	34	92	213	0	12	0	12	0	6	0	0	0	0	12	0	12	0	0	6	0	0	9	7	3	8	24
71	3	109	32	89	209	0	12	0	12	0	6	0	0	0	0	0	0	12	8	0	3	0	0	6	7	3	8	32
71	6	109	32	89	209	0	12	0	12	0	6	0	0	0	0	0	0	12	8	0	3	0	0	6	7	3	8	32
197	5	108	35	118	252	0	12	0	12	0	6	0	0	0	0	0	0	18	0	0	6	0	0	0	7	3	12	32
227	5	106	33	125	263	0	6	0	6	0	0	0	0	0	0	0	0	18	8	0	9	0	0	0	4	3	12	40
85	2	105	32	95	213	0	12	0	12	0	6	0	0	0	0	6	0	12	0	0	6	0	0	9	7	3	8	24
85	1	105	32	92	211	0	12	0	12	0	6	0	0	0	0	6	0	12	0	0	6	0	0	9	7	3	8	24
69	4	105	32	88	203	0	12	0	12	0	6	0	0	0	0	12	0	12	0	0	3	0	0	6	7	3	8	24
255	7	105	29	55	155	0	0	0	0	0	0	0	0	0	0	0	0	30	8	0	0	4	0	0	7	0	0	56
71	5	103	32	89	209	0	12	0	12	0	6	0	0	0	0	0	0	12	8	0	3	0	0	0	7	3	8	32
165	3	102	30	120	247	0	6	0	6	0	6	0	0	0	0	0	0	18	0	0	6	0	0	9	7	0	12	32
165	6	102	30	120	247	0	6	0	6	0	6	0	0	0	0	0	0	18	0	0	6	0	0	9	7	0	12	32
85	6	99	30	90	205	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	6	0	0	9	7	3	8	24
69	2	99	30	90	202	0	12	0	12	0	6	0	0	0	0	6	0	12	0	0	3	0	0	6	7	3	8	24
85	3	99	30	88	201	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	6	0	0	9	7	3	8	24
225	3	99	29	120	245	0	6	0	6	0	0	0	0	0	0	0	0	18	0	0	9	0	0	9	4	3	12	32
225	6	99	29	120	245	0	6	0	6	0	0	0	0	0	0	0	0	18	0	0	9	0	0	9	4	3	12	32
165	5	93	30	120	247	0	6	0	6	0	6	0	0	0	0	0	0	18	0	0	6	0	0	0	7	0	12	32
69	3	93	28	84	191	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	3	0	0	6	7	3	8	24
69	6	93	28	84	191	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	3	0	0	6	7	3	8	24
89	2	92	27	83	188	0	6	0	6	0	0	0	0	0	0	6	0	12	0	0	10	4	4	9	4	3	4	24
89	1	92	27	80	185	0	6	0	6	0	0	0	0	0	0	6	0	12	0	0	10	4	4	9	4	3	4	24
89	4	92	27	80	185	0	6	0	6	0	0	0	0	0	0	6	0	12	0	0	10	4	4	9	4	3	4	24
207	7	91	25	45	129	0	0	0	0	0	0	0	0	0	0	0	0	24	8	0	0	4	0	0	7	0	0	48
85	5	90	30	90	205	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	6	0	0	0	7	3	8	24
225	5	90	29	120	245	0	6	0	6	0	0	0	0	0	0	0	0	18	0	0	9	0	0	0	4	3	12	32
69	5	87	28	84	191	0	12	0	12	0	6	0	0	0	0	0	0	12	0	0	3	0	0	0	7	3	8	24
193	2	87	26	92	187	0	6	0	6	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	3	8	24
193	1	87	26	90	185	0	6	0	6	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	3	8	24
193	4	87	26	90	185	0	6	0	6	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	3	8	24
89	6	86	25	78	179	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	10	4	4	9	4	3	4	24
89	3	86	25	76	175	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	10	4	4	9	4	3	4	24
79	7	77	21	36	107	0	0	0	0	0	0	0	0	0	0	0	0	18	8	0	0	4	0	0	7	0	0	40
193	3	75	22	86	173	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	6	0	0	6	4	3	8	24
89	5	77	25	78	179	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	10	4	4	0	4	3	4	24
193	6	75	22	86	173	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	6	0	0	6	4	3	8	24
67	1	73	21	61	138	0	6	0	6	0	0	0	0	0	0	6	0	6	8	0	3	0	0	3	4	3	4	24
67	2	73	21	61	138	0	6	0	6	0	0	0	0	0	0	6	0	6	8	0	3	0	0	3	4	3	4	24
67	4	73	21	61	138	0	6	0	6	0	0	0	0	0	0	6	0	6	8	0	3	0	0	3	4	3	4	24
199	7	73	20	36	103	0	0	0	0	0	0	0	0	0	0	0	0	18	8	0	0	0	0	0	7	0	0	40
161	2	72	21	96	184	0	0	0	0	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	0	8	24
161	1	72	21	92	180	0	0	0	0	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	0	8	24
69	1	99	30	88	201	0	12	0	12	0	6	0	0	0	0	6	0	12	0	0	3	0	0	6	7	3	8	24

Figure 9. Ranked Risk Matrix (ranked according to the summary metric: Total pathway score only 3-4s).

Hazard profile	End use	Total pathway score (3-4)	Total pathways (3-4)	Total pathways (1-4)	Total pathway score (1-4)	Total score for individual pathways (scoring only 3-4)																					
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
161	4	72	21	92	180	0	0	0	0	0	0	0	0	0	0	12	0	12	0	0	6	0	0	6	4	0	8	24
229	7	71	20	41	111	0	0	0	0	0	0	0	0	0	0	0	0	24	0	0	0	0	0	0	7	0	0	40
227	7	70	19	36	102	0	0	0	0	0	0	0	0	0	0	0	0	18	8	0	0	0	0	0	4	0	0	40
193	5	69	22	86	173	0	6	0	6	0	0	0	0	0	0	0	0	12	0	0	6	0	0	0	4	3	8	24
67	3	67	19	57	130	0	6	0	6	0	0	0	0	0	0	0	0	6	8	0	3	0	0	3	4	3	4	24
67	6	67	19	57	130	0	6	0	6	0	0	0	0	0	0	0	0	6	8	0	3	0	0	3	4	3	4	24
67	5	64	19	57	130	0	6	0	6	0	0	0	0	0	0	0	0	6	8	0	3	0	0	0	4	3	4	24
81	2	63	19	59	129	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	6	0	0	6	4	3	4	16
81	1	63	19	58	128	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	6	0	0	6	4	3	4	16
81	4	63	19	58	128	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	6	0	0	6	4	3	4	16
93	7	61	17	33	93	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	4	0	0	7	0	0	32
77	7	61	17	32	91	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	4	0	0	7	0	0	32
161	3	60	17	88	168	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	6	0	0	6	4	0	8	24
161	6	60	17	88	168	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	6	0	0	6	4	0	8	24
71	7	59	16	27	81	0	0	0	0	0	0	0	0	0	0	0	0	12	8	0	0	0	0	0	7	0	0	32
81	6	57	17	58	126	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	6	0	0	6	4	3	4	16
81	3	57	17	56	122	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	6	0	0	6	4	3	4	16
65	1	57	17	54	118	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	3	0	0	3	4	3	4	16
65	2	57	17	54	118	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	3	0	0	3	4	3	4	16
65	4	57	17	54	118	0	6	0	6	0	0	0	0	0	0	6	0	6	0	0	3	0	0	3	4	3	4	16
197	7	57	16	32	87	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	7	0	0	32
165	7	57	16	32	87	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	7	0	0	32
161	5	54	17	88	168	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	6	0	0	0	4	0	8	24
225	7	54	15	32	86	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	4	0	0	32
81	5	51	17	58	126	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	6	0	0	0	4	3	4	16
65	3	51	15	52	112	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	3	0	0	3	4	3	4	16
65	6	51	15	52	112	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	3	0	0	3	4	3	4	16
65	5	48	15	52	112	0	6	0	6	0	0	0	0	0	0	0	0	6	0	0	3	0	0	0	4	3	4	16
89	7	44	12	24	68	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	4	0	0	4	0	0	24
85	7	43	12	24	67	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	7	0	0	24
69	7	43	12	23	65	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	7	0	0	24
67	7	42	11	18	56	0	0	0	0	0	0	0	0	0	0	0	0	6	8	0	0	0	0	0	4	0	0	24
193	7	40	11	23	62	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	4	0	0	24
161	7	40	11	23	62	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	4	0	0	24
3	1	28	7	27	55	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	2	28	7	27	55	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	4	28	7	27	55	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	3	28	7	25	53	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	5	28	7	25	53	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	6	28	7	25	53	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
3	7	28	7	9	32	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	4	0	0	16
81	7	26	7	15	42	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	4	0	0	16
65	7	26	7	14	40	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	4	0	0	16
1	1	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	2	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	3	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	4	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	5	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	6	12	3	20	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8
1	7	12	3	5	16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	8

Figure 9. Ranked Risk Matrix (ranked according to the summary metric: Total pathway score only 3-4s).

Shading has been applied to the columns containing the scores for the 23 exposure pathways to help with the visualisation of patterns. The boxes with the highest scores are shaded in the darkest colour. Boxes with lower scores are shaded in lighter colours

or are left unshaded. This shading is based on an arbitrary scale and has been done to aid the reader to see trends in the results and help identify the key drivers of exposure for each scenario.

It is clear from Figure 9 that certain pathways consistently received higher scores than others, as one would both expect and deduce from common knowledge. Examples include pathways 23 (direct ingestion of AD residues); pathway 13 (ingestion of soil contaminated with AD residues); pathways 2 and 4 (contamination of private water supplies by surface and subsurface routes); and pathway 11 (ingestion of contaminated crops). This is a consequence of the application of the descriptors of pathway availability described in Section 3 Stage viii. These pathways were considered to be of relatively high availability. By contrast pathways 1 & 3 (contamination of public water supplies by surface and subsurface routes) were never assigned scores of 3 or 4 (high availability). In this case the judgement was made that a longer flow path and greater level of process control is likely to reduce pathway availability when compared to the private water supply example. This analysis highlights pathways of particular concern that may be candidates for active risk management during the AD QP.

Additional information on pathways of concern can be derived from the table in Appendix 12 (Ratio of Available Pathways High and Medium). This table presents the extent to which exposure assessment decisions were driven by pathways assigned an availability score of 3 or 4; that is, the proportion of exposures for a given pathway judged to be highly available. This additional analysis is valuable in that some of the exposure pathways involve a small number of hazards and therefore are unlikely to receive large aggregate scores. The contact with plant tissue pathway (16) is a good example. In Figure 9, pathway 16 is not highlighted strongly whereas in the table in Appendix 12 it is. We infer from this that pathway 16 contributes relatively little to the summary metrics like Total Pathway Score (3-4) but that it remains one of the important pathways of concern. This example highlights the need to consider more than one metric when interpreting the exposure assessment.

We move onto the ranking. The hazard profile – end use couples are ranked using the magnitude of the Total Pathway Score (3-4). Hazard profile – end use couples with the highest score for this summary metric have the greatest number of highly available pathways and as such pose the greatest potential exposure. The first column in the table denotes the hazard profile. Certain hazard profiles are clustered at the top of the table (i.e. present the greatest aggregate likelihood of exposure); for example profiles 255, 207, 229 and 199. This clustering indicates that the principal factor influencing the Total Pathway Score (3-4) is the hazard profile. Put simply, wastes judged to contain a wide spectrum of significant residual hazards at a significant concentration present the the greatest opportunity for exposure of sensitive receptors, as one would intuitively expect.

This is exemplified by the 'control' hazard profile 255. No such waste fits this profile. It is a 'catch-all' profile where all of the hazard categories are arbitrarily switched on. Hazard profiles 207 and 199 are examples of wastes with a high content of animal faeces. Hazard profile 229 is an example of a leather industry waste. Hazard profiles 1

and 3 appear towards the bottom of the table. These are wastes derived from wood processing and were assigned low status across the hazard profile.

ABP wastes were assigned low values for biological agents, as it was assumed that they had been subject to an effective pasteurisation step. As such, these wastes were represented by hazard profiles (e.g. 65 and 67) which are ranked lower in the the table.

The application of a thermophilic AD process resulted in some wastes being assigned a new, less hazardous waste profile. For example, in the application of thermophilic AD to green waste, the human and animal pathogens were "switched off" producing a new, less hazardous waste profile. This results in a lower ranking for the post AD waste (profile 89) than the pre AD waste (profile 93). In other cases, the application of a high temperature (thermophilic) AD process has no effect on the waste profile as we were insufficiently confident (based on literature review and available expert evidence) to change the hazard profile in cases where the content of biological agents in the feedstock was judged to be very high.

Which hazardous agents are we concerned about?

For users of this analysis, the questions arises, for highly ranked hazard profile-end uses in Figure 9, which hazards should we be concerned about? The AD QP affords potential opportunities to exclude certain wastes on the basis of their content. The answer to this lies in the hazard screening exercise. Whilst each of the European Waste Catalogue (EWC) categories has been assigned a hazard profile based on its likely constituents across a range of hazards (called here a 'hazard profile'), which individual hazardous agents in each of the constituent groups should we reserve concern for? The answer is provided by those hazardous agents in Appendix 5. Appendix 5 represents those hazardous agents passing the hazard screening process within this work; that is those agents that are judged to:

- be potent toxic agents; and
- have the potential to evade destruction in AD processes; and
- be capable of moving distances within the environment; and
- be capable of presenting themselves to a receptor of concern at a sufficient dose to cause potential harm.

Which end uses should we be concerned about?

In all considerations of exposure, it is critical to remember that without a dose, there can be no risk. And so the end uses of greatest concern in this study will be those where there is the potential for significant exposures to occur. Figure 9 offers some guidance. Scanning across and down the 23 exposure pathways, we can identify those end uses where the potential for exposure is higher, denoted by the higher scores. End uses that allow access to (consistently shaded) pathways 2, 4, 11, 13, 16, 19, 22 and 23 offer greater opportunities for exposure. Figure 9 provides further information on the end uses of concern. As noted previously, the principal factor influencing the Total Pathway Score (3-4) is the hazard profile. However, if we look at the rankings for the seven end

uses associated with each hazard profile we see a common pattern. Below (Figure 10) is an extract from Figure 9 showing the top seven rows of the risk matrix. As stated earlier, end uses coupled with hazard profile 255 are found at the top of the table.

	End use	Total pathway score only 3-4s	Pathways count 3-4	Total available pathways (1-4)	Total pathway score	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
255	4	216	64	193	435	0	12	0	12	0	6	0	0	0	0	24	0	30	8	0	16	4	4	18	7	3	16	56
255	2	210	62	202	441	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	1	210	62	193	433	0	12	0	12	0	6	0	0	0	0	18	0	30	8	0	16	4	4	18	7	3	16	56
255	6	192	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
255	3	192	56	181	405	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	18	7	3	16	56
207	4	180	53	153	347	0	12	0	12	0	6	0	0	0	0	18	0	24	8	0	10	4	4	12	7	3	12	48
255	5	174	56	183	409	0	12	0	12	0	6	0	0	0	0	0	0	30	8	0	16	4	4	0	7	3	16	56

Figure 10. Extract from the Ranked Risk Matrix (Figure 9).

You will see that end use 4 (ready to eat crops) tops the table, followed by end use 2 (grazing & animal feed) and end use 1 (non-ready to eat crops). All of these land uses are linked to the human food chain. End uses 6 (land restoration), 3 (industrial crops) and 5 (bulbs, cut flowers, nursery stock) appear lower in the ranking. This pattern is repeated (with some minor variations in order) for the other hazard profiles in Figure 9. Again, this ranking is what would be expected from common knowledge and suggests a need to impose greater risk management controls on end uses associated with the human food chain. End use 7 does not appear in this extract. This is because the rankings for end use 7 (technical uses e.g. biofilters) generally appeared lower down the risk matrix. This highlights the fact that some end uses are intrinsically less risky than others and may require less stringent control.

5. Conclusions

This study is a generalised exposure assessment for the application of AD residues in various end uses. The residues have been assessed by reference to hazardous constituents in the input waste streams for AD treatment as single waste inputs. The study has been conducted to inform the development of an AD Quality Protocol (QP) in consultation with the technical advisory group (TAG) established by WRAP for this specific purpose. The AD QP is the means by which risks will be managed and this study identifies the key waste streams, exposure pathways and end uses of concern through codifying rational and, where possible, evidenced judgements about the likelihood and significance of exposure to physical, chemical and biological hazards. The main results of this study are presented in Figure 9. Here, a series of metrics are used as surrogates for the likelihood of exposure through these routes.

Before discussing the conclusions, it is worth noting what the study does <u>not</u> do, so to avoid misuse of the results. The study does not:

- advise on site-specific exposures from the use of AD residues;
- address waste mixtures;
- distinguish between waste technologies other than in their capacity to reduce pathogens and weed propagules at temperature;
- prescribe the quality protocol;
- account for local environmental settings.

Recall there can be no risk without exposure, or 'the dose makes the poison'. That is, for a human, animal, plant or environment feature such as a river to be affected and suffer harm, hazardous agents must reach them at a dose sufficient to be of concern. The worst case situation, though improbable, is likely to be where people ingest AD residues directly because they are directly exposed to hazardous constituents without significant attenuation. Along with the ready availability of exposure pathways, the other key determinants of risk are the potency of the hazard (how inherently toxic it is) and the sensitivity of the receptor, the latter being a site-specific factor beyond our consideration here.

In summary, we reserve most concern for situations where significant hazards are readily available to receptors. That is, where potent, hazardous constituents in input streams remain unaffected by AD treatment and can migrate through the environment in sufficient quantities to cause harm. Opportunities for this are few, other than where there is direct, unattenuated exposure.

We conclude from our analysis:

1. The hazard profile (i.e. the characteristics of different wastes) is the principal variable that governs the exposure ranking. That is, the more hazardous the input stream, the greater the concern. Our control, the "catch-all" hazard profile 255, tops the ranked matrix. No wastes were assigned this hazard profile.

2. Hazard profiles 207 (animal faeces, urine, manure – EWC 020106 with mesophilic treatment or pre-digestion) and 199 (animal faeces, urine, manure – EWC 020106 post thermophilic) that represent wastes with a high proportion of animal faeces appear towards the top of the table. This happens due to the fact that the material has not been pasteurised. Hazard profiles representing wastes derived from the leather industry (229 ECW 040105 and 040107 & 197 ECW 040101) were ranked highly in the table, corresponding to a higher aggregate exposure potential.

3. Those pathways judged to present the greatest opportunity for exposure were pathways 23 (direct ingestion of AD residues) and pathway 13 (ingestion of soil contaminated with AD residues). Other highly available pathways were 2 & 4 (contamination of private water supplies by surface and subsurface routes) and 11 (ingestion of contaminated crops). Such pathways of high availability (e.g. the direct ingestion of a product) have no significant barriers to exposure to certain hazards. This finding provides a basis for identifying priorities for the control of exposure pathways of concern.

4. Whilst hazard profile is the principal variable governing exposure ranking, end use consistently affects ranking where single hazard profiles are considered. The end uses that received the highest exposure ranking were ready to eat crops (end use 4) and grazing and animal feed (end use 2). This is because these end uses offer the highest number of available pathways

These conclusions offer insights into where control might be most effective; through the exclusion of certain waste types or categories, through the application of codes of practice backed up by the quality protocol for specific exposure routes and through specific attention being given to certain end uses.

6. References and bibliography

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Appendices

Appendix 1: Members of AD QP TAG and risk assessment working group

Suzanne Laidlaw	Environment Agency
Nina Sweet	Environment Agency (seconded to WRAP)
Richard Swannell	Waste Resources and Action Programme (WRAP)
Sarah Clayton	Waste Resources and Action Programme (WRAP)
Iain Notman	Department for the Environment, Food and Rural Affairs (Defra)
Aoife O'Sullivan	Welsh Assembly Government
Peter Olsen	Scottish Environment Protection Agency (SEPA)
Tony Osbourne	Department of Energy, Northern Ireland
Justin French-Brooks	Environmental Services Association (ESA)
Jane Gilbert	Composting Association
David Collins	Renewable Energy Association (REA)
Vicky Heslop	AD Technical Specialist
Kate Lister	Biogen
Emily Nichols	The Composting Association
Victoria Sturt	Environment Agency
Hannah Lawrie	Hyder consulting
Simon Pollard	Cranfield University
Phil Longhurst	Cranfield University
Sean Tyrell	Cranfield University
Raffaella Villa	Cranfield University
Adrian Jones	Welsh Assembly Government
Roger Unwin	Consultant
Brian Chambers	ADAS
Lucy Lewis	Greenfinch Ltd.
Sandra Esteves	University of Glamorgan

Appendix 2: EWC Waste Categories suitable for AD treatment

The list was provided by the AD QP TAG. Some of the waste were removed by Dr Nina Sweet because regulated elsewhere (i.e. sludges) or not suitable for AD processes.

EWC No	Category	Types of Waste
02	WASTES FROM AGRICULTURAL, HORTICULTURAL, HUNTING, FISHING AND AQUACULTURAL PRIMARY PRODUCTION, FOOD PREPARATION AND PROCESSING	
02 01	Primary Food Production Wastes	
02 01 01	Sludges from washing & cleaning	– Food processing waste, food washing waste
02 01 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste – Category 2 ABP – paunch contents
02 01 03	Plant tissue waste	– Husks, cereal dust, waste animal feeds
02 01 06	Animal faeces, urine, manure including spoiled straw, collected separately and treated off site	– Poultry droppings – Pig & Cattle Slurry – Manure – Old Straw
02 01 07	Wastes from Forestry	– Green waste, plant tissue
02 01 99	Non specified	– Residues from commercial mushroom cultivation
02 02	Wastes from preparation and processing of meat, fish and other foods of animal origin	
02 02 01	Sludges from washing & cleaning	– Process water – Food washing waste
02 02 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste
02 02 03	Materials unsuitable for consumption or processing	– Coffee, food processing waste, Jam, Kitchen Waste, fruit, vegetable oil, tobacco, tea, vegetable waste – Waste fat from processing of meat or fish
02 02 99	Non specified[1]	– Sludges from gelatine production – Animal gut contents
02 03	Wastes from fruit, vegetables, cereals, edible oils. Cocoa, tea & tobacco preparation and processing; conserve production	
02 03 01	Sludges from washing, cleaning, peeling, centrifuging and separation	– Sludge from food processing – Starch Sludge
02 03 02	Sludges from washing, cleaning peeling, centrifuging & separation	– Coffee, mushroom compost, food processing waste, food washing waste, tobacco

[1] "Non specified" categories are included in each section to allow additional categories of feedstocks

Appendix 2: EWC waste categories suitable for AD treatment

EWC No	Category	Types of Waste
02 03 04	Materials unsuitable for consumption or processing	– Out of date foodstuffs – Tinning process residues – Tobacco dust, veins, sludge – Defective cigarette batches – Residues from processing coffee, tea, cocoa – Oilseed residues
02 03 05	Effluent from the processes referred to in sources of waste	–
02 03 99	Non specified	– Sludge from production of edible fats & oils – Seasoning residues – Molasses residues – Residues from production of potato, corn or rice starch
02 04	**Wastes from Sugar processing**	
02 04 03	Sludges from on-site effluent treatment	– Biological sludge
02 04 99	other biodegradeable wastes	–
02 05	**Wastes from dairy products industry**	
02 05 01	Materials unsuitable for consumption or processing	– Solid & Liquid dairy products, milk, food processing wastes, yoghurt, whey
02 05 02	Sludges from on-site effluent treatment	– As above in sludge form
02 06	**Wastes from baking and confectionary industry**	
02 06 01	Materials unsuitable for consumption or processing	– Food condemned, food processing wastes, biscuits, chocolate, yeast, bread, bakery wastes
02 06 03	Sludges from on-site effluent treatment	– As above in sludge form
02 07	**Wastes from production of alcoholic and non-alcoholic beverages (except tea, coffee)**	
02 07 01	Wastes from washing, cleaning & mechanical reduction of raw materials	– Brewing waste, food processing waste, fermentation waste
02 07 02	Wastes from spirits distillation	– Spent grains, fruit and potato pulp – Sludge from distilleries
02 07 04	Materials unsuitable for consumption or processing	Brewing waste, food processing waste, fermentation waste, beer, alcoholic drinks, fruit juice stored for too long
02 07 99	Non specified	– Malt husks, malt sprouts, malt dust – Spent hops – Lees & sludge from breweries – Sludge from wine making – Yeast and yeast-like residues

Appendix 2: EWC waste categories suitable for AD treatment

EWC No	Category	Types of Waste
03	WASTES FROM WOOD PROCESSING AND THE PRODUCTION OF PAPER, CARDBOARD, PULP, PANELS & FURNITURE	
03 03	Wastes from pulp, paper and cardboard production & processing	
03 03 02	Green liquor sludge	– Paper sludge, green liquor
03 03 08	Wastes from sorting of paper and cardboard destined for re-cycling	– Cardboard, newspaper, tissues, paper
03 03 10	Fibre rejects & sludges	– Paper pulp (de-inked only), paper fibre
04 01 01	Wastes from leather industry –	– Fleshings
04 01 05		– Tanning liquor free of chromium
04 01 07		– Sludges not containing chromium
04 02 10	Wastes from the textile industry	– Organic matter from natural products e.g. grease, wax
15 01 01	Packaging	– Paper and cardboard packaging
19		
19 05	Wastes from the aerobic treatment of wastes (source separated)	
19 06	Wastes from the anaerobic treatment of wastes (source separated)	
19 08 09		– Grease & oil mixture containing only edible oils & fats
19 08 12		– Sludge from industrial biological treatment
20	MUNICIPAL WASTES & SIMILAR COMMERCIAL, INDUSTRUAL & INSTITUTIONAL WASTES INCLUDING SEPARATELY COLLECTED FRACTIONS	
20 01	Separately collected fractions	
20 01 01	Paper & Cardboard	– Cardboard, newspaper, office paper, paper towels, tissues – only soiled materials where recycling not possible – high gloss papers and toxic dyes excluded
20 01 08	Biodegradable kitchen and canteen waste	– Kitchen waste from canteens, restaurants, dairy products (liquid and solid) canteen waste, beer, biscuits, chocolates, alcoholic and non-alcoholic drinks
20 01 25	Edible Oil & Fat	– Cooking oil, animal fat
20 02	Garden & Park Wastes (including cemetery waste)	
20 02 01	Biodegradable Waste	Animal faeces, manure, garden waste, green waste, horticultural waste, plant tissue, parks and garden waste, hedge & tree trimmings, grass cuttings and leafy materials
20 03	Other Municipal Wastes	
20 03 01	Mixed Municipal Waste	– separately collected biowastes from private households and small businesses
20 03 02	Waste from Markets	– Waste from Markets which has been source separated

Appendix 3: List of waste hazard profiles

The tables contain the EWC waste code and waste description and the waste profile obtained for the risk analysis pre-treatment (mesophilic) and post-treatment (thermophilic).

Pre-treatment and mesophilic

Waste hazard profile	EWC Code	Waste description	
71	02 01 01	Sludges from washing & cleaning	– Food processing waste, food washing waste
67	02 01 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste – Category 2 ABP – paunch contents
89	02 01 03	Plant tissue waste	– Husks, cereal dust, waste animal feeds
207	02 01 06	Animal faeces, urine, manure including spoiled straw, collected separately and treated off site	– Poultry droppings – Pig & Cattle Slurry – Manure – Old Straw
89	02 01 07	Wastes from Forestry	– Green waste, plant tissue
65	02 01 99	Non specified	– Residues from commercial mushroom cultivation
69	02 02 01	Sludges from washing & cleaning	– Process water – Food washing waste
69	02 02 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste
71	02 02 03	Materials unsuitable for consumption or processing	– Coffee, food processing waste, Jam, Kitchen Waste, fruit, vegetable oil, tobacco, tea, vegetable waste – Waste fat from processing of meat or fish
69	02 02 99	Non specified[2]	– Sludges from gelatine production – Animal gut contents
65	02 03 01	Sludges from washing, cleaning, peeling, centrifuging and separation	– Sludge from food processing – Starch Sludge
89	02 03 02	Sludges from washing, cleaning peeling, centrifuging & separation	– Coffee, mushroom compost, food processing waste, food washing waste, tobacco

Appendix 3: List of waste hazard profiles

[2] "Non specified" categories are included in each section to allow additional categories of feedstocks

Waste hazard profile	EWC Code	Waste description	
89	02 03 04	Materials unsuitable for consumption or processing	– Out of date foodstuffs – Tinning process residues – Tobacco dust, veins, sludge – Defective cigarette batches – Residues from processing coffee, tea, cocoa – Oilseed residues
89	02 03 05	Effluent from the processes referred to in sources of waste	–
89	02 03 99	Non specified	– Sludge from production of edible fats & oils – Seasoning residues – Molasses residues – Residues from production of potato, corn or rice starch
85	02 04 03	Sludges from on-site effluent treatment	– Biological sludge
85	02 04 99	other biodegradeable wastes	–
69	02 05 01	Materials unsuitable for consumption or processing	– Solid & Liquid dairy products, milk, food processing wastes, yoghurt, whey
69	02 05 02	Sludges from on-site effluent treatment	– As above in sludge form
69	02 06 01	Materials unsuitable for consumption or processing	– Food condemned, food processing wastes, biscuits, chocolate, yeast, bread, bakery wastes
85	02 06 03	Sludges from on-site effluent treatment	– As above in sludge form
65	02 07 01	Wastes from washing, cleaning & mechanical reduction of raw materials	– Brewing waste, food processing waste, fermentation waste
65	02 07 02	Wastes from spirits distillation	– Spent grains, fruit and potato pulp – Sludge from distilleries
65	02 07 04	Materials unsuitable for consumption or processing	Brewing waste, food processing waste, fermentation waste, beer, alcoholic drinks, fruit juice stored for too long
65	02 07 99	Non specified	– Malt husks, malt sprouts, malt dust – Spent hops – Lees & sludge from breweries – Sludge from wine making – Yeast and yeast-like residues
1	03 03 02	Green liquor sludge	– Paper sludge, green liquor

Appendix 3: List of waste hazard profiles

Waste hazard profile	EWC Code	Waste description	
161	03 03 08	Wastes from sorting of paper and cardboard destined for re-cycling	– Cardboard, newspaper, tissues, paper
161	03 03 10	Fibre rejects & sludges	– Paper pulp (de-inked only), paper fibre
197	04 01 01	Wastes from leather industry –	– Fleshings
229	04 01 05		– Tanning liquor free of chromium
229	04 01 07		– Sludges not containing chromium
69	04 02 10	Wastes from the textile industry	– Organic matter from natural products e.g. grease, wax
65	04 02 21	Wastes from unprocessed textile fibres	
65	04 02 22	Wastes from processed textile fibres	
225	07 06 10	Other filters cakes and spent adsorbants	
67	15 01 01	Packaging	– Paper and cardboard packaging
67	15 01 02	Plastic packaging	Starch based
67	15 01 03	Wooden packaging	Only if any non-bio coating or preserving substance present
67	15 01 09	Textile packaging	
65	19 08 09		– Grease & oil mixture containing only edible oils & fats
225	19 08 12		Sludge from industrial biological treatment
227	20 01 01	Paper & Cardboard	– Cardboard, newspaper, office paper, paper towels, tissues – only soiled materials where recycling not possible – high gloss papers and toxic dyes excluded
67	20 01 08	Biodegradable kitchen and canteen waste	– Kitchen waste from canteens, restaurants, dairy products (liquid and solid) canteen waste, beer, biscuits, chocolates, alcoholic and non-alcoholic drinks
65	20 01 25	Edible Oil & Fat	– Cooking oil, animal fat
255	20 01 99	Other fraction of municipal waste not otherwise specified	
93	20 02 01	Biodegradable Waste	– Animal faeces, manure, garden waste, green waste, horticultural waste, plant tissue, parks and garden waste, hedge & tree trimmings, grass cuttings and leafy materials (Tree trunks, branches and other material high in lignin, should be removed, because of resistance to digestion)
69	20 03 01	Mixed Municipal Waste	– separately collected biowastes from private households and small businesses
89	20 03 02	Waste from Markets	– Waste from Markets which has been source separated

Post-treatment thermopilic

Waste Hazard profile	EWC Code	Waste description	
67	02 01 01	Sludges from washing & cleaning	– Food processing waste, food washing waste
67	02 01 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste – Category 2 ABP – paunch contents
89	02 01 03	Plant tissue waste	– Husks, cereal dust, waste animal feeds
199	02 01 06	Animal faeces, urine, manure including spoiled straw, collected separately and treated off site	– Poultry droppings – Pig & Cattle Slurry – Manure – Old Straw
89	02 01 07	Wastes from Forestry	– Green waste, plant tissue
65	02 01 99	Non specified	– Residues from commercial mushroom cultivation
65	02 02 01	Sludges from washing & cleaning	– Process water – Food washing waste
65	02 02 02	Animal tissue waste	– Category 3 Animal By Products including: – Blood, animal flesh, fish processing waste, fish carcasses, poultry waste
71	02 02 03	Materials unsuitable for consumption or processing	– Coffee, food processing waste, Jam, Kitchen Waste, fruit, vegetable oil, tobacco, tea, vegetable waste – Waste fat from processing of meat or fish
	02 02 04	Sludges from on site waste effluent treatment	–
69	02 02 99	Non specified[3]	– Sludges from gelatine production – Animal gut contents
65	02 03 01	Sludges from washing, cleaning, peeling, centrifuging and separation	– Sludge from food processing – Starch Sludge
89	02 03 02	Sludges from washing, cleaning peeling, centrifuging & separation	– Coffee, mushroom compost, food processing waste, food washing waste, tobacco
81	02 03 04	Materials unsuitable for consumption or processing	– Out of date foodstuffs – Tinning process residues – Tobacco dust, veins, sludge – Defective cigarette batches – Residues from processing coffee, tea, cocoa – Oilseed residues
81	02 03 05	Effluent from the processes referred to in sources of waste	
81	02 03 99	Non specified	– Sludge from production of edible fats & oils – Seasoning residues – Molasses residues – Residues from production of potato, corn or rice starch

Appendix 3: List of waste hazard profiles

[3] "Non specified" categories are included in each section to allow additional categories of feedstocks

Waste Hazard profile	EWC Code	Waste description	
81	02 04 03	Sludges from on-site effluent treatment	– Biological sludge
85	02 04 99	other biodegradeable wastes	–
65	02 05 01	Materials unsuitable for consumption or processing	– Solid & Liquid dairy products, milk, food processing wastes, yoghurt, whey
65	02 05 02	Sludges from on-site effluent treatment	– As above in sludge form
65	02 06 01	Materials unsuitable for consumption or processing	– Food condemned, food processing wastes, biscuits, chocolate, yeast, bread, bakery wastes
81	02 06 03	Sludges from on-site effluent treatment	– As above in sludge form
65	02 07 01	Wastes from washing, cleaning & mechanical reduction of raw materials	– Brewing waste, food processing waste, fermentation waste
65	02 07 02	Wastes from spirits distillation	– Spent grains, fruit and potato pulp – Sludge from distilleries
65	02 07 04	Materials unsuitable for consumption or processing	Brewing waste, food processing waste, fermentation waste, beer, alcoholic drinks, fruit juice stored for too long
81	02 07 05	Sludges from washing, cleaning, peeling, centrifuging and separation	– Sludge from food processing – Starch Sludge
65	02 07 99	Non specified	– Malt husks, malt sprouts, malt dust – Spent hops – Lees & sludge from breweries – Sludge from wine making – Yeast and yeast-like residues
3	03 01 01	Waste bark and cork	
3	03 01 05	Sawdust, shavings, cuttings	
3	03 03 01	Waste bark and wood	
1	03 03 02	Green liquor sludge	– Paper sludge, green liquor
3	03 03 07		
161	03 03 08	Wastes from sorting of paper and cardboard destined for re-cycling	– Cardboard, newspaper, tissues, paper
161	03 03 10	Fibre rejects & sludges	– Paper pulp (de-inked only), paper fibre
161	03 03 11		
193	04 01 01	Wastes from leather industry –	– Fleshings
225	04 01 05		– Tanning liquor free of chromium
225	04 01 07		– Sludges not containing chromium
65	04 02 10	Wastes from the textile industry	– Organic matter from natural products e.g. grease, wax
65	04 02 21	Wastes from unprocessed textile fibres	

Appendix 3: List of waste hazard profiles

Waste Hazard profile	EWC Code	Waste description	
65	04 02 22	Wastes from processed textile fibres	
225	07 06 10	Other filters cakes and spent adsorbants	
67	15 01 01	Packaging	– Paper and cardboard packaging
67	15 01 02	Plastic packaging	Starch based
67	15 01 03	Wooden packaging	Only if any non-bio coating or preserving substance present
67	15 01 09	Textile packaging	
65	19 08 09		– Grease & oil mixture containing only edible oils & fats
225	19 08 14	Sludges from other treatment of industrial waste water (not containing dangerous substances)	
227	20 01 01	Paper & Cardboard	– Cardboard, newspaper, office paper, paper towels, tissues – only soiled materials where recycling not possible – high gloss papers and toxic dyes excluded
67	20 01 08	Biodegradable kitchen and canteen waste	– Kitchen waste from canteens, restaurants, dairy products (liquid and solid) canteen waste, beer, biscuits, chocolates, alcoholic and non-alcoholic drinks
65	20 01 25	Edible Oil & Fat	– Cooking oil, animal fat
255	20 01 99	Other fraction of municipal waste not otherwise specified	
89	20 02 01	Biodegradable Waste	– Animal faeces, manure, garden waste, green waste, horticultural waste, plant tissue, parks and garden waste, hedge & tree trimmings, grass cuttings and leafy materials (Tree trunks, branches and other material high in lignin, should be removed, because of resistance to digestion)
69	20 03 01	Mixed Municipal Waste	– separately collected biowastes from private households and small businesses
81	20 03 02	Waste from Markets	– Waste from Markets which has been source separated

Appendix 4: Hazard master list

Potential Toxic Elements (PTEs)

Cd,
Cr,
Pb,
Hg,
Ni,
As,
Ba,
Zn,
Cu,

Nutrients

N03
NH4
P
K
Micronutrients
BOD

Organic pollutants

PAHs
DEPH
LAS
NP and NPE
PCBs
PCDD
Antibiotics
Pesticides,
Disinfectants
Inks

Plant pathogens

Fusarium oxysporum spp
Phytophtora spp.
Pythium spp.
Plasmodiophora brassicae
Rhizoctonia solani
Thielaviopsos basicola
Verticillium dahliae
Xanthomonas spp.
Microdochium nivale
Armillaria mellia
Pepino Mosaic Virus
Tobacco Mosaic Virus
Tobacco rattle Virus,
Sclerotium cepivorum
Nematodes (*Globodera*)
Streptomyces spp.
Pseudomonas spp.

Invasive weeds / exotic species / plant toxins

Ragwort
Yew

Animal and human pathogens

Salmonella sp.
Streptococcus sp.
E. coli sp.,
E. coli O157:H
Enteric viruses
Bacillus sp.
Cryptosporidium sp.
BSE
Q-Fever (*Coxiella burnetii*)
Ringworm
Leptospirosis (*Leptospira* sp.)
M. bovis (Tuberculosis)
Psittacosis (*Chlamydia* sp.)
Giarda entamoeba
Staphylococcus aureus
Campylobacter sp.
Mycobacterium paratuberculosis
Clostridium perfringens/botulinum
Ascaris suum
Foot and Mouth Disease
Swine Fever
Pasteurellosis
Tapeworm
Toxocariasis
Toxoplasmosis
Trichinosis
Yersiniosis
Listeriosis
Brucella abortus (Brucellosis)

Physical contaminants

Glass
Stones
Plastic
Metal

Odorous chemicals / bioaerosols

Methane
SOx
Ammonia
NOx
Bioaerosols

Appendix 5: Application of filters to hazard master list

	Filter 4
	Is the final exposure quantity of concern?
Hazards passing Filter 3	**DOSE?**
	Filter 4
PTEs	
Cd	Cd,
Cr	
Pb,	Pb,
Hg	Hg,
Ni	Ni,
As	As,
Ba	
Zn	Zn,
Cu	Cu,
Nutrients	
N03	N03,
NH4	NH4,
P	P
K	
Micronutrients	Micronutrients,
BOD	BOD,
Organic pollutants	
PAHs	
DEPH	DEHP,
LAS	
NP and NPE	
PCBs	
PCDD	
Antibiotics	
Pesticides	
Disinfectants	
Inks	
Plant pathogens	
Fusarium oxysporum spp	*Fusarium oxysporum* spp.
Phytophtora spp.	*Phytophtora* spp.
Pythium spp.	*Pythium* spp.,
Plasmodiophora brassicae	*Plasmodiophora brassicae*
Rhizoctonia solani	*Rhizoctonia solani*
Thielaviopsos basicola	*Thielaviopsos basicola*
Verticillium dahliae	*Verticillium dahliae*
Xanthomonas spp.	*Xanthomonas* spp.
Microdochium nivale	*Microdochium nivale*
Armillaria mellia	*Armillaria mellia*
Pepino Mosaic Virus	Pepino Mosaic Virus
Tobacco Mosaic Virus	Tobacco Mosaic Virus

Appendix 5: Application of filters to hazard master list

	Filter 4
	Is the final exposure quantity of concern?
Hazards passing Filter 3	**DOSE?**
	Filter 4
Tobacco rattle Virus	Tobacco rattle Virus
Sclerotium cepivorum	*Sclerotium cepivorum*
Nematodes (*Globodera*)	Nematodes (*Globodera*)
Streptomyces spp.	*Streptomyces* spp.
Pseudomonas spp.	*Pseudomonas* spp.,
Invasive weeds and exotic species and plant toxins e.g. Ragwort - Yew	Invasive weeds and exotic species and plant toxins e.g. Ragwort - Yew
Animal and human pathogens	
Salmonella spp.	*Salmonella* spp.
Streptococcus spp.	*Streptococcus* spp.
E. coli spp.	*E. coli* spp.
E. coli O157:H	*E. coli* O157:H
Enteric viruses	Enteric viruses
Bacillus spp.	*Bacillus* spp.
Cryptosporidium sp.	*Cryptosporidium* sp.
BSE	
Q-Fever (*Coxiella burnetii*)	Q-Fever (*Coxiella burnetii*)
Ringworm	Ringworm
Leptospirosis (*Leptospira* spp.)	Leptospirosis (Leptospira spp.)
M. bovis (Tuberculosis)	*M. bovis* (Tuberculosis)
Psittacosis (*Chlamydia* sp.)	Psittacosis (*Chlamydia* sp.)
Giarda entamoeba	*Giarda entamoeba*
Staphylococcus aureus	*Staphylococcus aureus*
Campylobacter sp.	*Campylobacter* sp.
Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*
Clostridium perfringens/botulinum	*Clostridium perfringens/botulinum*
Ascaris suum	
Foot and Mouth Disease	Foot and Mouth Disease
Swine Fever	Swine Fever
Pasteurellosis	Pasteurellosis
Tapeworm	
Toxocariasis	
Toxoplasmosis	Toxoplasmosis
Trichinosis,	Trichinosis
Yersiniosis	Yersiniosis
Listeriosis	Listeriosis
Brucella abortus (Brucellosis)	*Brucella abortus* (Brucellosis)
Physical contaminants	
Glass	Glass
Stones	Stones
Plastics, Metals	Plastics, Metals

Appendix 5: Application of filters to hazard master list

	Filter 4
	Is the final exposure quantity of concern?
Hazards passing Filter 3	**DOSE?**
	Filter 4
Odorous chemicals / bioaerosols	
Methane	
SOx	
Ammonia,	Ammonia
NOx	
Bioaerosols	Bioaerosols

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

HAZARD	TAD conditions	References
Salmonella t.	Inactivated Thermophilic 55° C 24 hrs T-90 of 0.7 hours at 53° C	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886 Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
Salmonella d.	Inactivated Thermophilic 55° C 24 hrs T-90 of 0.6 hours at 53° C	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886 Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
Temperature resistant Salmonella might survive		
Staphilococcus .aureus	Inactivated Thermophilic 55° C 24 hrs T-90 of 0.5 hours at 53° C	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

HAZARD	TAD conditions	References
M. paratubercolosis	Inactivated Thermophilic 55° C 24 hrs	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste
	T-90 of 0.7 hours at 53° C	Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
St. faecalis	Inactivated Thermophilic 55° C 24 hrs	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste
	T-90 of 1.0 hours at 53° C	Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
E. coli	Inactivated Thermophilic 55° C 24 hrs	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste
	T-90 of 0.4 hours at 53° C	Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886 Clare T. Lukehurst, Methane production: an enterprise for sustainable agricultural enterprises?, 2006, A discussion paper prepared for the Technical Study Tour of Swedish Biogas Plants Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

HAZARD	TAD conditions	References
E. coli 0157:H7	Inactivated Thermophilic 55° C 24 hrs	Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886 Aitken M.D., Sobsey M.D.,. Van Abel N. A, Blauth K.E., Singleton D.R., Crunk P.L., Nichols C., Walters G.W., Schneider M., Inactivation of Escherichia coli O157:H7 during thermophilic anaerobic digestion of manure from dairy cattle, Water Research, 1 (2007) 1659 – 1666
B. cereus	Inactivated Thermophilic 55° C 24 hrs BUT NOT SPORES Reported not inactivated	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste. Aitken M., Sobsey M., Blauth K., Shehee M., Crunk P. and Walters G., Inactivation of Ascaris suum and Poliovirus in Biosolids under Thermophilic Anaerobic Digestion Conditions, Environ. Sci. Technol. 2005, 39, 5804-5809 Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886
C. perfringens	Inactivated Thermophilic 55° C 24 hrs BUT NOT SPORES Reported not inactivated	Sahlstrom L., A Review of Survival of Pathogenic Bacteria in Organic Waste used in Biogas Plants. Biores. Technol. 2003, 87, 161–166. Al Seadi T., 2001, "Good practice in Quality Management of AD residues from biogas production", IEA Bioenergy report, Task 24 Energy from Biological Conversion of Organic Waste. Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886
Enterococci	NOT INACTIVATED	Elisabeth Bagge, Leena Sahlstrom and Ann Albihn, The effect of hygienic treatment on the microbial flora of biowaste at biogas plants, Water Research 39 (2005) 4879–4886
Poliovirus	Log removal of 8.431 with pasteurisation or log removal of 8.43 at 55° C for 240 hrs	Godfree A. and Farrell J., 2005, Processes for managing pathogens, J. Environ. Qual., 34, 105-113.
Ascaris suum	Inactivated Thermophilic 55° C 24 hrs BUT NOT EGGS	Aitken M., Sobsey M., Blauth K., Shehee M., Crunk P. and Walters G., Inactivation of Ascaris suum and Poliovirus in Biosolids under Thermophilic Anaerobic Digestion Conditions, Environ. Sci. Technol. 2005, 39, 5804-5809

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

HAZARD	TAD conditions	References
Criptosporidium	Inactivated Thermophilic 55° C 24 hrs BUT NOT OOCYSTS Viability down to 1.3% with 55° C for 240 hrs	Aitken M., Sobsey M., Blauth K., Shehee M., Crunk P. and Walters G., Inactivation of Ascaris suum and Poliovirus in Biosolids under Thermophilic Anaerobic Digestion Conditions, Environ. Sci. Technol. 2005, 39, 5804-5809 Godfree A. and Farrell J., 2005, Processes for managing pathogens, J. Environ. Qual., 34, 105-113.
Swine fever	Inactivation time at 55° C 1 hour	Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
Eggs of: gastrointestinal worms, nodular worms, round worms, tapeworms	Loss of viability 1-4 hours at 53° C	Bendixen, H.J, Safeguards against Pathogens in Danish Biogas Plants, 1994, Water Science and Technology, 30(12), 171-180
Enteric viruses		
Campylobacter		
Pasteurellossi		
Avian influenza*		
M.Bovis (TB)		
Group of D-streptococci		
L. monocytogenes		
Yersinia		
Toxocariosis		
Trichinosis		
Toxoplasmosis		
Brucella		
Foot and mouth disease		

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

Plant Pathogens	TAD	References
*P. brassica**	Inactive but sclerotia might survive	Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
*S. cepivorum**	Inactive but sclerotia might survive	Termorshuizen A.J.; Volker D.; Blok W.J.; Brummeler E. ten; Hartog B.J.; Janse J.D.; Knol W.; Wenneker M., Survival of Human and Plant Pathogens during Anaerobic Mesophilic Digestion of Vegetable, Fruit, and Garden Waste. European Journal of Soil Biology, 2003, 39, 165-171.
Ralstonia s.	inactive	Ryckeboer *etal* . (2002a) Termorshuizen A.J.; Volker D.; Blok W.J.; Brummeler E. ten; Hartog B.J.; Janse J.D.; Knol W.; Wenneker M., Survival of Human and Plant Pathogens during Anaerobic Mesophilic Digestion of Vegetable, Fruit, and Garden Waste. European Journal of Soil Biology, 2003, 39, 165-171.
Tobacco rattle virus	Survive	Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
TMV	Survive even 70C for 6 weeks Survive	Sanford C., 2003, Plant pathogens and pests in composting. In: Proceedings of the "Pathogen control in composting and anaerobic digestion: ABPO 2002, current knowledge, and technology aspects conference"; York. Cal Recovery Europe Ltd, Contemporary Waste Management Series, 9-29. Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
Corynebacterium michiganense	inactive	Turner J., Stafford D.A., Hughes D.E. and Clarkson J., 1993, The reduction of three plant pathogens (*Fusarium, Corynebacterium* and *Globodera*) in anaerobic digesters, Agric. Wastes, 6, 1-11
Fusarium oxysporum f. sp. *dianthi*	inactive	Turner J., Stafford D.A., Hughes D.E. and Clarkson J., 1993, The reduction of three plant pathogens (*Fusarium, Corynebacterium* and *Globodera*) in anaerobic digesters, Agric. Wastes, 6, 1-11

Appendix 6 - Animal, human and plant pathogen reduction – reference literature

Plant Pathogens	TAD	References
Fusarium oxysporum	inactive	Termorshuizen A.J.; Volker D.; Blok W.J.; Brummeler E. ten; Hartog B.J.; Janse J.D.; Knol W.; Wenneker M., Survival of Human and Plant Pathogens during Anaerobic Mesophilic Digestion of Vegetable, Fruit, and Garden Waste. European Journal of Soil Biology, 2003, 39, 165-171. Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
Cucumber green mottle mosaic virus	Survive	Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
*Phytophtora**		
Heterodera	Inactive but cysts might survive	Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.
Globodera	inactive	Turner J., Stafford D.A., Hughes D.E. and Clarkson J., 1993, The reduction of three plant pathogens (*Fusarium, Corynebacterium* and *Globodera*) in anaerobic digesters, Agric. Wastes, 6, 1-11 Lisbeth Mikkelsen, John Elphinstone, Dan Funck Jensen, 2006, "Literature review on detection and eradication of plant pathogens in sludge, soils and treated biowaste" , HORIZONTAL-HYG DL 2/5 Report – SSPI-CT-2004-513660.

Personal Communication (Prof. R. Noble): all the plant pathogens are likely to survive MAD conditions. *Plasmodiora* and other viruses might survive TAD.

Appendix 7: Hazard combinations and waste profiles (meso- and thermophilic)

(1 = Likely to be a significant hazard (High concentrations; 0 = low hazard)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophillic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophili
02 01 01	0	1	0	0	0	1	1	1	01000111	71	02 01 01	0	1	0	0	0	0	1	1	01000011	67
02 01 02	0	1	0	0	0	0	1	1	01000011	67	02 01 02	0	1	0	0	0	0	1	1	01000011	67
02 01 03	0	1	0	1	1	0	0	1	01011001	89	02 01 03	0	1	0	1	1	0	0	1	01011001	89
02 01 06	1	1	0	0	1	1	1	1	11001111	207	02 01 06	1	1	0	0	0	1	1	1	11000111	199
02 01 07	0	1	0	1	1	0	0	1	01011001	89	02 01 07	0	1	0	1	1	0	0	1	01011001	89
02 01 99	0	1	0	0	0	0	0	1	01000001	65	02 01 99	0	1	0	0	0	0	0	1	01000001	65
02 01 06	1	1	0	0	1	1	1	1	01001111	207	02 01 06	1	1	0	0	0	1	1	1	01000001	199
02 02 01	0	1	0	0	0	1	1	1	01000111	71	02 02 01	0	1	0	0	0	0	1	1	01000011	67
02 02 02	0	1	0	0	0	0	0	1	01000001	65	02 02 02	0	1	0	0	0	0	0	1	01000001	65

Appendix 7: Hazard combinations and waste profiles (meso- and thermophilic)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophilic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophilic
02 02 03	0	1	0	0	0	1	1	1	01000111	71	02 02 03	0	1	0	0	0	1	1	1	01000111	71
02 02 04	0	1	0	0	0	1	0	1	01000101	69	02 02 04	0	1	0	0	0	0	0	1	01000001	65
02 02 99	0	1	0	0	0	1	0	1	01000101	69	02 02 99	0	1	0	0	0	1	0	1	01000101	69
02 03 01	0	1	0	0	0	0	0	1	01000001	65	02 03 01	0	1	0	0	0	0	0	1	01000001	65
02 03 02	0	1	0	1	1	0	0	1	01011001	89	02 03 02	0	1	0	1	1	0	0	1	01011001	89
02 03 04	0	1	0	1	1	0	0	1	01011001	89	02 03 04	0	1	0	1	0	0	0	1	01010001	81
02 03 05	0	1	0	1	1	0	0	1	01011001	89	02 03 05	0	1	0	1	0	0	0	1	01010001	81
02 03 99	0	1	0	1	1	0	0	1	01011001	89	02 03 99	0	1	0	1	0	0	0	1	01010001	81
02 04 03	0	1	0	1	0	1	0	1	01010101	85	02 04 03	0	1	0	1	0	0	0	1	01010001	81

Appendix 7: Hazard combinations and waste profiles (meso- and thermophilic)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophilic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophilic
02 04 99	0	1	0	1	0	1	0	1	01010101	85	02 04 99	0	1	0	1	0	1	0	1	01010101	85
02 05 01	0	1	0	0	0	1	0	1	01000101	69	02 05 01	0	1	0	0	0	0	0	1	01000001	65
02 05 02	0	1	0	0	0	1	0	1	01000101	69	02 05 02	0	1	0	0	0	0	0	1	01000001	65
02 06 01	0	1	0	0	0	1	0	1	01000101	69	02 06 01	0	1	0	0	0	0	0	1	01000001	65
02 06 03	0	1	0	1	0	1	0	1	01010101	85	02 06 03	0	1	0	1	0	0	0	1	01010001	81
02 07 01	0	1	0	0	0	0	0	1	01000001	65	02 07 01	0	1	0	0	0	0	0	1	01000001	65
02 07 02	0	1	0	0	0	0	0	1	01000001	65	02 07 02	0	1	0	0	0	0	0	1	01000001	65
02 07 04	0	1	0	0	0	0	0	1	01000001	65	02 07 04	0	1	0	0	0	0	0	1	01000001	65
02 07 05	0	1	0	1	0	1	0	1	01010101	85	02 07 05	0	1	0	1	0	0	0	1	01010001	81
02 07 99	0	1	0	0	0	0	0	1	01000001	65	02 07 99	0	1	0	0	0	0	0	1	01000001	65

Appendix7: Hazard combinations and waste profiles (meso- and thermophilic)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophilic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophilic
03 01 01	0	0	0	0	0	0	1	1	00000011	3	03 01 01	0	0	0	0	0	0	1	1	00000011	3
03 01 05	0	0	0	0	0	0	1	1	00000011	3	03 01 05	0	0	0	0	0	0	1	1	00000011	3
03 03 01	0	0	0	0	0	0	1	1	00000011	3	03 03 01	0	0	0	0	0	0	1	1	00000011	3
03 03 02	0	0	0	0	0	0	0	1	00000001	1	03 03 02	0	0	0	0	0	0	0	1	00000001	1
03 03 07	0	0	0	0	0	0	1	1	00000011	3	03 03 07	0	0	0	0	0	0	1	1	00000011	3
03 03 08	1	0	1	0	0	0	0	1	10100001	161	03 03 08	1	0	1	0	0	0	0	1	10100001	161
03 03 10	1	0	1	0	0	0	0	1	10100001	161	03 03 10	1	0	1	0	0	0	0	1	10100001	161
03 03 11	1	0	1	0	0	1	0	1	10100101	165	03 03 11	1	0	1	0	0	0	0	1	10100001	161
04 01 01	1	1	0	0	0	1	0	1	11000101	197	04 01 01	1	1	0	0	0	0	0	1	11000001	193
04 01 05	1	1	1	0	0	1	0	1	11100101	229	04 01 05	1	1	1	0	0	0	0	1	11100001	225

Appendix7: Hazard combinations and waste profiles (meso- and thermophilic)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophilic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophilic
04 01 07	1	1	1	0	0	1	0	1	11100101	229	04 01 07	1	1	1	0	0	0	0	1	11100001	225
04 02 10	0	1	0	0	0	1	0	1	01000101	69	04 02 10	0	1	0	0	0	0	0	1	01000001	65
04 02 21	0	1	0	0	0	0	0	1	01000001	65	04 02 21	0	1	0	0	0	0	0	1	01000001	65
04 02 22	0	1	0	0	0	0	0	1	01000001	65	04 02 22	0	1	0	0	0	0	0	1	01000001	65
07 06 10	1	1	1	0	0	0	0	1	11100001	225	07 06 10	1	1	1	0	0	0	0	1	11100001	225
15 01 01	0	1	0	0	0	0	1	1	01000011	67	15 01 01	0	1	0	0	0	0	1	1	01000011	67
15 01 02	0	1	0	0	0	0	1	1	01000011	67	15 01 02	0	1	0	0	0	0	1	1	01000011	67
15 01 03	0	1	0	0	0	0	1	1	01000011	67	15 01 03	0	1	0	0	0	0	1	1	01000011	67
19 07 03	1	1	1	0	0	0	0	1	11100001	225	19 07 03	1	1	1	0	0	0	0	1	11100001	225
15 01 09	0	1	0	0	0	0	1	1	01000011	67	15 01 09	0	1	0	0	0	0	1	1	01000011	67

Appendix 7: Hazard combinations and waste profiles (meso- and thermophilic)

EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile mesophilic	EWC code	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals	Binary code	Hazard profile Thermophilic
19 08 09	0	1	0	0	0	0	0	1	01000001	65	19 08 09	0	1	0	0	0	0	0	1	01000001	65
19 08 12	1	1	1	0	0	0	0	1	11100001	225	19 08 12	1	1	1	0	0	0	0	1	11100001	225
19 08 14	1	1	1	0	0	0	0	1	11100001	225	19 08 14	1	1	1	0	0	0	0	1	11100001	225
20 01 01	1	1	1	0	0	0	1	1	11100011	227	20 01 01	1	1	1	0	0	0	1	1	11100011	227
20 01 08	0	1	0	0	0	0	1	1	01000011	67	20 01 08	0	1	0	0	0	0	1	1	01000011	67
20 01 25	0	1	0	0	0	0	0	1	01000001	65	20 01 25	0	1	0	0	0	0	0	1	01000001	65
20 02 01	0	1	0	1	1	1	0	1	01011101	93	20 02 01	0	1	0	1	1	0	0	1	01011001	89
20 03 01	0	1	0	0	0	1	1	1	01000111	71	20 03 01	0	1	0	0	0	1	1	1	01000111	71
20 03 02	0	1	0	1	1	0	0	1	01011001	89	20 03 02	0	1	0	1	0	0	0	1	01010001	81
20 01 99	1	1	1	1	1	1	1	1	11111111	255	20 01 99	1	1	1	1	1	1	1	1	11111111	255

Appendix 8 – Hazard profiles defined for individual EWC codes

EWC Code	Hazard Profiles Pre-digestion/post-mesophilic																	
	0	1	3	65	67	69	71	85	89	93	161	165	197	207	225	227	229	255
02 01 01							71											
02 01 02					67													
02 01 03									89									
02 01 06														207				
02 01 07									89									
02 01 99				65														
02 02 01						71												
02 02 02						65												
02 02 03							71											
02 02 04						69												
02 02 99						69												
02 03 01				65														
02 03 02									89									
02 03 04									89									
02 03 05									89									
02 03 99									89									
02 04 03								85										
02 04 99								85										
02 05 01						69												
02 05 02						69												
02 06 01						69												
02 06 03								85										
02 07 01				65														
02 07 02				65														
02 07 04				65														
02 07 05								85										
02 07 99				65														
03 01 01			3															
03 01 05			3															
03 03 01			3															
03 03 02		1																
04 01 01													197					
04 01 05																	229	
04 01 07																	229	
04 02 10						69												

Appendix 8 – Hazard profiles defined for individual EWC codes

EWC Code	Hazard Profiles Pre-digestion/post-mesophilic																	
	0	1	3	65	67	69	71	85	89	93	161	165	197	207	225	227	229	255
04 02 21				65														
04 02 22				65														
07 06 10															225			
15 01 01					67													
15 01 02					67													
15 01 03					67													
15 01 09					67													
19 07 03															225			
19 08 09				65														
19 08 12															225			
19 08 14															225			
20 01 01																227		
20 01 08					67													
20 01 25				65														
20 01 99																		255
20 02 01										93								
20 03 01							71											
20 03 02									89									

EWC Code	Hazard Profiles Post-thermophilic															
	0	1	3	65	67	69	71	81	85	89	161	193	199	225	227	255
02 01 01					67											
02 01 02					67											
02 01 03										89						
02 01 06													199			
02 01 07										89						
02 01 99				65												
02 02 01					67											
02 02 02				65												
02 02 03							71									
02 02 04				65												
02 02 99						69										
02 03 01				65												

Appendix 8 – Hazard profiles defined for individual EWC codes

	Hazard Profiles Post-thermophilic															
EWC Code	0	1	3	65	67	69	71	81	85	89	161	193	199	225	227	255
02 03 02										89						
02 03 04								81								
02 03 05								81								
02 03 99								81								
02 04 03								81								
02 04 99									85							
02 05 01				65												
02 05 02				65												
02 06 01				65												
02 06 03								81								
02 07 01				65												
02 07 02				65												
02 07 04				65												
02 07 05								81								
02 07 99				65												
03 01 01			3													
03 01 05			3													
03 03 01			3													
03 03 02		1														
03 03 07			3													
03 03 08											161					
03 03 10											161					
03 03 11											161					
04 01 01												193				
04 01 05														225		
04 01 07														225		
04 02 10				65												
04 02 21				65												
04 02 22				65												
07 06 10														225		
15 01 01					67											
15 01 02					67											
15 01 03					67											
15 01 09					67											
19 07 03														225		

Appendix 8 – Hazard profiles defined for individual EWC codes

	Hazard Profiles Post-thermophilic															
EWC Code	0	1	3	65	67	69	71	81	85	89	161	193	199	225	227	255
19 08 09				65												
19 08 12														225		
19 08 14														225		
20 01 01															227	
20 01 08					67											
20 01 25				65												
20 01 99																255
20 02 01										89						
20 03 01							71									
20 03 02								81								

Appendix 9: Exposure pathway availability matrix

	Source: Release and exposure from AD residues						Receptor	End-use						
	Pathway	Exposure medium	Mechanism	Human	Animal	Environment		Ag_1:Non-ready to eat crops e.g. cereals for human food chain	Ag_2:Grazing & animal feed	Ag_3:Industrial crops (e.g. biomass)	Ag_4:Ready to eat crops	Htcl_5:Bulbs, cut flowers, garden centre plants	LndRst_6: Land restoration and soft landsape applications	Tchl_7:Technical uses. e.g. biofilters
1	subsurface transport to aquifer	public water supply	ingestion of drinking water (public)	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
2	subsurface transport to aquifer	private water supply	ingestion of drinking water (private)	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
3	surface transport to surface water	public water supply	ingestion of drinking water (public)	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
4	surface transport to surface water	private water supply	ingestion of drinking water (private)	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
5	transport to surface or groundwater then irrigation, harvest and onward food chain	food crops	ingestion of contaminated crops	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
6	transport to surface or groundwater then harvest and onward food chain	edible fish and shellfish	ingestion of contaminated fish or shellfish	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0

Appendix 9: Exposure pathway availability matrix

	Source: Release and exposure from AD residues						Receptor	End-use						
	Pathway	Exposure medium	Mechanism	Human	Animal	Environment		Ag_1:Non-ready to eat crops e.g. cereals for human food chain	Ag_2:Grazing & animal feed	Ag_3:Industrial crops (e.g. biomass)	Ag_4:Ready to eat crops	Htcl_5:Bulbs, cut flowers, garden centre plants	LndRst_6: Land restoration and soft landsape applications	Tchl_7:Technical uses. e.g. biofilters
7	transport to surface water then incidental ingestion of contaminated surface water	recreational water	ingestion of recreational surface water	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
8	transport to surface water then contact with contaminated surface water	recreational water	skin contact	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
9	transport to surface water then contact with contaminated surface water	irrigation water	skin contact	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
10	transport to surface water then inhalation of contaminated surface water	irrigation water	inhalation	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0
11	direct contamination of crops from use of AD residue on soil	food crops	ingestion of contaminated crops	1	1	0	e.g. human & animal pathogens and toxins	1	1	0	1	0	0	0

Appendix 9: Exposure pathway availability matrix

	Source: Release and exposure from AD residues						Receptor	End-use						
	Pathway	Exposure medium	Mechanism	Human	Animal	Environment		Ag_1:Non-ready to eat crops e.g. cereals for human food chain	Ag_2:Grazing & animal feed	Ag_3:Industrial crops (e.g. biomass)	Ag_4:Ready to eat crops	Htcl_5:Bulbs, cut flowers, garden centre plants	LndRst_6: Land restoration and soft landsape applications	Tchl_7:Technical uses. e.g. biofilters
12	contamination of meat from use of AD residue on soil	animal products	ingestion of contaminated animal products	1	1	0	e.g. human & animal pathogens and toxins	0	1	0	0	0	0	0
13	direct ingestion of AD residue on soil	contaminated soil	ingestion of contaminated soil	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	1
14	contamination of skin from use of AD residue on soil	contaminated soil	skin contact	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	1
15	airborne dust from use of AD residue on soil	contaminated soil	inhalation	1	1	0	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	1
16	contamination of soil by application of AD residue	contaminated soil	contact with plant tissue	0	0	1	e.g. plant pathogens & weeds	1	1	1	1	1	1	0
17	airborne dust from use of AD residue on soil	airborne dust	contact with plant tissue	0	0	1	e.g. plant pathogens & weeds	1	1	1	1	1	1	1
18	transport to surface or groundwater then irrigation	irrigation water	contact with plant tissue	0	0	1	e.g. plant pathogens & weeds	1	1	1	1	1	1	0
19	run off to surface water	run off	run off to surface water	0	0	1	e.g. water pollutants	1	1	1	1	1	1	0

Appendix 9: Exposure pathway availability matrix

	Source: Release and exposure from AD residues						Receptor	End-use						
	Pathway	Exposure medium	Mechanism	Human	Animal	Environment		Ag_1:Non-ready to eat crops e.g. cereals for human food chain	Ag_2:Grazing & animal feed	Ag_3:Industrial crops (e.g. biomass)	Ag_4:Ready to eat crops	Htcl_5:Bulbs, cut flowers, garden centre plants	LndRst_6: Land restoration and soft landsape applications	Tchl_7:Technical uses. e.g. biofilters
20	airborne	air	inhalation	1	0	0	e.g. odour nuisance	1	1	1	1	1	1	1
21	leaching to groundwater	recharging groundwater	leaching to groundwater	0	0	1	e.g. water pollutants	1	1	1	1	1	1	1
22	direct contamination of soil biota from use of AD residue on soil	contaminated soil	contact with soil biota	0	0	1	e.g. impact on soil biota	1	1	1	1	1	1	0
23	direct consumption of AD residue	physical handling	ingestion	1	1	0	e.g. impact on human and animal metabolism	1	1	1	1	1	1	1

Appendix 10: Exposure pathway – end use combination ranking

Source: Release and exposure from AD residues					Hazard Categories							
					1	2	3	4	5	6	7	8
	Pathway	Exposure medium	Mechanism	Receptor	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals
1	subsurface transport to aquifer	public water supply	ingestion of drinking water (public)	e.g. human & animal pathogens and toxins	1	1	1	1	0	1	0	1
2	subsurface transport to aquifer	private water supply	ingestion of drinking water (private)	e.g. human & animal pathogens and toxins	1	1	1	1	0	1	0	1
3	surface transport to surface water	public water supply	ingestion of drinking water (public)	e.g. human & animal pathogens and toxins	1	1	1	1	0	1	0	1
4	surface transport to surface water	private water supply	ingestion of drinking water (private)	e.g. human & animal pathogens and toxins	1	1	1	1	0	1	0	1
5	transport to surface or groundwater then irrigation, harvest and onward food chain	food crops	ingestion of contaminated crops	e.g. human & animal pathogens and toxins	1	1	1	1	0	1	0	1
6	transport to surface or groundwater then harvest and onward food chain	edible fish and shellfish	ingestion of contaminated fish or shellfish	e.g. human & animal pathogens and toxins	1	0	1	1	0	1	0	1

Appendix 10: Exposure pathway – end use combination ranking

Source: Release and exposure from AD residues					Hazard Categories							
					1	2	3	4	5	6	7	8
	Pathway	**Exposure medium**	**Mechanism**	Receptor	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals
7	transport to surface water then incidental ingestion of contaminated surface water	recreational water	ingestion of recreational surface water	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	0
8	transport to surface water then contact with contaminated surface water	recreational water	skin contact	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	0
9	transport to surface water then contact with contaminated surface water	irrigation water	skin contact	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	0
10	transport to surface water then inhalation of contaminated surface water	irrigation water	Inhalation	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	1
11	direct contamination of crops from use of AD residue on soil	food crops	ingestion of contaminated crops	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	1	0
12	contamination of meat from use of AD residue on soil	animal products	ingestion of contaminated animal products	e.g. human & animal pathogens and toxins	1	0	1	1	1	1	0	0

Appendix 10: Exposure pathway – end use combination ranking

Source: Release and exposure from AD residues					Hazard Categories							
					1	2	3	4	5	6	7	8
	Pathway	Exposure medium	Mechanism	Receptor	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals
13	direct ingestion of AD residue on soil	contaminated soil	ingestion of contaminated soil	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	0
14	contamination of skin from use of AD residue on soil	contaminated soil	skin contact	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	1	0
15	airborne dust from use of AD residue on soil	contaminated soil	inhalation	e.g. human & animal pathogens and toxins	1	1	1	1	1	1	0	1
16	contamination of soil by application of AD residue	contaminated soil	contact with plant tissue	e.g. plant pathogens & weeds	1	1	1	1	1	1	0	0
17	airborne dust from use of AD residue on soil	airborne dust	contact with plant tissue	e.g. plant pathogens & weeds	1	1	1	1	1	1	0	0
18	transport to surface or groundwater then irrigation	irrigation water	contact with plant tissue	e.g. plant pathogens & weeds	1	1	1	1	1	1	0	0
19	run off to surface water	run off	run off to surface water	e.g. water pollutants	1	1	1	1	1	1	1	0
20	airborne	air	inhalation	e.g. odour nuisance	0	0	1	1	0	1	0	1
21	leaching to groundwater	recharging groundwater	leaching to groundwater	e.g. water pollutants	1	1	1	1	0	1	0	1

Appendix 10: Exposure pathway – end use combination ranking

Source: Release and exposure from AD residues					Hazard Categories							
					1	2	3	4	5	6	7	8
	Pathway	**Exposure medium**	**Mechanism**	Receptor	PTEs	Nutrients	POPs	Plant pathogens	Weeds	Human & animal pathogens	Physical contaminants	Odorous chemicals
22	direct contamination of soil biota from use of AD residue on soil	contaminated soil	contact with soil biota	e.g. impact on soil biota	1	1	1	1	0	1	0	0
23	direct consumption of AD residue	physical handling	ingestion	e.g. impact on human and animal metabolism	1	1	1	1	1	1	1	1

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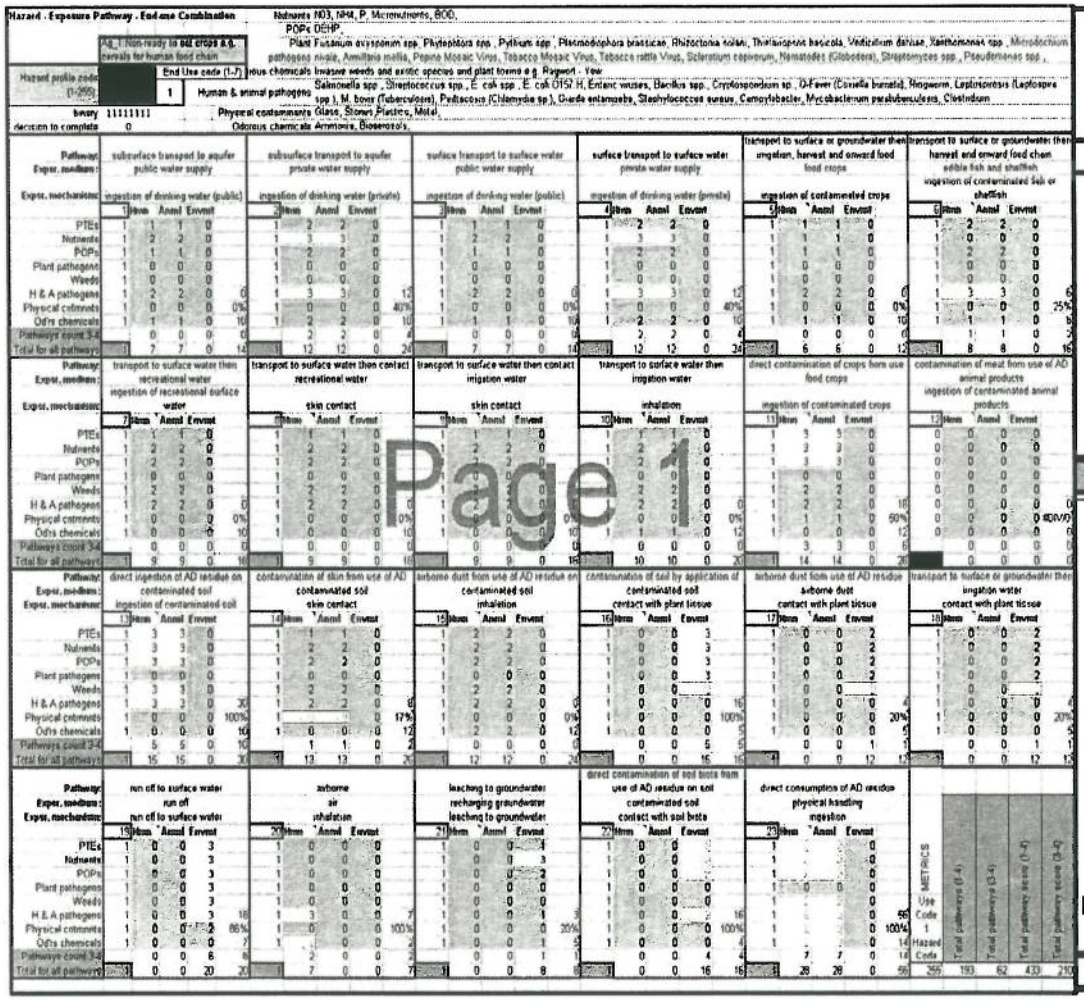
Appendix 11: Example exposure assessment for one hazard profile - end-use couple



direct contamination of soil biota from use of AD residue on soil				
contaminated soil contact with soil biota				
22	Hmn	Anml	Envmt	
1	0	0	4	
1	0	0	4	
1	0	0	4	
1	0	0	0	
1	0	0	0	
1	0	0	4	16
1	0	0	0	100%
1	0	0	0	4
	0	0	4	4
1	0	0	16	16

METRICS	Total pathways (1-4)	Total pathways (3-4)	Total pathway score (1-4)	Total pathway score (3-4)
Use Code 1 Hazard Code				
255	193	62	433	210

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Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4)

This table presents the extent to which exposure assessment decisions were driven by pathways assigned an availability score of 3 or 4; that is, the proportion of exposures for a given pathway judged to be highly available.

Key: **Hazard profiles coloured**: blue = MAD, orange = TAD and yellow = unchanged waste profiles after TAD.
Hazard profile – end use – exposure pathway scores shading is done using arbitrary ranges for visual effect. Red shading = values >1; Pink shading = values between 0.5-1; yellow shading = values between 0-0.5; no shading = values =0.

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
255	4	216	64	193	435	0	0.4	0	0.4	0	0.3	0	0	0	0	0.7		1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
255	2	210	62	202	441	0	0.4	0	0.4	0	0.3	0	0	0	0	0.5	0	1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
255	1	210	62	193	433	0	0.4	0	0.4	0	0.3	0	0	0	0	0.5		1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
255	6	192	56	183	409	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
255	3	192	56	181	405	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
207	4	180	53	153	347	0	0.5	0	0.5	0	0.3	0	0	0	0	0.6		1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
255	5	174	56	183	409	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0.2	0	1	0.2	0.2	0.9	1	0.2	1	1
207	2	174	51	159	350	0	0.5	0	0.5	0	0.3	0	0	0	0	0.4	0	1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
207	1	174	51	153	345	0	0.5	0	0.5	0	0.3	0	0	0	0	0.4		1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
229	4	165	50	160	348	0	0.4	0	0.4	0	0.3	0	0	0	0	1		1	0	0	1	0	0	1	1	0.2	1	1
207	3	162	47	143	323	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
207	6	162	47	143	323	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
229	2	159	48	166	351	0	0.4	0	0.4	0	0.3	0	0	0	0	0.8	0	1	0	0	1	0	0	1	1	0.2	1	1
229	1	159	48	160	346	0	0.4	0	0.4	0	0.3	0	0	0	0	0.8		1	0	0	1	0	0	1	1	0.2	1	1
199	4	151	45	131	290	0	0.5	0	0.5	0	0.3	0	0	0	0	0.8		1	0.3	0	1	0	0	0.8	1	0.3	1	1
207	5	150	47	143	323	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.2	0	1	0.3	0.3	0.8	1	0.3	1	1
199	2	145	43	135	291	0	0.5	0	0.5	0	0.3	0	0	0	0	0.5	0	1	0.3	0	1	0	0	0.8	1	0.3	1	1

Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4)

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
199	1	145	43	131	288	0	0.5	0	0.5	0	0.3	0	0	0	0	0.5		1	0.3	0	1	0	0	0.8	1	0.3	1	1
229	3	141	42	152	324	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.2	1	1
229	6	141	42	152	324	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.2	1	1
93	4	140	42	114	270	0	0.7	0	0.7	0	0.5	0	0	0	0	0.7		1	0	0	1	0.3	0.3	1	1	0.3	1	1
197	4	135	41	124	270	0	0.5	0	0.5	0	0.3	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
93	2	134	40	119	272	0	0.7	0	0.7	0	0.5	0	0	0	0	0.3	0	1	0	0	1	0.3	0.3	1	1	0.3	1	1
93	1	134	40	114	268	0	0.7	0	0.7	0	0.5	0	0	0	0	0.3		1	0	0	1	0.3	0.3	1	1	0.3	1	1
227	2	133	39	137	287	0	0.3	0	0.3	0	0	0	0	0	0	0.8	0	1	0.3	0	1	0	0	0.8	1	0.3	1	1
227	1	133	39	133	283	0	0.3	0	0.3	0	0	0	0	0	0	0.8		1	0.3	0	1	0	0	0.8	1	0.3	1	1
227	4	133	39	133	283	0	0.3	0	0.3	0	0	0	0	0	0	0.8		1	0.3	0	1	0	0	0.8	1	0.3	1	1
199	3	133	39	123	270	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
199	6	133	39	123	270	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
229	5	129	42	152	324	0	0.4	0	0.4	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.2	1	1
197	2	129	39	128	271	0	0.5	0	0.5	0	0.3	0	0	0	0	0.7	0	1	0	0	1	0	0	1	1	0.3	1	1
197	1	129	39	124	268	0	0.5	0	0.5	0	0.3	0	0	0	0	0.7		1	0	0	1	0	0	1	1	0.3	1	1
93	6	128	38	110	258	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.3	1	1
93	3	128	38	108	254	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.3	1	1
199	5	124	39	123	270	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
71	4	121	36	95	223	0	0.7	0	0.7	0	0.5	0	0	0	0	0.7		1	0.3	0	1	0	0	0.7	1	0.3	1	1
165	4	120	36	126	265	0	0.3	0	0.3	0	0.3	0	0	0	0	1		1	0	0	1	0	0	1	1	0	1	1
225	2	117	35	130	267	0	0.3	0	0.3	0	0	0	0	0	0	1	0	1	0	0	1	0	0	1	1	0.3	1	1
225	1	117	35	126	263	0	0.3	0	0.3	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
225	4	117	35	126	263	0	0.3	0	0.3	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
197	3	117	35	118	252	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
197	6	117	35	118	252	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
93	5	116	38	110	258	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.3	1	1
71	2	115	34	97	222	0	0.7	0	0.7	0	0.5	0	0	0	0	0.3	0	1	0.3	0	1	0	0	0.7	1	0.3	1	1
71	1	115	34	95	221	0	0.7	0	0.7	0	0.5	0	0	0	0	0.3		1	0.3	0	1	0	0	0.7	1	0.3	1	1

Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4).

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
227	3	115	33	125	263	0	0.3	0	0.3	0	0	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
227	6	115	33	125	263	0	0.3	0	0.3	0	0	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
165	2	114	34	132	268	0	0.3	0	0.3	0	0.3	0	0	0	0	0.7	0	1	0	0	1	0	0	1	1	0	1	1
165	1	114	34	126	263	0	0.3	0	0.3	0	0.3	0	0	0	0	0.7		1	0	0	1	0	0	1	1	0	1	1
85	4	111	34	92	213	0	0.7	0	0.7	0	0.5	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
71	3	109	32	89	209	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0.3	0	1	0	0	0.7	1	0.3	1	1
71	6	109	32	89	209	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0.3	0	1	0	0	0.7	1	0.3	1	1
197	5	108	35	118	252	0	0.5	0	0.5	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
227	5	106	33	125	263	0	0.3	0	0.3	0	0	0	0	0	0			1	0.3	0	1	0	0	0.8	1	0.3	1	1
85	2	105	32	95	213	0	0.7	0	0.7	0	0.5	0	0	0	0	0.5	0	1	0	0	1	0	0	1	1	0.3	1	1
85	1	105	32	92	211	0	0.7	0	0.7	0	0.5	0	0	0	0	0.5		1	0	0	1	0	0	1	1	0.3	1	1
69	4	105	32	88	203	0	0.7	0	0.7	0	0.5	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
255	7	105	29	55	155													1	0.2	0		0.2			1			1
71	5	103	32	89	209	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0.3	0	1	0	0	0.7	1	0.3	1	1
165	3	102	30	120	247	0	0.3	0	0.3	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
165	6	102	30	120	247	0	0.3	0	0.3	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
85	6	99	30	90	205	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
69	2	99	30	90	202	0	0.7	0	0.7	0	0.5	0	0	0	0	0.5	0	1	0	0	1	0	0	1	1	0.3	1	1
85	3	99	30	88	201	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
69	1	99	30	88	201	0	0.7	0	0.7	0	0.5	0	0	0	0	0.5		1	0	0	1	0	0	1	1	0.3	1	1
225	3	99	29	120	245	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
225	6	99	29	120	245	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
165	5	93	30	120	247	0	0.3	0	0.3	0	0.3	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
69	3	93	28	84	191	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
69	6	93	28	84	191	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
89	2	92	27	83	188	0	0.5	0	0.5	0	0	0	0	0	0	0.5	0	1	0	0	1	0.3	0.3	1	1	0.5	1	1
89	1	92	27	80	185	0	0.5	0	0.5	0	0	0	0	0	0	0.5		1	0	0	1	0.3	0.3	1	1	0.5	1	1
89	4	92	27	80	185	0	0.5	0	0.5	0	0	0	0	0	0	0.5		1	0	0	1	0.3	0.3	1	1	0.5	1	1

Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4)

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
207	7	91	25	45	129													1	0.2	0		0.3			1			1
85	5	90	30	90	205	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
225	5	90	29	120	245	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
69	5	87	28	84	191	0	0.7	0	0.7	0	0.5	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
193	2	87	26	92	187	0	0.3	0	0.3	0	0	0	0	0	0	1	0	1	0	0	1	0	0	1	1	0.3	1	1
193	1	87	26	90	185	0	0.3	0	0.3	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
193	4	87	26	90	185	0	0.3	0	0.3	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.3	1	1
89	6	86	25	78	179	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.5	1	1
89	3	86	25	76	175	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.5	1	1
89	5	77	25	78	179	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0.3	0.3	1	1	0.5	1	1
193	3	75	22	86	173	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
193	6	75	22	86	173	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
67	1	73	21	61	138	0	0.5	0	0.5	0	0	0	0	0	0	0.5		1	0.5	0	1	0	0	0.5	1	0.5	1	1
67	2	73	21	61	138	0	0.5	0	0.5	0	0	0	0	0	0	0.5		1	0.5	0	1	0	0	0.5	1	0.5	1	1
67	4	73	21	61	138	0	0.5	0	0.5	0	0	0	0	0	0	0.5		1	0.5	0	1	0	0	0.5	1	0.5	1	1
199	7	73	20	36	103													1	0.3	0		0			1			1
161	2	72	21	96	184	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	1	1	0	1	1
161	1	72	21	92	180	0	0	0	0	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0	1	1
161	4	72	21	92	180	0	0	0	0	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0	1	1
229	7	71	20	41	111													1	0	0		0			1			1
227	7	70	19	36	102													1	0.3	0		0			1			1
193	5	69	22	86	173	0	0.3	0	0.3	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.3	1	1
67	3	67	19	57	130	0	0.5	0	0.5	0	0	0	0	0	0			1	0.5	0	1	0	0	0.5	1	0.5	1	1
67	6	67	19	57	130	0	0.5	0	0.5	0	0	0	0	0	0			1	0.5	0	1	0	0	0.5	1	0.5	1	1
67	5	64	19	57	130	0	0.5	0	0.5	0	0	0	0	0	0			1	0.5	0	1	0	0	0.5	1	0.5	1	1
81	2	63	19	59	129	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1
81	1	63	19	58	128	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1
81	4	63	19	58	128	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1

Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4)

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
93	7	61	17	33	93													1	0	0		0.3			1			1
161	3	60	17	88	168	0	0	0	0	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
161	6	60	17	88	168	0	0	0	0	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
71	7	59	16	27	81													1	0.3	0		0			1			1
81	6	57	17	58	126	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
81	3	57	17	56	122	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
65	1	57	17	54	118	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1
65	2	57	17	54	118	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1
65	4	57	17	54	118	0	0.5	0	0.5	0	0	0	0	0	0	1		1	0	0	1	0	0	1	1	0.5	1	1
197	7	57	16	32	87													1	0	0		0			1			1
165	7	57	16	32	87													1	0	0		0			1			1
161	5	54	17	88	168	0	0	0	0	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0	1	1
225	7	54	15	32	86													1	0	0		0			1			1
81	5	51	17	58	126	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
65	3	51	15	52	112	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
65	6	51	15	52	112	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
65	5	48	15	52	112	0	0.5	0	0.5	0	0	0	0	0	0			1	0	0	1	0	0	1	1	0.5	1	1
89	7	44	12	24	68													1	0	0		0.3			1			1
85	7	43	12	24	67													1	0	0		0			1			1
69	7	43	12	23	65													1	0	0		0			1			1
67	7	42	11	18	56													1	0.5	0		0			1			1
193	7	40	11	23	62													1	0	0		0			1			1
161	7	40	11	23	62													1	0	0		0			1			1
3	1	28	7	27	55	0	0	0	0	0	0				0	0			1	0				0	1	0		1
3	2	28	7	27	55	0	0	0	0	0	0				0	0			1	0				0	1	0		1
3	4	28	7	27	55	0	0	0	0	0	0				0	0			1	0				0	1	0		1
3	3	28	7	25	53	0	0	0	0	0	0				0				1	0				0	1	0		1
3	5	28	7	25	53	0	0	0	0	0	0				0				1	0				0	1	0		1

Appendix 12 Ranked Risk Matrix – Ratio of available pathways High & Medium (3-4)

	End use	Total pathway score (3-4)	Total path ways (3-4)	Total path ways (1-4)	Total path way score (1-4)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
3	6	28	7	25	53	0	0	0	0	0	0				0				1	0				0	1	0		1
3	7	28	7	9	32														1	0					1			1
81	7	26	7	15	42													1	0	0		0			1			1
65	7	26	7	14	40													1	0	0		0			1			1
1	1	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	2	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	3	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	4	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	5	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	6	12	3	20	35	0	0	0	0	0	0				0					0					1	0		1
1	7	12	3	5	16															0					1			1

Appendix13: TAG Meeting – Banbury 14th of August 2007, List of participants and report of the meeting

Project/Contract Title	Risk Assessment Inception Meeting	Project No	OFW002-001
Name and title of WRAP attendee(s)	Nina Sweet (NS) - WRAP		
Name and title of attendee(s)	Sean Tyrrel (ST) - Cranfield University Raffaella Villa (RV) - Cranfield University Aoife O'Sullivan (AO'S) - Welsh Assembly Victoria Sturt (VS) - Environment Agency Emily Nichols (EN) - The Composting Association Kate Lister (KL) - Biogen (UK) Ltd Roger Unwin (RU) - Independent Consultant David Collins (DC) - REA Vicky Heslop (VH) - Independent Consultant Peter Olsen (PO) - SEPA Hannah Lawrie (HL) - Hyder Consulting		
Contractor company	Cranfield University		
Meeting date/time/place	10:30am, 14th August 2007		
Apologies	Jane Gilbert (TCA), Sal Burgess (Defra), Tony Osbourne (Defra), Suzanne Laidlaw (EA), Justin French-Brooks (ESA), Iain Notman (Defra)		

Objective of the meeting	Inception Meeting and Risk Assessment Workshop

The following issues were discussed and the following agreements reached:	
Issue 1	**Welcome and Introductions** Cranfield set out the objectives of the meeting which were to: ▪ Introduce the project team to their proposed methodology, ▪ Identify ways to refine their approach and to brainstorm hazards, ▪ Screen hazards, ▪ Develop conceptual exposure models This will feed into a technical workshop planned for the 17th September 2007 when the methodology will be finalised and applied.
Issue 2	**Brief presentation on risk assessment methodology** RV went through the proposed risk assessment methodology and confirmed that the model is based on a source-pathway-receptor model that will take into consideration environmental impacts (e.g. run-off from AD facilities) but not compensatory impacts (these will be covered under the regulatory impact assessment).
Issue 3	**Brainstorm Hazard Pool** The hazards identified are those that apply to digesters generally and not those conforming to the Standard. ST presented the hazards that had already been identified in the TID and by Cranfield to see whether they had all been identified. In addition to those identified in the list under point 2.3 of the tender Cranfield added: ▪ Human Pathogens ▪ Physical Contaminants e.g. plastics, glass ▪ Odour ▪ BOD For each hazard type identified ST then led the team through a more detailed sub-list of all possible

	hazards across waste inputs. The group then refined this list to identify the hazards that would survive the AD process (least line of resistance) to feed into source-pathway-receptor model. ST will refine this ahead of the workshop on the 17th September and circulate to the project AD QP TAG in the interim to incorporate their feedback. The list will then be reviewed on the 17th September 2007.
Issue 4	**Hazards Screening** ST explained the screening process: **Filter 1** - Screening out those hazards that do not present a serious risk **Filter 2** - Screens out those hazards that are unlikely to find their way to a receptor (i.e. they will be destructed). A good example is LAS which will persist through Filter 1 (i.e. in anaerobic conditions) but will degrade in aerobic conditions. **Filter 3** - Filter 3 relates to whether the final exposure quantity is of concern e.g. if people are exposed to bacteria, some bacteria cause no problems in small doses whereas others will cause infection if you are exposed to just a handful of cells. This may be dictated by regulatory limits in some cases and therefore the regulatory limits may be ahead of the point at which the parameter is identified as becoming a hazard.
Issue 5	**Conceptual Model** There was insufficient time to complete this portion of the workshop so the list of proposed end uses was developed for which exposure pathways will be modelled by Cranfield. These were identified as follows: ▪ Agricultural - this will be split into layers extending from ready to eat crops at one end of the scale to industrial crops (biomass) at the other ▪ Horticultural ▪ Land Restoration and Soft Landscape Applications ▪ Technical Uses - DC is going to clarify the various technical uses at the REA AD Committee Meeting on the 21st August 2007. Filter Bed for odour control was identified by VH as one potential technical use.
Issue 6	**AOB** Cranfield and NS stressed that this must be a two way process between the contractors and the AD QP TAG. Cranfield will be sending through information for review ahead of the workshop on the 17th September. Cranfield to identify possible attendees for the workshop on the 17th September 2007 and send this to Nina in the next few weeks. Suggestions from the meeting included: ▪ FSA - Gordon Nicholls ▪ Animal Health ▪ Fish Expert - Trevor Hastings ▪ Plant Expert ▪ Department of Health ▪ Crop Specialist - Roger Unwin ▪ ESA - Justin French-Brookes or a member of the ESA Biological Treatment Group ▪ University of Glamorgan Twenty people will be around the right size. To inform those attending Cranfield will produce a short briefing note, stressing that it will be a technical day, which will outline the work to be done and how it will be done. This will accompany invites to the workshop. RV to send out a list to the AD QP TAG of the documentation that they have so the team can identify other documentation that may be of use. VH identified a contact at the National University of Ireland, Galway who has 30 years experience in

	AD research.

Actions arising from the meeting	
Name	Action
ST/RV	To progress the risk assessment for technical review on the 17th September 2007.
AD QP TAG	To review all information sent through by Cranfield and send back comments.
ST/RV	To identify a list of appropriate attendees for the 17th September 2007 workshop and send to Nina by the 31st August 2007.
RV/ST	To create a short briefing note to issue with the workshop attendees outlining the purpose and methodology of the risk assessment.
RV	To circulate to the AD QP TAG a list of the documentation already at Cranfield so the AD QP TAG can identify other documents that will be useful for the Risk Assessment.

Follow-up call/meeting planned for	Proposed for the 17th September 2007.

This report (including the attached meeting minutes if applicable) represents an accurate record of the meeting:

Name: _Hannah Lawrie_____ Signed: ___ _____Date: 17th August 2007_

Appendix 14: Workshop – Banbury 17th of September 2007, List of participants and report of the meeting

Project/Contract Title	Risk Assessment	Project No	OFW002-001
Name and title of WRAP attendee(s)	Nina Sweet (NS) - WRAP		
Name and title of attendee(s)	Jake Prior: digester technical expert Roger Unwin:consultant (WRAP), soil and science background Brian Chambers: from ADAS, soil scientist Lucy Lewis: Greenfinch, expert in the process engineering of AD Vicky Heslop: AD Consultant and Farmer, Emily Nichols, Compost Association, Sandra Esteves, University of Glamorgan, Kate Lister, Biogen, AD specialist David Collins, Renewable Energy Association – specialising in biodigestion Adrian Jones: Welsh Assembly Government Simon Pollard, Cranfield University Sean Tyrrel, Cranfield University Raffaella Villa, Cranfield University Phil Longhurst, Cranfield University		
Contractor company	Cranfield University		
Meeting date/time/place	10:00am, 17th September 2007		

Objective of the meeting	Risk Assessment TAG meeting

The following issues were discussed and the following agreements reached:	
Issue 1	**Welcome and Introductions** Nina introduced the purpose of the workshop and the basis of this assessment to complete the basis to underpin the development of a quality protocol. This is a first step, the workshop purpose is to build consensus on the risk assessment method.
Issue 2	**Aims of workshop and ground rules (Simon Pollard)** The workshop is a "collective team effort", to work in consensus to inform and agree on the aspects that will inform the Quality Protocol. Preparatory work and literature has informed the workshop which was then presented to agree the method of risk assessment and the basis of determining risks. Need of consensus on the work done so far for the risk analysis. Consensus on: • the hazards • the key exposure pathways The TAG will try to rank some of the pathways
Issue 3	<u>Item 1 Risk principles (Simon Pollard)</u> Professor Pollard introduced the following concepts and their relevance to the risk assessment process. - potency of the hazard - availability of a dose (exposure) - sensitivity / vulnerability of a receptor Analysis of the risk of AD quality and procedure, the work is similar to the work done by the Cranfield group on the Avian flu, modified to the need of the AD.

	There is a large range of waste with hazards the TAG needs to agree on the hazards post-treatment. The number of waste need to be condensed. The hazards will be filtered in terms of - potency of the hazard - availability of a dose (exposure) - sensitivity / vulnerability of a receptor General agreement
Issue 4	Item 2 Consensus on risk assessment assumptions (Simon Pollard) - what 'credit' do we give for treatment efficacy? - what 'credit' do we give for environmental attenuation? - assumption of normal regulation - application of Codes of Good Practice - AD QP does not yet apply The objective is to consider and state baseline conditions and assumptions that inform the protocol from the risk assessment. The risk will be considered from sources to receptors, we apply barriers: • Waste acceptance • Treatment efficacy • Process control • End-uses control Assumption made for the risk assessment that the TAG need to agree on: 1. The treatment is effective 2. There is some attenuation of hazards within the environment 3. The complete digestate represents the highest risk, i.e. chemical hazards that are available within the solid fraction as well as liquid hazards that can travel within the environment. 4. The process is normal regulated 5. Operators adopt Code of Good Practice The panel recognised the variation in processes and the variation within differing systems. The TAG agree on the need of including operator competency into the QP. Not part of the risk analysis. Nina Sweet asks for comment on the attenuation in the environment Simon Tyrell explains that in the exposure assessment, different exposure pathways will have different level of attenuation. This method will allow us to look at different environmental events according to the pathways taken nto account. Transport within the environment is integral to the risk assessment and will be considered as this has temporal significance (sub-surface) compared to rapid flow of liquids above ground. The TAG agrees on this assumptions.
Issue 5	Item 3 Overview of methodology and reminder of risk assessment outcomes (Sean Tyrrel) Explanation of the methodology: • Hazard identification, screening and prioritisation • Waste identification, screening and categorisation • Identification of exposure pathways relevant to identified end uses for AD residues • AD process type, AD residue type and end use permutations representative of the full range of possible permutations • Exposure assessment for the representative waste type, AD process type, AD residue type and end use permutations • Ranking of the representative waste type, AD process type, AD residue type and end use

	permutations and development of a "safe AD product matrix" ST explains the rank risk matrix. Permutations (waste type) Process type (different output) Product type (1-3) end-uses (6-7). This generates a big list which needs to be ranked. The basic idea is that permutations with more pathways have more risks and pathways more available have higher risk. The combination of the two gives the rank. If there is no pathway there is no risk. Low availability is low risk. TAG agrees on the collapsing of the hazards
Issue 6	Item 4 Consensus on hazard screening (Simon Pollard) SP Need of reducing the list of hazards to principal hazards. Application of the 4 filters. Plant/Human pathogens need an expert on it. TAG agree on keeping all the hazards for the two categories until expert judgement .
Issue 7	Item 5 Collapsing the permutation of waste types (Phil Longhurst) The list of waste under EWC classification. Can this be categorised into high and low hazards? Initially, pre-treatment and after, post-treatment. It's the concentration of that hazard in that waste. We need your approval on this categorisation. TAG agree on the waste categorisation. Assumption about process control. Not Agreed
Issue 8	Item 6 Conceptual models of exposure (Sean Tyrrel) to include: - confirmation of master list of exposure pathways - amendment of master list ST Asks for any forgotten pathways VH Asks to change recreational water to all water (no 7-8 and9) BC Suggest to add direct ingestion of the AD products Tag agree on the exposure pathways
Issue 9	Item 7 Ranking pathways (Sean Tyrrel) BC. Asks to amend 12, meat should say animal products VH silviculture need to be inserted PL to summarise and show the permutation table Compilation of waste process-product-end use permutation table NS. Fish pathogens will be considered separately. Seek advice with SEPA NS. Asks about difference between mesophilic and thermophilic PL Differences between mesophilic and thermophilic/ABPreg. We have ABPreg waste but with the same profile as nonABPthermophilic. We would like you to confirm that you are happy/not with this TAG agrees

Actions arising from the meeting	
Name	Action

ST/RV/SP and PL	To finish the risk assessment. • Check baseline waste profile • Plant/human pathogen expert • Cranfield team to have a first cut at the risk assessment • Add pathway 23 + end use silviculture Plant pathogen: Ralph Nobel (HRI), John Elphistone Human Pathogen: Alan Godfree (Uplc), Phil Jones (IAH), Paul Gayford (Defra, SVS), Nick Gent (HPA)
AD QP TAG	To review all information sent through by Cranfield and send back comments.

This report (including the attached meeting minutes if applicable) represents an accurate record of the meeting:

Name: _Raffaella Villa___ Signed: ___ _____Date: 18th September 2007

Comparison of risk assessment approaches for manufactured nanomaterials

Report compiled as part of Defra project (CB403)

Final report

30th May 2008

Report compiled by Dr S Rocks, Prof S Pollard, Dr R Dorey, Prof L Levy, Dr P Harrison (Cranfield University) and Dr R Handy (University of Plymouth)

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Section 1

Introduction

1.1 Aims and statements

1.1.1. Aims and objectives

The overall aim of this project is to evaluate and make recommendations on risk assessment approaches for manufactured nanomaterials through information exchange (across the Organisation for Economic Co-operation and Development; OECD) and, through an understanding of any unique challenges nanomaterials present, to identify opportunities to strengthen and enhance risk assessment capacity.

This overarching aim will be achieved through the following objectives:

1. exchanging, collating and synthesising information on current risk assessment approaches for industrial chemicals that may apply to manufactured nanomaterials;
2. undertaking a gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials;
3. making recommendations to the OECD Steering Group for addressing and filling identified gaps; and
4. recognising that there will be limitation to the applicability of risk assessment to engineered nanomaterials given the current evidence base on dose-response assessment and exposures beyond occupational settings.

The first report (Rocks et al., 2008) addressed Objective 1. The purpose of this report is to build on the conclusions of the first report and convey the findings of a gap analysis on the risk assessment approaches (with particular emphasis on those that apply to industrial chemicals) as they apply to manufactured nanomaterials, and to make recommendations for addressing and filling the identified gaps. This report addresses the final three objectives and reports the results from a workshop held at Cranfield University on 15th May 2008.

1.1.2. First report summary

The first report considered the current regulatory frameworks available across the world (concentrating on those from US, UK, EU and Australia) and identified areas for further discussion as to whether manufactured nanomaterials would be sufficiently covered by these guidelines. Data have been collected by extensive literature searches and responses to the OECD's questionnaire to the Working Party on Manufactured Nanomaterials.

The regulatory guidelines were considered in terms of the manufacture or importation of a chemical species. The described guidelines give the general principles applied to the risk assessment of chemicals and pointed to more detailed information and resources where available.

A summary of a general regulatory framework was produced (Figure 1.1), and it was determined that international risk assessment frameworks mainly followed the same overall procedure, with the notable exception of the regulation of chemical species in New Zealand where the act of manufacture or importation is enough to require the manufacturer to start the risk assessment process. The industrial chemical risk assessment in the European Union (EU) is covered under the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH; Regulation (EC) No 1907/2006) which applies to existing and new chemicals being manufactured or imported in amounts greater than 1 tonne/year, which are collated by the European Chemicals Agency (ECHA). Regulation of chemical substances under REACH is based on the principle "that industry should manufacture, import or use substances or place them on the market in a way that, under reasonably foreseeable conditions, human health and the environment are not adversely affected" (ECHA, 2000).

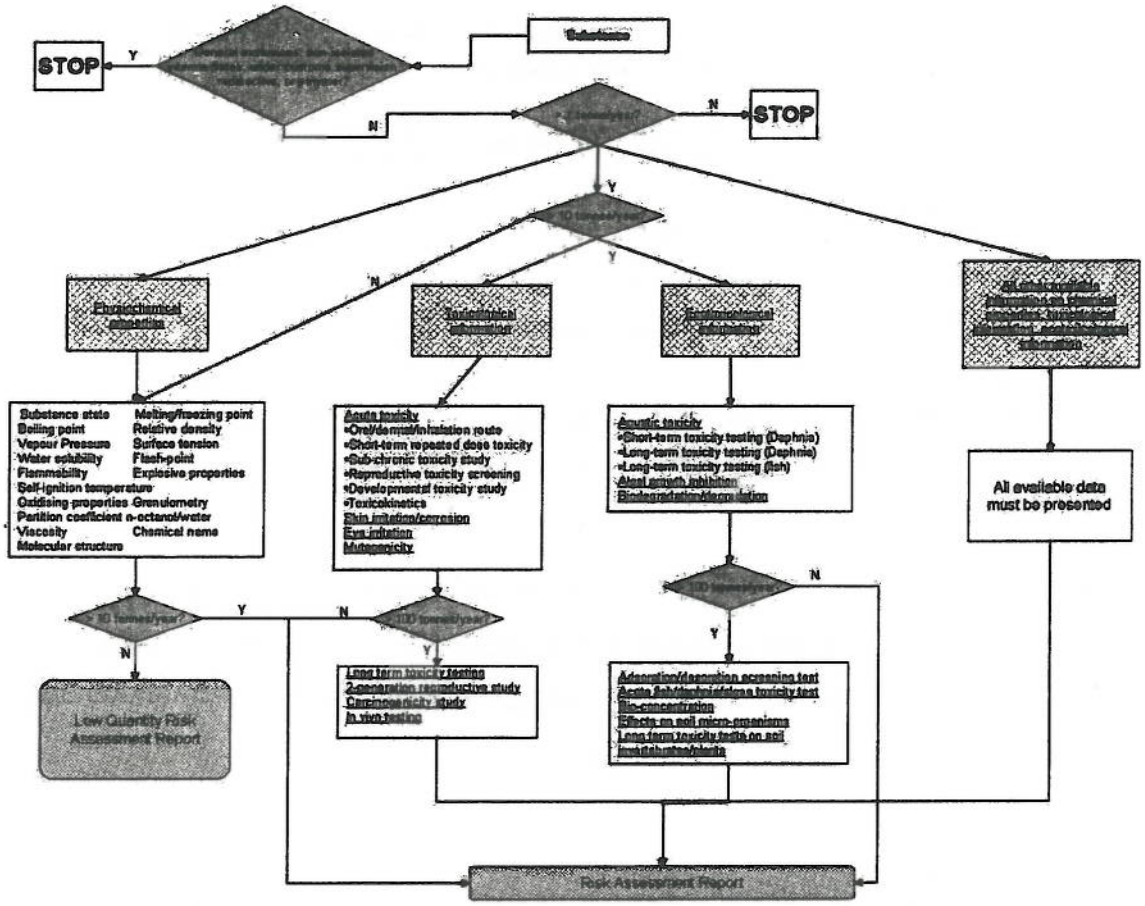

Figure 1.1. Schematic showing a general summary for the risk assessment of chemical substances. The schematic indicates the areas in which testing is normally required with the type of tests involved. The normal trigger for the risk assessment of a chemical substance is for the production to exceed 1tonne/year.

The initial requirement for the risk assessment of a chemical substance occurred generally after the amount produced exceeded 1 tonne/year (as seen in Table 1.1).

Table 1.1. International weight limits for the request for more information (i.e. triggers) in the risk assessment of chemicals

	Australia	European Community	Canada	United States of America	Japan	New Zealand
Initial trigger for (limited) regulation	1 tonne/year	1 tonne/year	1 tonne/year	10 tonnes/year	0.907 tonne/year	Act of manufacture or importing
	-	10 tonnes/year	10 tonnes/year	11 tonnes/year (4 year IUR)	9 tonnes/year	-
Further triggers for information	-	100 tonnes/year	100 tonnes/year	136 tonnes/year (4 year IUR)	-	-
	-	1000 tonnes/year	-	-	-	-

The amount of substance manufactured or imported is considered to be the initial trigger for the risk assessment process. Further weight triggers require more information to be generated about a chemical; however toxicological findings could also trigger this request.

1.2. Toxicological effects of manufactured nanomaterials

Chemicals, and manufactured nanomaterials, can enter the body via the lungs, skin and gastro-intestinal tract (Klaassen, 2001). The extent of initial entry into the body is likely to depend on the size and surface properties of the nanomaterial (Nemmar et al, 2002a; Gieser et al., 2005;). There has been some indication that the surface properties of nanomaterials are less important than the size and shape of the material (Poland et al., 2008; Ferin et al., 1990; Oberdoerster et al, 1990; Brown et al., 2001; Dankovic et al., 2008), however it is likely that a combination of a number of physicochemical characteristics and the chemical properties will cause the overall toxic effect of nanomaterials (Nemmar et al, 2002b; Figure 1.2), which is supported by similar observations in ultrafine particles (Kreyling et al, 2004).

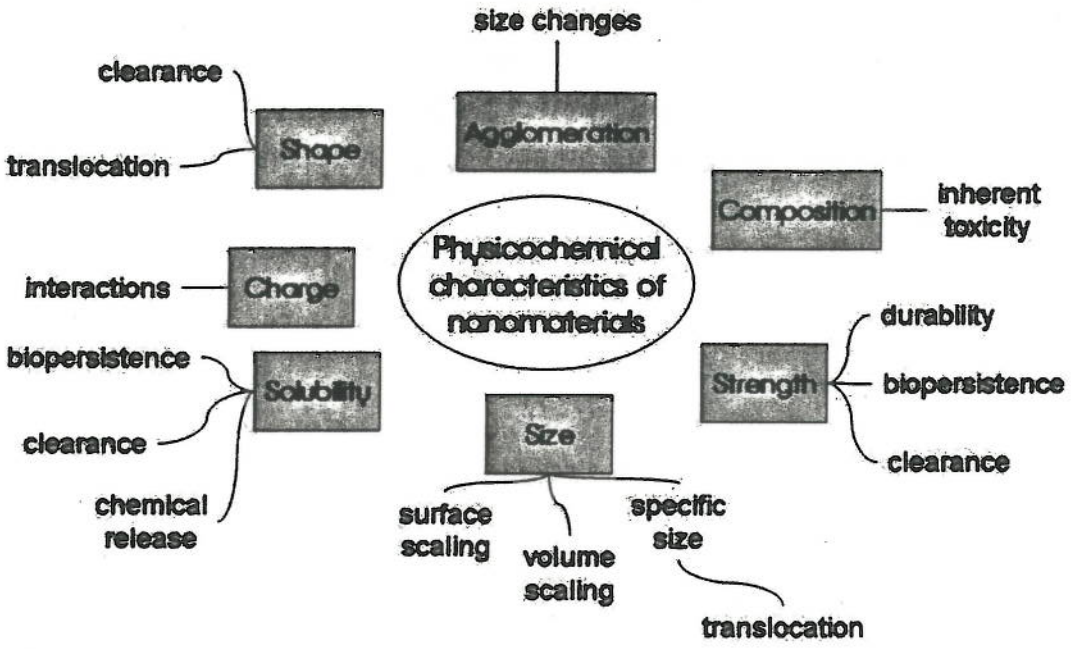

Figure 1.2. Schematic of the physicochemical properties of nanomaterials and their likely effect on biological interactions.

The size of the nanomaterial has been shown to affect the surface area and therefore the chemical reactivity (Duffin et al, 2002; Duffin et al, 2007) as well as the translocation potential of nanomaterials, which will in turn increase the toxicological effects of nanomaterials (Stone et al., 2007). Therefore, it is likely that a combination of many different characteristics and properties determine the toxicological effect of nanomaterials. However, the likelihood of exposure must also be assessed before the associated risk of manufactured nanomaterials can be determined.

1.3. Summary

The manufacture and importation of manufactured nanomaterials will be covered under REACH in the EU and, apart from the initial requirement for a weight trigger, will generally be appropriate for the risk assessment of nanomaterials depending on the quality of data used.

This report firstly considers the physicochemical and toxicity methods (as adopted by OECD; Section 2), the knowledge gaps presented by these methods, the risk assessment framework and determination of quality of data

(Section 3), potential risk assessment tools and the reported opinions on whether the risk assessment frameworks are appropriate for use with nanomaterials. We then present the findings from the workshop identifying further knowledge gaps with associated recommendations (Section 4).

Section 2

Assessment of hazard

2.1 Assessment methods

2.1.1. General overview

The assessment of the effects of chemical exposure on human health and organisms in any environment involves the consideration of a range of properties, principles and characteristics. The starting point is normally an assessment of the physicochemical and toxicological properties of a substance (Klaassen, 2001; Barille, 2004). The latter requires an understanding of how the substance behaves in different environments, including consideration of its persistence, bioavailability, internal distribution and bioaccumulation, which can be indicated by its physicochemical properties (van Leeuwen and Vermeire, 2007). The evaluation of the relative significance of the possible exposure pathways is essential as this determines not only the extent to which various tissues might be exposed, and therefore which toxicity data are most relevant, but also whether significant exposure is likely to occur at all (Harrison and Holmes, 2006).

In chemical risk assessment, a range of critical toxicity endpoints and associated test guidelines have been established by regulatory bodies worldwide (including OECD, Environmental Protection Agency (EPA), EU). These are described in more detail below (along with their suitability to determine the toxicity of nanomaterials), but typically involve the assessment of acute toxicity (e.g. lethal dose for 50% of test animals; LD_{50}), repeat dose toxicity, irritancy, sensitization potential, mutagenicity, clastogenicity, carcinogenicity and reproductive toxicity. The specific tests conducted and the routes of exposure used in the testing regime are governed by the physicochemical properties of the substance, as well as its likely use and human exposure scenarios. Exposure routes include oral (delivered in the feed or by gavage), dermal, and inhalation, as well as other, less common, routes such as sub-dermal, intravascular and intraperitoneal, which may be used if appropriate in the health risk assessment of pharmaceuticals and in

special circumstances (e.g. determination of toxicological mechanisms of action; van Leeuwen and Vermeire, 2007). The use of toxicological endpoints in risk assessment frameworks is discussed in more detail in Section 3.

The European Chemicals Bureau (ECB) controls the implementation and harmonisation of test methods on chemical substances in the EU, in close collaboration with the OECD and other International Organisations. The legally binding EU standardised Testing Methods to determine the hazardous properties of chemicals are contained in Annex V of Dir 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances (accessed at http://ecb.jrc.it/testing-methods/). The tests enable the determination of the intrinsic properties of chemicals, but further testing requirements have been determined for particulate materials and man-made fibres (EUR 20268 EN, 2002) which are currently being developed. The knowledge of these properties allows the identification and assessment of the hazards that the chemicals pose and provide the information needed for exposure assessment as well as fate and pathways of chemicals in the environment. These tests aim to identify any adverse effects that the chemicals have an inherent capacity to cause and, where appropriate, estimation of the relationship between dose or level of exposure to a substance and the incidence and severity of an effect. The Testing Methods are split into three parts: Part A, physicochemical properties; Part B, human health effects; and Part C, environmental effects. The Testing Methods are summarised in Table 2.1, where the corresponding OECD Technical Guidance Document number (OECD TG) is also quoted as well as the general concerns over the use of the methods for the risk assessment of manufactured nanomaterials. The discussion of those points is continued below.

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
A.	**Physicochemical properties**			
	Substance state			
	Melting freezing temperature (OECD TG102)			Capillary method in liquid bath or in metal block (visual identification)
				Kofler hot bar (visual identification)
		Melt microscope (using microscope hot stages)		
		Method to determine the freezing temperature (temperature measured)		
		Apparatus with photocell detection		
		Differential Thermal Analysis (DTA)		
		Differential Scanning Calorimetry (DSC)		
	Boiling point (OECD TG103)	Ebulliometer		
		Dynamic method		
		Distillation method		
		Method according to Siwoloboff		
		Photocell detection		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Boiling point (OECD TG103) (continued)	Differential Thermal Analysis (DTA)		
		Differential Scanning Calorimetry (DSC)		
	Relative Density*(OECD TG109)	Hydrostatic balance[2]		
	** nanomaterials assumed to be solid and not liquid*	Pycnometer[2]		
		Air comparison pycnometer[2]		
	Vapour Pressure (OECD TG104)		Dynamic method (Cottrell's method, only if low melting point)	
		Static method		
		Isoteniscope		
			Effusion method: vapour pressure balance[2]	
			Effusion method: loss of weight[2]	
		Gas saturation method		
		Spinning rotor		
	Surface tension (OECD TG115)		Plate method[4]	
			Stirrup method[4]	
			Ring method[4]	

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Water Solubility (OECD TG105)[5]			Preliminary test (visual determination of dissolved amount)
		Column elution method		
			Flask method	
	Partition Coefficient (*n*-octanol/ water)		Shake-flask method (OECD 107)[3,5,8,]	
			HPLC method [3,5,8]	
	Flash point			Liquids only
	Flammability (solids)		Preliminary screening test[2]	
			Burning rate test (NF T20-042)[2]	
	Flammability (contact with water)	Step-by-step testing (not suitable for substances that spontaneously combust with air)		
	Self-ignition Temperature (Pyrophoric)		Powdery solid poured from height and observed (NF T20-039)[2,6]	
		Relative Self-ignition Temperature (solids; NF T-20-036)		
	Explosive Properties (NF T20-038)	Thermal sensitivity (DIN 1623)		
		Mechanical sensitivity (shock)		
		Mechanical sensitivity (friction)		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Oxidising Properties (NF T20-035)		Preliminary test[7] mixture of solid with cellulose by weight	
			Train test[7] mixture of solid with cellulose by weight	
	Grannulometry			
	Stability in organic solvents and identity of relevant degradation products			
	Dissociation constant			
	Viscosity			
	Particle size distribution	Microscopy examination (OECD TG110) using light or electron microscopy		
			Sieving (OECD TG110)[6,12]	
		Sedimentation (gravitational settling; OECD TG110)		
		Electrical sensing zone (OECD TG110)		
		Phase Doppler anemometry (PDA) – assumes particles are spherical and have a known refractive index		
		Determination of fibre length and diameter distributions (OECD TG110)		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Particle size distribution (contd)	Cascade impaction		
		Laser scattering/diffraction		
		Rotation drum method		
			Elutriation (OECD TG110)	
			Air jet sieve	
			Cycone	
A.	**Toxicity testing**			
	Eye Irritation/Corrosion		Acute eye irritation (OECD TG405)[2,7,9]	
	Skin Sensitisation		Guinea pig maximisation test (OECD TG406)[2,7,9]	
			Buehler test (OECD TG406)[2,7,9]	
	Acute Oral Toxicity			Fixed dose procedure (OECD TG420)[2,7,9] – administration of substance by tube (volume required for standard doses)
				Acute toxic class method (OECD TG423)[2,7,9] – administration of substance by tube (volume required for standard doses)

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Acute Inhalation Toxicity		Acute inhalation toxicity (OECD TG403)[2,6,7,9] - range of doses not exceeding 5% volume of test chamber	
	Acute Dermal Toxicity		Acute dermal toxicity (OECD TG402)[2,7,9]	
	Acute Dermal Irritation/Corrosion		Acute dermal irritation/corrosion (OECD TG404)[2,7,9,10] -	
	Repeated Dose (28 days) Toxicity		Oral administration (OECD TG407)[2,7,9]	
			Inhalation administration (OECD TG412)[2,7,9]	
			Dermal administration (OECD TG412)[2,7,9]	
	Mutagenicity	*In vitro* mammalian chromosome aberration test (OECD TG473) – test substance dissolved or suspended, range of concentrations administered (up to 5mg/mL or 0.01M)[7]		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Mutagenicity (continued)	Reverse mutation test using bacteria (OECD TG471) - test substance dissolved or suspended, range of concentrations administered (up to 5mg/plate)[7]		
			In vivo mammalian chromosome aberration test (OECD TG475) – test substance dissolved or suspended, limit test (2000mg/kg), length of exposure 1 – 14 days[2,7,11]	
			In vivo mammalian erythrocyte micronucleus test (OECD TG474) – test substance dissolved or suspended, limit test (2000mg/kg), length of exposure 1 – 14 days[2,7,11]	
		In vitro gene mutation assay *Saccharomyces cerevisiae* (OECD TG480) – test substance dissolved or suspended, relatively insoluble substances tested up to limit of solubility [2,7]		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Mutagenicity (continued)	*In vitro* mitotic recombination assay *Saccharomyces cerevisiae* (OECD TG481) – test substance dissolved or suspended, relatively insoluble substances tested up to limit of solubility [2,7]		
		In vitro mammalian cell mutation assay (OECD TG476) – test substance dissolved or suspended, maximum concentration 5mg/mL or 0.01M[2,7]		
		DNA Damage and Repair - Unscheduled DNA synthesis mammalian cells i*n vitro* (OECD TG482) – test substance dissolved or suspended, range of concentrations (maximum with some cytotoxic effect)[2,7,9]		

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Mutagenicity (continued)	*In vitro* sister chromatid exchange assay in mammalian cells (OECD TG479) – test substance dissolved or suspended, range of concentrations (maximum with significant toxic effect, non-soluble tested up to limit of solubility)[2,7,9]		
			Sex linked recessive lethal test in *Drosophila melanogaster* – range of exposures (one either maximum tolerated concentration or indications of toxicity)[2,7,9]	
		In vitro mammalian cell transformation tests — range of exposures (yielding a concentration-related toxic effect), varying duration[2,7,9]		
			Rodent dominant lethal test (OECD TG478) – three dose levels, high dose causing some toxicity, generally single administration[2,4,7,11]	

		Suitable for use with nanomaterials	Concerns over use with nanomaterials	Unsuitable for use with nanomaterials
	Mutagenicity (continued		Mammalian spermatogonial chromosome aberration test (*in vivo*, OECD TG483) – range of doses (maximum to no toxicity), limit test of 2000mg/kg body weight/day, one administration[2,7,11]	
		Mouse spot test (*in vivo*, OECD TG484) – two dose levels (one showing toxicity)		
		Mouse heritable translocation (*in vivo*, OECD TG485) – appropriate dose and exposure routes used		

[1]visual identification is not possible without microscope
[2]is there enough test substance to enable these tests to be done to a satisfactory standard
[3]elution of nanomaterials may not be possible (interaction with column material)
[4]only suitable for materials that are soluble at concentrations of or greater than 1mg/L
[5]the distinction between a solution and suspension of nanomaterials must be elucidated
[6]concern over nanomaterials becoming airborne during experiment
[7]mixture by weight (another method of determining amount may be more suitable)
[8]not suitable for surface active materials
[9]concern over whether the mentioned endpoints are sufficient – translocation of non-soluble particles should be considered
[10]removal of substance after test
[11]appropriate duration/route
[12]appropriate container for size of material

2.2. Physicochemical testing

2.2.1. Overview

The physicochemical properties of a substance will determine the exposure route to be used in further toxicity studies. There are many published sources of physicochemical data, including the Merck Index (2006) and IUPAC Solubility Data Series (http://srdata.nist.gov/solubility/), which can be used within risk assessments rather than experimental results. However, the data should be considered carefully and the state of the substance and range of values must be evaluated. Within general risk assessment frameworks there is a suggested tiered process to determine the physicochemical properties of a substance in order to eliminate unnecessary tests (Figure 2.1.).

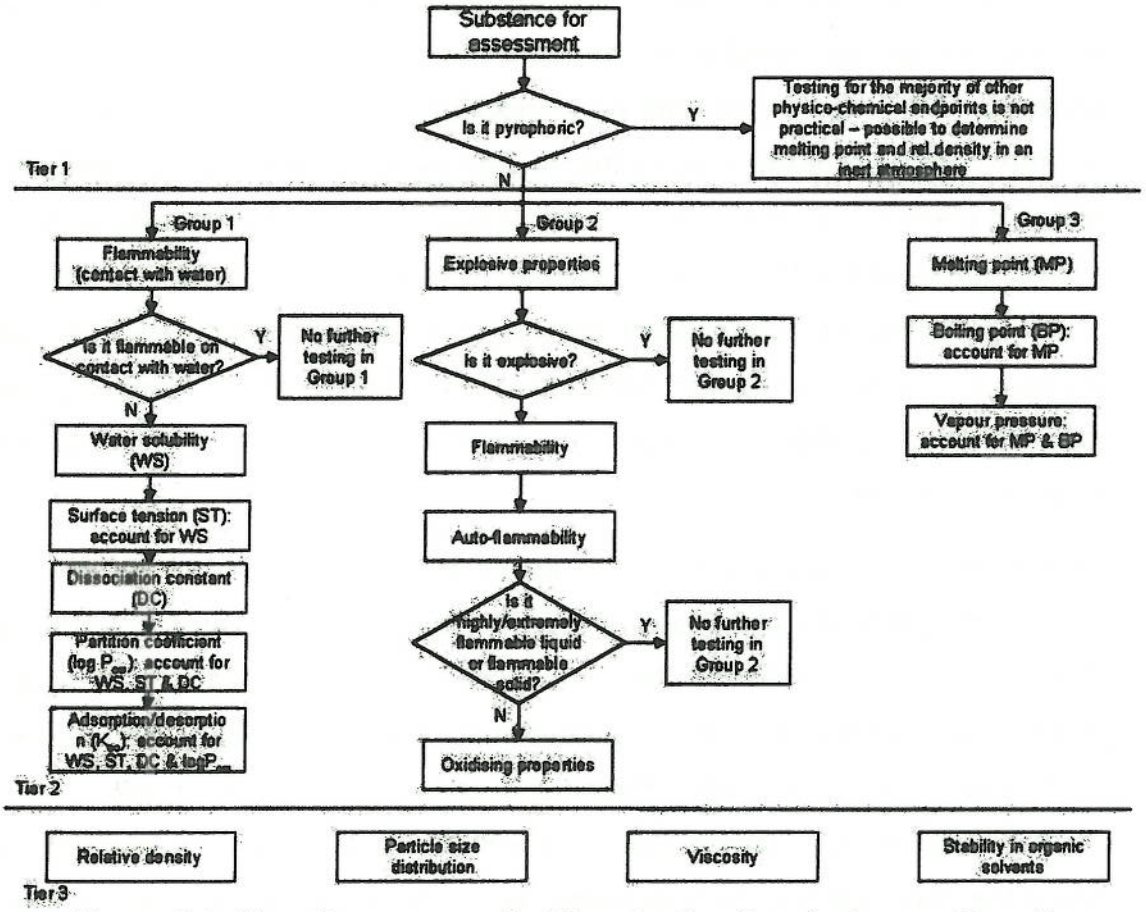

Figure 2.1. Tiered assessment of the physicochemical properties of a chemical substance [where melting point (MP), boiling point (BP), water solubility (WS), surface tension (ST), dissociation constant (DC) are determined]. If a test substance is considered to be pyrophoric (i.e. can spontaneously ignite in air) then the other tests are not necessary.

In the recommended physicochemical testing scheme, the particle size distribution is determined at the later stage (Tier 3, Figure 2.1). When the toxicity of nanomaterials is assessed then the particle size distribution may affect the results of tests in the previous tiers. However, as long as the sample of material selected for testing is representative of the whole material, then the results and testing scheme would be considered as appropriate for use with nanomaterials. The individual testing methods are described and critiqued in more detail in Section 2.2.2.

2.2.2. Testing methods

Melting/Freezing and Boiling Temperatures

The melting temperature is defined as the temperature (or temperature range) at which the phase transition from solid to liquid state occurs at atmospheric pressure. This may or may not be coincident with the freezing temperature. For the majority of particle sizes this is unlikely to be affected by changes in scale of material, as the melting (and boiling) temperature is determined by atomic bonds rather than size. However, for very small particles (<50nm) a reduction in melting temperature has been observed due to the very high surface to volume ratio of nanoparticles. A corresponding change in freezing temperature is unlikely to occur as nanoparticles should not be produced when the melt freezes.

Nanomaterials are used extensively to reduce the sintering temperature of powder compacts (Qi and Wang, 2004; Roduner, 2006). Sintering is the act of producing dense materials from powders through the action of heat and pressure without the need to produce a melt. During sintering nanoparticles will coalesce and grow in size. Sintering occurs in a temperature range of 1/2 - 2/3 of the melting temperature. Therefore it may not be possible to determine the melting temperatures of certain types of manufactured nanomaterials as they will coalesce and grow beyond the critical size before the temperature reaches the melting point of the nanoparticle. The purity of the test substance will also affect the measured melting and boiling temperatures, which may vary considerably with manufacturing method, starting chemicals, and production site.

To determine the melting temperature, the method can be a type of capillary method, hot stage method, freezing temperature determination method or thermal analysis methods. The methods most suitable for manufactured nanomaterials are those that do not require human observation (i.e. Melt Microscope, Photocell Detection, Differential Thermal Analysis [DTA], or Differential Scanning Calorimetry [DSC]), as the size of the material will make observation difficult. To prevent sintering effects melting studies on individual nanoparticles can be conducted using transmission electron microscopy.

As with melting temperature, boiling temperature of nanomaterials will be expected to reduce when the particle is below a critical size. However, liquid nanoparticles (or more accurately nanodrops) would be expected to coalesce very rapidly to produce a single melt. The measurement of the boiling point of a single nanodrop is therefore not expected to be of relevance to real world systems as such measurements should be no different from those of bulk materials. As with bulk materials, many nanomaterials will decompose or sublime at high temperatures instead of boiling. The normal boiling temperature is defined as the temperature at which the vapour pressure of a liquid is 101325 kPa. If Photocell Detection, DTA or DSC is used to determine the Melting Temperature, then the Boiling Temperature can be determined at the same time, reducing the experimental demand, as well as the material demand. However, the methods do not require human observation of change from liquid to gas which eliminates an area of error.

Relative Density

The relative density of solids is the ratio between the mass of a volume of substance determined at 20°C and the mass of the same volume of water determined at 4°C. The Testing Methods used are Hydrostatic Balance, Pcynometer Methods, and Air Compression Pycnometer, which measure the change in weight on addition of a material to a container of known volume. These methods are likely to be appropriate for use with manufactured nanomaterials as long as defined guidelines are used with the type and size of container and the method of filling (to enable reproducibility allowing for

nanomaterials to settle down and ensure that the same volume is measured). When conducting these measurements it is critical to ensure that the density of the material is measured as opposed to the density of the agglomerate or aggregate as nanoparticles are very prone to agglomeration/aggregation.

Vapour Pressure

The vapour pressure of a substance is defined as the saturation pressure above a solid substance. Impurities and surface curvature will affect the vapour pressure, which will therefore change depending on the manufacturing method, production site, starting chemicals and particle size. However, determining the vapour pressure does require the material to boil, and will therefore not be possible to determine for a range of manufactured nanomaterials.

Surface Tension

The measurement of surface tension is based on the measurement of the maximum force necessary to exert vertically in order to draw up a film formed between the liquid and a stirrup or ring in contact with the surface of it. Surface tension can only be measured for substances with a water solubility of greater than 1mg/L. For a number of manufactured nanomaterials, this measurement will not be possible as the substance will not be water soluble and instead will form a suspension.

Water Solubility

The solubility in water of a substance is specified by the saturation mass concentration of the substance in water at a given temperature. The column elution test method is for substances with low solubility (less than 1mg/L) and is determined by measuring the elution of a test material with water from a micro-column filled with an inert support material (glass beads or sand) coated with an excess of test substance; the solubility is determined when the mass concentration of the eluate is constant. The flask method is suitable for

substances with higher solubility. The eluate is analysed using gas or liquid chromatography, titration methods, photometric methods, or voltammetric methods. Due to the small size of the nanomaterials, it may be difficult to distinguish between solubility of the substance and suspension of the substance in water as both solution and suspension will appear equally transparent to the human eye. The only difference is that the suspended particles will separate out over a period of time, however this may be an excessive length of time in the case of nanomaterials (Joesten et al., 1998). In addition, it may be that chemical reactions occur between the nanomaterial and water which means that the water solubility cannot be determined, however this is also a possibility with bulk materials.

Partition Coefficient

The partition coefficient is defined as the ratio of the equilibrium concentrations of a dissolved substance in a two-phase system consisting of two immiscible solvents (normally *n*-octanol and water). The substance must be soluble in both of the solvents, which may exclude a large number of manufactured nanomaterials (and will depend on the water solubility results).

The shake flask test (with analysis of the separate phases using photometric methods, gas chromatography, or high performance liquid chromoatography [HPLC]) can be used as a testing method for pure substances soluble in water and *n*-octanol, but cannot be used for surface active materials (which may form a large proportion of manufactured materials). HPLC can also be used as testing method, but cannot be used for strong acids or bases, metal complexes, surface active materials, or substances that react with the eluent. Impurities will affect the analysis, although less so for HPLC.

Flash-point

The flash-point is the lowest temperature (corrected to a pressure of 101 325kPa) at which a liquid evolves vapours in such an amount that a

flammable vapour/air mixture is produced in the test vessel. The test is only applicable to liquid substances whose vapours can be ignited by ignition sources, and is therefore not applicable to manufactured nanomaterials as they will coalesce to form a single body and behave as a bulk material. Airborne suspensions of some nanomaterials may behave as a vapour exhibiting a flash point. Such behaviour would be considered along with explosivity, flammability, etc.

Flammability (solids)

The test involves the substance formed into an unbroken strip or powder train which is then ignited by a gas flame to determine whether burning or smouldering occurs within a specified time. If the substance is flammable, then further testing will determine the burning rate. Whilst the test is suitable for nanomaterials, there is some concern over the preparation of the test sample: including the amount of material required; the potential aerosol behaviour of the material (during preparation and burning); the method of mould filling (currently dropped from height to ensure that the mould is filled uniformly, which would be unsuitable for nanomaterial sample preparation); the effect of surface coating and/or impurities on the burn rate; and the position of the test rig inside a fume hood (which may add to the aerosol behaviour of the test substance).

Flammability (contact with water)

The test method is not applicable to substances which spontaneously ignite when in contact with the air (e.g. some metal nanomaterials). The test substance is exposed to water or damp air to determine whether dangerous amounts of gases are released (that could be flammable). A material is considered to be highly flammable when it releases flammable gases in dangerous quantities in excess of 1 L/Kg/hour. The Testing Method is a sequential process where (1) the substance is placed in water at 20°C and the evolved gas is tested for flammability; (2) the test substance is placed on filter paper (to contain the substance) floating on the water surface at 20°C; (3) the

substance is made into a pile (2 cm high and 3 cm in diameter) to which drops of water are added and the evolved gas tested for flammability; and (4) substance is mixed with water at 20°C and the rate of evolution of gas is measured. If the substance does not react violently with water, then the first three steps can be missed. Whilst the overall test method is considered to be suitable for determining the flammability on contact with water of nanomaterials, the amount of material available and the likelihood of the nanomaterial being contained on the filter paper in Step 2 may mean that the method should be adapted.

Pyrophoric properties of solids and liquids

Substances are considered to be pyrophoric if they ignite or cause charring under specified test conditions. The substance is added to an inert carrier and brought into contact with air at ambient temperature for five minutes. If the solid substance ignites, then the substance is considered to be pyrophoric. The Testing Method requires for powdery substances to be poured into a porcelain cup filled with diatomaceous earth from a height of 1 metre, which is likely to be unsuitable for nanomaterials where such behaviour is likely to result in them becoming airborne for a long period of time.

Explosive properties

The test substance must be evaluated for its explosive potential when subjected to flame, shock, or friction, demonstrating the action of thermal or mechanical stimuli, respectively. Small amounts of the test substance are subjected to flame (in a steel container, for 5 minutes), shock (when a specified mass is dropped from a defined height), and friction (under specified conditions of load and relative motion). The Testing Methods are suitable for use with nanomaterials as long as precautionary operating procedures are maintained to prevent the material becoming airborne. In addition, the application of shock and friction loads may result in a degree of uncertainty relating to the correct location of the nanaomaterials (i.e. are they between the sfriction or shock plates during the test)

Relative self-ignition temperature for solids

The Testing Method is suitable for substances that are not explosive or ignite spontaneously in contact with air. The self-ignition temperature is the minimum ambient temperature at which a certain volume of substance will ignite under defined conditions. A certain volume of the test substance is place in an oven and the temperature/time curve is recorded whilst the temperature is increased to 400°C at a set rate. A stainless steel wire mesh with 45µm openings is used to form a cube container for the test substance. The openings in the container are likely to allow for an amount of the test substance to escape, therefore this method will need to be adapted for use with manufactured nanomaterials.

Oxidising properties (solids)

The dried test substance is mixed with a combustible substance (powdered cellulose) in a set ratio of 2 portions of test substance to 1 portion of combustible substance (by weight), placed into a container and an ignition source added. The vigour and duration of the resultant reaction (burning rate) are observed. If the initial test does not prove that the substance is oxidising, then a full test involving a number of substance to combustible substance ratios will be performed and compared to the burning rate of the reference mixture (using barium nitrate and powdered cellulose). As this method involves the weight ratio of nanomaterial to combustible substance, it is likely that the volume of the nanomaterial required will far exceed that of the powdered substance and may cause confusion in the interpretation of the result. Therefore the methodology of this experiment must be reconsidered, with the amount of test substance and combustible substance being measured in a different fashion.

Particle size distribution

Particle size distribution is not currently included in EU Directives currently in force (containing the Testing Methods of Annex V to Dir. 67/548/EEC). The OECD has presented a supplementary guidance document on the determination of the particle size distribution, fibre length and diameter distribution of chemical substances (EUR20268 EN; 2002).

2.2.3. General knowledge gaps

With the testing methods described in the previous section, there are areas that will provide difficulties when assessing the physicochemical properties of nanomaterials. These are:

1. Observation of material - Manufactured nanomaterials are generally assumed to be solid particles with at least one dimension less than 100 nm. The materials will not be observable with the human eye, and testers will need a microscope to be able to observe the particles. With a number of the physicochemical tests, the endpoint is assumed to be observable by eye using the apparatus listed in the Testing Methods.
2. Amount of material - A number of methods require large amounts of material to be used in the test. This may pose a problem with nanomaterials in development where the amounts yielding during manufacture may be in the region of grams.
3. Use of appropriate controls - It is likely that some nanomaterials will behave differently to other material forms due to quantum effects. Therefore it is reasonable that any Testing Method should be standardised using "known" nanomaterials to ensure that the results are reproducible.
4. Appropriate tests - As it is assumed that manufactured nanomaterials are solid in nature, a number of tests are not appropriate for solid materials. These include surface tension, flash-point, flammability (liquids), There are also a number of physicochemical properties that are not possible to determine for a large proportion of manufactured nanomaterials, for example metal oxides that do meal at very high

temperatures (<2000°C) or that not melt cannot have their melting, boiling temperatures or vapour pressure determined.

5. Analysis testing – whilst the use of analytical techniques such as HPLC, voltmetric measurements, gas chromatography and liquid chromatography are likely to be suitable for the application to the detection of chemical species, there is uncertainty as to whether they are suitable for use with nanomaterials with variable surface chemistry, solubility and reactivity. The numbers and range of nanomaterials will mean that new analytical protocols will have to be developed and validated for each new variation, which is likely to be a long and laborious process. The use of electron microscopy in detecting the presence of nanomaterials within samples is a reasonably quick process, and the use of Energy Dispersive X-ray (EDX) analysis and X-ray photoelectron spectroscopy (XPS) can determine the composition of the nanomaterial. For larger amounts, techniques such as X-ray Diffraction (XRD) and electron paramagnetic resonance spectroscopy (EPR) can be used to identify crystal structure.

2.3. Toxicity testing

2.3.1. Overview

The toxicity testing of a substance is used to determine the humanand animal health effects based on the appropriate exposure route determined by the physicochemical assessment. The acute (single exposure with observation for at least than 14 days), sub chronic (exposure for a short period of life span) and chronic (exposure for a significant portion of life span) effects of a substance are determined by *in vivo* and *in vitro* testing according to the regulatory guidelines (see Table 2.1). The toxicological endpoints within the studies vary, however the LD_{50}, LC_{50} (lethal concentration where 50% of test animals die after being exposed for a certain length of time), MTD (maximum tolerated dose), and NOAEL (no adverse effects level) are identified endpoints that can then be used to determine the acceptable level of human exposure. The determination of toxic effects in animals is detailed in OECD TG19

(2000). With all experiments, the overall requirement to reduce, replace and refine animal use remains (Klaassen, 2001; van Leeuwen and Vermiere, 2007).

The exposure route used for the experiments is determined by the physicochemical properties of a substance as well as the likely route of human exposure (van Leeuwen and Vermiere, 2007). The histological examination of tissue samples normally uses light microscopy techniques which will not detect nanoscale material.

2.3.2. Testing methods

Acute Oral Toxicity – fixed dose and acute toxic class method

The acute oral toxicity determined by the fixed dose method exposes a group of rodents (rat) to fixed doses of 5, 50, 300, and 2000mg/Kg by gavage. The initial dose is selected to produce some signs of toxicity (sighting study) without causing severe toxic effects or mortality. Groups of animals (5 per group) are dosed at higher or lower fixed levels (main study; 14 days observation) until clinical signs of toxicity are noted.

The acute oral toxicity determined by the acute toxic class method uses three rodents for a single dose in a constant volume of substance by gavage at one of four fixed dose levels 5, 50, 300, and 2000mg/Kg body weight. The starting dose is selected to be the one that is most likely to produce mortality in some of the dosed animals. If there is unlikely to be any toxicity at 2000mg/kg then a limit test should be performed, however if there is no information about the toxicity of the substance, then the starting dose should be 300mg/kg.

Whilst the doses may be increased or decreased, dependant on the material's toxicity or lack of, it is likely that the mass concentration of doses will mean that a non-representative exposure of nanomaterials will be used in these experiments and any toxic effects are likely to be due to the amount of foreign material in the stomach (preventing the ingestion of nutrients) rather than the toxic effects of the material. The physicochemical properties of the test substance will determine the vehicle for administration to the test animals. The recorded observations (body weight, body weight changes, signs and onset of toxicity, gross pathology and microscopic evaluation of organs) are

unlikely to show the potential toxic effects of nanomaterials (as discussed in Section 2.2.3.). The microscopic evaluation of organs, using a light microscope, will not detect the presence of nanomaterials.

Other Oral Toxicity Tests

Further oral toxicity tests (repeated dose, chronic administration) will all have the same issues for the administration of nanomaterials. If nanomaterials are not shown to pass into the body through the gastrointestinal tract in health organisms in short term studies, there is little reason to continue to test oral administration.

Inhalation Toxicity

The acute inhalation toxicity is determined by exposure of rodents to an aerosol substance in an inhalation chamber at 5mg/litre for particulates for four hours. The generation and characteristics of the aerosol substance are recorded (including the median aerosol diameter and the particle geometry) along with the toxicological endpoints of the observation. The mass concentration of particulate matter will likely mean that the number of individual particles will be potentially excessive and the toxic effects observed may be due clogging of airways due to excessive particle number (as seen with ultrafine particles) rather than the actual toxic effect. The test also does not take into account the potential absorption of material through the skin or eye.

Dermal Toxicity

The acute dermal toxicity is determined by the exposure of animals (rat or rabbit) to graduated doses of the test substance using a small amount of water as a vehicle. The dose levels should be designed to produce a range of toxic effects and mortality rates. The substance should be removed at the end of the exposure period, which may prove to be problematic for some nanomaterials. The test does not take into account any aerosol potential of the material as the test area dries out.

Dermal Irritation/Corrosion

The dermal irritation (reversible damage to skin) and the dermal corrosion (irreversible damage to skin) are measured by the application of substance as a single dose to rabbit skin using a small amount of water as a vehicle for 4 hours. The substance should be removed at the end of the exposure period, which may prove to be problematic for some nanomaterials and the test does not take into account any aerosol potential of the material as the test area dries out.

In vitro tests, e.g. transcutaneous electrical resistance, human skin model or membrane barrier test method can be used to determine whether a substance is corrosive, however, there are no OECD/EU adopted tests for skin irritation.

Skin Sensitisation

The test animals (guinea pigs) are exposed to the test substance by intradermal injections (using an appropriate vehicle) as well as epidermal applications. Following a rest period, the animals are exposed to a challenge dose at which time the extent and degree of skin reaction to the material is measured. The induction dose is selected to be well-tolerated systemically and should cause mild skin irritation whilst the challenge dose should be the highest non-irritant dose. The test does not consider the potential systemic effects of repeated dermal dosing with nanomaterials which may also translocate within the body.

Eye Irritation/Corrosion

The eye irritation (reversible damage to skin) and the eye corrosion (irreversible damage to skin) are determined by the application of a test substance to one eye of a test animal (rabbit). The substance should have a volume of 0.1mL and a weight below 100mg and should be left in for one hour after which the eye can be washed. The removal of the test substance at the end of the exposure period may be problematic and the endpoints of the test do not consider the potential translocation of the material (as the test is not replicated in any other form). The test does not take into account any aerosol potential of the material as the test area dries out and the end scoring may not

show the microscopic changes to the surface of the eye due to the administration of the nanomaterial.

In Vitro Toxicity Tests

In vitro gene mammalian mutation studies, mouse lymphoma assay and *hprt* test can be used as initial screening tests, after which *in vivo* mutagenicity tests in somatic (mammalian bone marrow chromosome aberration, erythrocyte micronucleus and unscheduled DNA synthesis test and germ (mammalian spermatogonial chromosome aberration and rodent dominant lethal test) can be used to determine whether the substance is genotoxic in somatic and/or germ cells. Whilst transgenic animal models and the Comet assay can be used for risk assessment, they are not yet adopted by OECD or EU.

The administration of materials to *in vitro* experiments is done using an appropriate solvent and at analysable concentrations with the maximum test concentration for relatively non-cytotoxic substances being 5mg/mL. This is likely to be unsuitable for use with nanomaterials due to the number of particles present in the mass concentration. The translocation of nanomaterials from the cell culture medium into the cells will be visible using electron microscopy, with the identification of the nanomaterials possible with EDX and XPS. However the experiments are unlikely to provide any indication of systemic or secondary toxicity effects and long term *in vivo* experiments, including reproduction and development toxicity studies, will be necessary to determine these effects.

Reproductive and Developmental Toxicity

If the substance has already been classed as a genotoxic carcinogen or a germ cell mutagen then further testing may not necessary and the substance can be classified. A two-generation reproductive toxicity study, using an appropriate administration route, is required for substances manufactured or imported in amounts ≥100 tonnes/annum, and for those ≥10 tonnes/annum if the reproductive and developmental toxicity screening study is positive or if repeated dose toxicity study indicates potential reproductive toxicity. The

toxicological endpoints and observations remain the same as those for the acute and repeat dose toxicity studies, however the investigation includes the fertility, gestation and viability of animals as well as the development of the foetuses. Oral administration is the normal route of administration in such tests, however in the case of nanomaterials dermal or inhalation administration may be more appropriate. Selection of the animal species (normally rat) will also need to be considered as it is possible that the inter-species differences may effect the results observed (IEH, 1999).

Repeat Dose Toxicity

Repeat dose toxicity studies are only required if indicators are seen in the acute toxicity testing or if the chemical is over the 10 tonnes/annum weight trigger. Such conditions are unlikely to be applicable to nanomaterials, however the duration and repeat exposure of an organism to a nanomaterial is more likely to occur in "real-life" circumstances. Again the normal route of administration is by oral methods, however dermal and inhalation methods can be used if more appropriate. Such studies are normally 28 days in duration and are used to determine the NOAEL (OECD TG 407, 410, and 412). If the data suggests that a substance accumulates, then a sub chronic repeated dose (90 days) study is required and if a NOAEL cannot be identified, a further chronic repeated dose study (12 months) is required and further toxicity studies may be requested. The toxicological endpoints observed are similar to those for acute and developmental toxicity, with further histological investigation of target organ pathology.

Carcinogenicity

Carcinogenicity studies are only required for chemicals in amounts greater than 1000 tonnes/annum but carcinogenicity indicators are normally incorporated into other toxicity tests by the investigators in order to fulfil the requirement of reduction, refinement and replacement of animal testing.

2.2.3. General knowledge gaps

In general, the toxicity testing methods described are suitable for the determination of the effects on human health of nanomaterials. However, the main concerns are:

1. Mass concentration – as previously stated (Section 2.1.3.) the mass concentration is not an appropriate measurement for the concentration of nanomaterials.
2. Appropriate route of exposure – the initial *in vivo* toxicity testing methods normally use the oral exposure route. This may not be sufficient for the toxicity testing of nanomaterials due to the potential of agglomeration within solution, the chance of crossing the barriers in the gastrointestinal tract, and the possibility of changes due to pH levels. Therefore administration via dermal or inhalation routes is likely to be more applicable for the toxicity testing of nanomaterials. The effect of oral administration of nanomaterials on gut flora has not been considered and may show toxic effects. This is a species dependent reaction and may not be identified during routine toxicity testing.
3. Duration of tests – as it is unlikely that the duration of human exposure to small amounts of nanomaterials will occur over a short period of time, sub-chronic or chronic studies are likely to be more appropriate to determine the toxic effect of nanomaterials. If single or short-term exposure does occur, it is likely to be with high (or excessively high) concentrations of nanomaterials as a result of accidental release.
4. Detection of nanomaterials - nanomaterials, individually or in small aggregates, will not be detectable by light microscopy. Therefore, to show the presence of nanomaterials within a histological sample it will be necessary to use electron microscopy techniques. However, this does not mean that the potential toxic effects of nanomaterials will not be detectable using light microscopy.
5. Distinction and identification of nanomaterials – as the normal analytical detection methods may not be suitable to detect the presence of nanomaterials within a sample (see Section 2.1.3.), and

the use of electron microscopy will only show the presence of nanomaterials but not distinguish between varieties, it will be necessary to confirm the chemical structure of the visualised nanomaterials in histological samples with techniques such as EDX and XPS. If this is not carried out, then the nanomaterial present cannot be identified and the results seen with manufactured nanomaterials cannot be distinguished from those observed due to accidental exposure or naturally occurring nanomaterials.

6. Systemic measurements of toxicity – whilst *in vitro* screening tests have been suggested for rapid identification of toxic nanomaterials, the most probable scenario is that the nanomaterial has a systemic effect and will translocate in the organism after administration. This cannot be determined by single cell *in vitro* studies and therefore the need for animal experimentation remains until more developed screening tests or the relationship between the physicochemical properties of a nanomaterial and its toxic effect can be determined.

7. Effect of particulate number - Whilst the dose administered in a toxicity study must be a mass concentration, there is a distinct possibility that a non-representative exposure of nanomaterials will be used and any toxic effects are likely to be due to the amount of foreign material in the stomach, lungs or cells preventing the normal functioning of the system rather than the toxic effects of the material. This problem has been noted before in inhalation studies with ultrafine particulates (IEH, 2000).

8. Solution or suspension of nanomaterial – the distinction and the potential disparages between a solution or suspension of a nanomaterial for use in material preparation must be considered. However, it is likely that this will only be a problem with long term administration of the test substance as the suspension may precipitate out over time.

9. Use of appropriate solvent – whilst the test nanomaterial may be soluble and stable in an organic solvent, the effects of the solvent on the test system must also be considered. Conversely the potential of

the nanomaterial to interact with the surrounding media (e.g. plastic of syringe, cell culture media) must also be considered in the administration of the nanomaterial.

2.4. Ecotoxicity testing

The ecotoxicological information required under REACH of manufactured nanomaterials was considered in depth by Crane and Handy (2006; Defra, 2000; Crane et al, 2007).

Depending on the ecotoxicological data already available and mitigating factors hazard assessment is performed and / or refined, involving short term (acute) toxicity testing (Daphnia and fish) and growth inhibition study on algae. Further, chronic (long term) testing is required to refine the risk assessment process if the substance is classified as PBT (Persistent, Bioaccummulative, Toxic) or vPvB (very Persitent, very Bioaccumulative; Crane and Handy, 2006). The areas where the current ecotoxicological strategies were identified as not fit for purpose were:

i. macroscale material toxicity cannot currently be related to nanoscale material toxicity
ii. the homogenous dispersion currently recommended in ecotoxicological testing may not reflect the behaviour of nanomaterials in the natural environment
iii. there is currently no empirical data to support the relationships between species when exposed to nanomaterials
iv. mass concentration is used as a determinant of dose

2.5. Addressing identified areas of concern

2.5.1. Physicochemical tests

A wide range of physical and chemical properties are required to characterise the experimental nanomaterials to ensure that any toxic effects are attributed to the correct and specific nanomaterials that are responsible. There are several approaches for basic particle and nanomaterial characterisation, including ISO, ASTM and BSI standards. The properties currently included in regulatory frameworks include the chemical composition and nomenclature as well as the defined properties discussed in Section 2.4. However, it may be necessary to impose further restrictions on the physicochemical testing of nanomaterials to ensure that the measurements are taken under conditions that mimic those of the potential human and environmental exposure.

Nanomaterials differ from the bulk material as the scale decreases due to specific size, volume scaling and surface scaling effects (Gogotsi, 2006; Roduner 2006). The change in scale affects the dispersion, dissolution, aggregation characteristics and the potential absorption surface area of the nanomaterial (Brayner, 2008). The change in scale can be determined by looking at the particle size and related shape, the surface area and the agglomeration potential of the nanomaterials.

The size of nanomaterials can be determined by observation using electron microscopy. Particle size can also be determined by using laser diffraction techniques, which will also give a measurement of particle size distribution (Wedd, 2003; Roduner, 2006). However, it is necessary to confirm the laser diffraction measurements with observations using electron microscopy as laser diffraction techniques assume a spherical particle (Wedd, 2003). The distribution of particle sizes is important to characterise the sample population for the manufactured nanomaterial and to ensure that the experimental samples selected are representative of the whole population and that errors are not added due to unrepresentative samples. Statistical methods can be used to determine the representative sample sizes.

The surface area of nanomaterials needs to be characterised for risk assessments, which can be done for a non-porous material by mathematical

derivation from measurements obtained from electron micrographs. Porous nanomaterials will have an increased surface area which is more difficult to determine by electron microscopy, however the BET theory measuring the physical adsorption of gas molecules on to a solid surface may be suitable to determine the surface area of porous nanomaterials (Brunauer, Emmett and Teller, 1938).

The particle size and shape characteristics should also be measured dispersed in the most relevant media, for example as a dry powder for nanomaterials likely to have aerosol exposure, or in aqueous solution for nanomaterials that will be found in freshwater streams. It will also be necessary to consider the likely exposure throughout the product cycle and the possibility that the different exposure media throughout the cycle may have an affect on the nanomaterial characteristics.

2.5.2. Toxicity tests

The most appropriate dose or concentration and the methods for evaluation should be used for the nanomaterial and hazard characterisation. The commonly used mass concentration is not appropriate for use with nanomaterials due to the significant size variation and the sheer number of particles that may be present within a small mass. Number concentration and surface area may be more appropriate measurements for the dose calculation, in terms of the dose -response relationship (RA/RAEng, 2004; Crane and Handy, 2006; SCENHIR, 2007).

Electron microscopy observation of histological samples will enable the detection of the translocation of nanomaterials from the point of introduction into the body. However, the electron micrograph will only show that a nanomaterial is present within the tissue sample and will not identify that nanomaterial (which is essential to prove that the object seen is related to the experimental exposure). In order to prove the existence of manufactured nanomaterials within a histological sample, and to prove the identity of the test substance, additional techniques such as EDX and XPS must be used to determine the chemical structure of the object and therefore prove its identity.

The distinction between manufactured and naturally occurring nanomaterials may also be necessary in fluid samples (e.g. cell culture, blood or urine) in which case the same techniques can be used.

2.6. Summary

In general the testing methods set out by the OECD require adaptation before they can be accurately and reproducibly used to analyse samples containing nanomaterials. The main concerns with the administration of nanomaterials into such test systems are the mass concentration doses suggested, the detection of nanomaterials within samples, the potential for translocation of nanomaterials within bodies, and the equipment used to administer and test the manufacture nanomaterial (see Table 2.1). There are also unanswered questions as to whether there are significant inter-species variations in test animals and which animals are suitable for use.

Section 3

Risk Assessment Framework

3.1 Risk assessment frameworks

3.1.1. General overview

Whilst the hazard of a substance is its potential to cause harm, the risk of a substance is the likelihood of that harm occurring, taking into account wider considerations of exposure and uncertainty (Klaassen 2001). The risk assessment of a substance requires information on both the potential hazard presented by the substance and the degree of exposure (Harrison and Holmes. 2006) and must consider the potential consequences of exposure on biological systems as well as the likelihood of release, exposure to other environments after release and long term effects. The basis of all risk assessment is that without exposure, there is no risk (van Leeuwan and Vermiere, 2007). The risk assessment process provides a level of confidence concerning the safety of such a chemical, ensuring that manufacture is authorised in a safe and responsible manner (discussed further in articles including IEH, 1999a, Eduljee, 2000, and Pollard et al., 2002).

In the first report, regulatory approaches to risk assessment were considered for industrial chemicals, pharmaceuticals and occupational exposure to chemicals (Rocks et al, 2008; summarised in Section 3.2). There are a number of risk assessment protocols and processes that have become 'standard practice' (e.g. OECD discussed by de Marcellus, 2003; WHO/IPCS harmonisation project accessed at www.who.int/ipcs/methods/harmonization /en/).

The quality of the output of a risk assessment varies significantly depending on the availability and the quality of the supporting science, evidence, and analysis, as well as the needs of the end-user (EA, 2005). The use of qualitative and quantitative data should not suggest, however, that the estimate of risk is precise, as a number of uncertainties are included in the process. A tiered risk assessment (in terms of sophistication) is normally

used to take quantitative and qualitative data into account (DETR, 2000), see Figure 3.1.

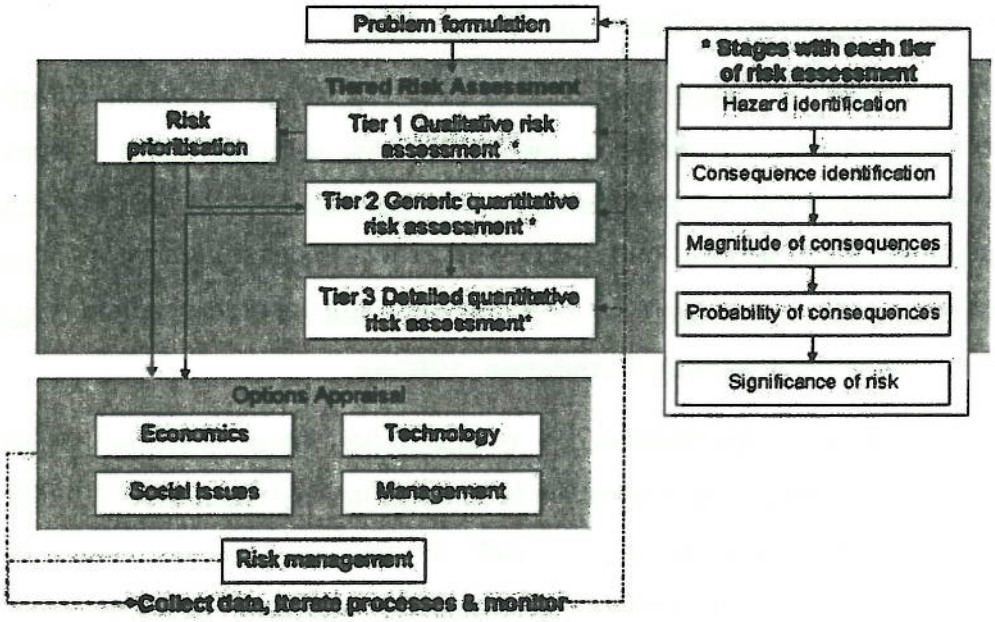

Figure 3.1. Design of risk assessment and risk management framework showing qualitative and quantitative risk assessment and the stages required for each tier (after DETR, 2000).

Problem formulation (determining who or what is at risk) must occur before risk assessment can take place and the appropriateness of the problem formulation determines the appropriateness of the risk analysis (Pollard, 2006; Owen and Handy, 2007), whilst good problem formulation guides the remainder of the assessment on other issues, including the relationship between the risk assessment and other decision components (see Figure 3.1).

In tiered risk assessment, qualitative (Tier 1) risk assessment involves the identification of the potential source (e.g. chemical), potential receptors (e.g. a particular species or population) and pathways (e.g. exposure) linking the sources and receptors (Pollard et al., 1995). Establishing source-pathway-receptor connectivity is important both for defining the details of the

subsequent risk assessment (e.g. the potential route of human exposure and thereby which hazard tests should be employed) and for justification of the risk assessment. Despite its importance, there has been little systematic consideration of problem formulation for manufactured nanomaterials, either generically within risk assessment methodologies or more specifically for one or more substances (Owen and Handy, 2007).

The legislative context of the risk assessment (discussed further later) contextualises and defines the standards required, and determines the constraints of the risk assessment. The risk assessment process itself can be presented within the basic framework for the assessment of chemicals, developed through national and international consensus (Risk Assessment and Toxicology Steering Committee, 1999a):

i. *Hazard identification* of a substance (e.g. adverse health effects associated with exposure to the substance) uses data from *in vitro* and *in vivo* studies and as well as models (e.g. QSARS). It includes hazards generated as reaction intermediates and metabolic products. The identification of sensitive receptors (e.g. individuals with underlying inflammatory conditions) also occurs in this step.

ii. *Hazard assessment* or characterisation establishes the existence of exposure pathways and quantitatively evaluates the observed adverse effects (including dose-response assessment, species differences or sensitivity distributions and mechanisms of action). Within this, quantitative estimates of hazard (e.g. predicted no effects concentrations, lethal or effects concentrations) can be calculated.

iii. *Risk estimation* addresses the potential risk to the identified receptors via each of the identified exposure pathways, and normally involves an estimation of intake or exposure (quantification) to a chemical in terms of its magnitude, duration and frequency for the general population, as well as sub-groups and individuals.

iv. *Risk evaluation* combines hazard identification, hazard assessment, and exposure assessment in order to predict the likelihood, nature and severity of effects in a given population, as well as identifying the

population affected (including vulnerable sub-populations) and estimating the likelihood of an event (e.g. accidental release of a toxic chemical), giving rise to an exposure of particular level and duration with a specified degree of effect upon the exposed population.

Managing uncertainty

Within any risk assessment there is a degree of uncertainty that needs to be identified, quantified (where possible), and its impact assessed. Although it is well understood that uncertainty is a feature of all decisions, uncertainty in risk assessment must be clearly characterised and explained. There are a number of different types of uncertainty in risk assessment (Stirling, 2001) and these can be categorised by the likelihood and consequences of the specific outcomes within the situation (see Figure 3.2). Whilst some uncertainties can be resolved by further research (e.g. additional data or through the statistical treatment of data), some are a feature of things that are unknown or risk assessors were unaware of. Within this, the population and sample data must be considered, including whether the population is unknown but can be estimated from the data set ("frequentist") or whether only the data set is real ("Bayesian"; Figure 3.2.).

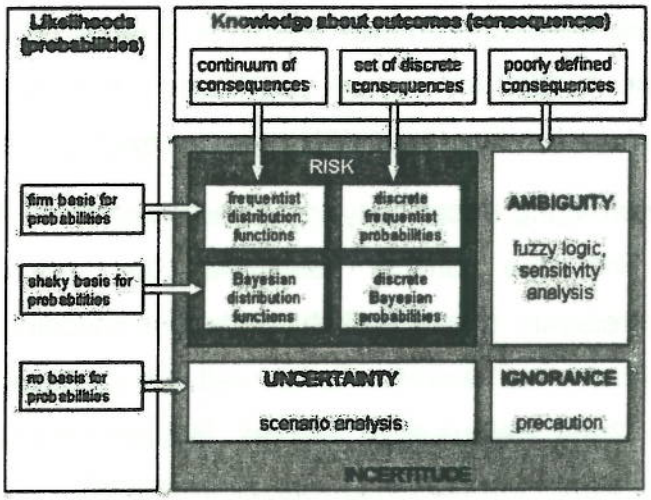

Figure 3.2. Risk, ambiguity, uncertainty and ignorance in decision-making (adapted from Stirling, 2001)

The lack of knowledge about the toxicological consequences of low-dose exposure (which are often environmentally-relevant) has received substantial attention, and has resulted in the use of appropriate 'uncertainty factors', or

'safety factors', which are used to introduce 'margins of safety' and compensate for uncertainties. These factors are influenced by uncertainties in the quality and/or quantity of data, the use of the data, the nature of any effect, and the risk management context in which the risk assessment is to be used (Risk Assessment and Toxicology Steering Committee, 1999b). An example of this is the application of an uncertainty factor to a predicted no effects concentration (PNEC) when calculating a regulatory Environmental Quality Standard (EQS). Uncertainty factors provide a level of reassurance of safety from the potentially harmful effects of exposure to chemicals in the face of limited or incomplete information (Interdepartmental Group on Health Risks from Chemicals, 2003). As we discuss later, in the case of manufactured nanomaterials the key issues for risk analysis relate to methodological issues and knowledge gaps, which have relatively high levels of uncertainty and have important regulatory implications.

Uncertainty is inherent to all risk problems; identifying specific types of uncertainty and their magnitude provides risk managers with a level of confidence for risk management decisions and guides the selection of appropriate risk analysis tools. The ability to distinguish between uncertainties that can be resolved (e.g. through additional research, monitoring or better analysis) from those that may not be easily resolved (e.g. synergistic effects between complex chemical mixtures at low doses) is key. It is widely acknowledged among risk practitioners that *how* uncertainties are addressed is as important to stakeholders as the existence of uncertainty.

It is clear that managing uncertainty in the risk assessment of manufactured nanomaterials will be critical because the relationship between environmentally relevant doses and the potential toxicological responses in human and environmental receptors is not well characterised (Nel *et al.*, 2006; Renn and Roco, 2006; Balbus *et al*, 2007a). Practitioners can expect to have to assemble and weigh the evidence (discussed further in Forbes and Calow, 2002; Balbus *et al.*, 2007b) from various research studies and apply precaution (discussed in ILGRA, 2001; Harrison and Holmes, 2006), especially where irresolvable uncertainties in the assessment suggest that significant consequences might occur.

Uncertainty due to extrapolation between species can be factored into a risk assessment using quantitative data by the use of safety factors (IEH, 2006; see Figure 3.3).

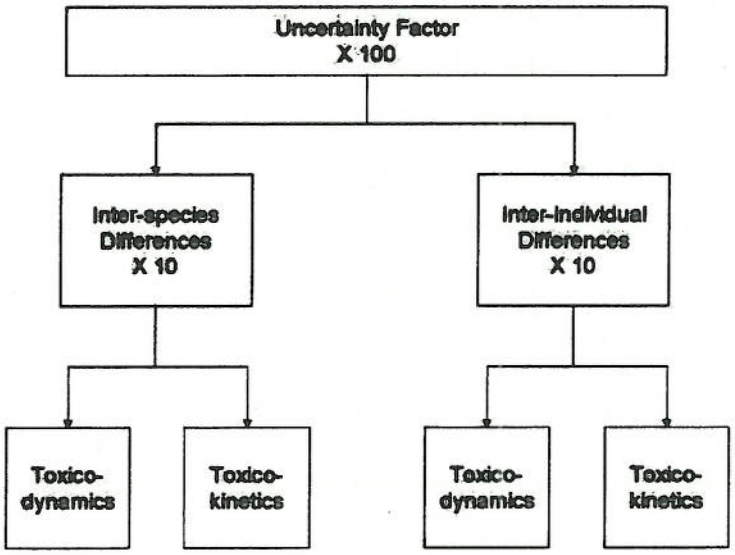

Figure 3.3. Diagram showing the safety factors involved in the extrapolation of toxicological data between species and individuals

Whilst there are known inter-species and inter-individual differences which are recognised in risk assessment processes, the risk assessment of nanomaterials using data from bulk materials or other formulations brings in another form of uncertainly that must be accounted for. Indeed it has not yet been determined whether such extrapolation can occur in the case of nanomaterials.

3.2. Risk assessment frameworks

This text has been used in a dissemination product (Rocks et al., 2008b) and will be published later on this year.

3.2.1. Pharmaceutical risk assessment framework

A pharmaceutical is defined in European legislation as a product for the treatment and prevention of disease, for administration to make medical diagnosis, or for restoring, correcting or modifying physiological functions in human beings (IGHRC, 2003). As medicines are intentionally administered to

humans for a beneficial effect, the administered dose (or exposure) can be controlled. An evaluation of the risk to benefit ratio (relating the possible harmful effects of the medicine to the beneficial effects) is also necessary and must take into account several factors, including the nature of the disease or condition to be treated, the effective dose to be administered, type of patient, and duration of the treatment. With terminally ill patients, a high risk to benefit ratio is more acceptable when the quality of life may be enhanced, but would not be acceptable for long term treatment. The risk-benefit ratio must be considered on a case-by-case basis for each pharmaceutical. Therefore, in general, the risk assessment questions for pharmaceuticals are:

- do the advantages outweigh the disadvantages of taking the medicine?
- does the medicine do the most good for the least harm for the majority of people who will be taking it?
- are the side affects acceptable for the target population?

Pharmaceutical products, including veterinary products, are regulated in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) and in the United States by the Food and Drug Administration (FDA; under the Federal Food, Drug and Cosmetic Act). Overall, international standards are set by the World Health Organisation (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (resolution WHA22.50; WHA28.65). In general, pharmaceutical product regulations apply to pharmaceutical manufacturers and importers for products including biological or chemical compounds, different brands of existing medicines, new forms (e.g. syrups or patches), new uses (e.g. for different diseases), and clinical trials of medicines and medical devices.

Within the EC, the legislation for medicinal products for veterinary and human use is stated under the EU medicines regulatory regime (Regulation 726/2004 and Directives 2004/27/EC [human] and 2004/28/EC [veterinary]) and controlled by the European Medicines Agency (EMEA), although individual countries still have their own governing bodies (e.g. MHRA). The directives govern the marketing authorisation, manufacture and distribution of products. Within the EU, a medicine can be marketed only after a national or EU

Marketing Authorisation (MA) has been granted. If companies or countries fail to comply with the regulation, the penalties are set out in Regulation (EC) No. 658/2007. These regulations consider the safety, quality and efficacy of the medicines only. The MHRA and expert advisory bodies within the UK control new medicine production to ensure that they meet the required standards on safety and effectiveness throughout the lifetime of the product (pharmacovigilance).

Pharmaceuticals must pass through preclinical assessment before entering into clinical trials (Phases 1 to 3; Harman, 2004). The guidelines followed during the risk assessment of pharmaceuticals are Good Laboratory Practice (GLP; OECD ENV/MC/CHEM(98)/17, 1998), Good Manufacturing Practice (GMP; EU Directive 2004/27/EC) and Good Clinical Practice (GCP; EU Directive 2005/28/EC). The toxicity testing of pharmaceutical products is summarised in Figure 3.4.

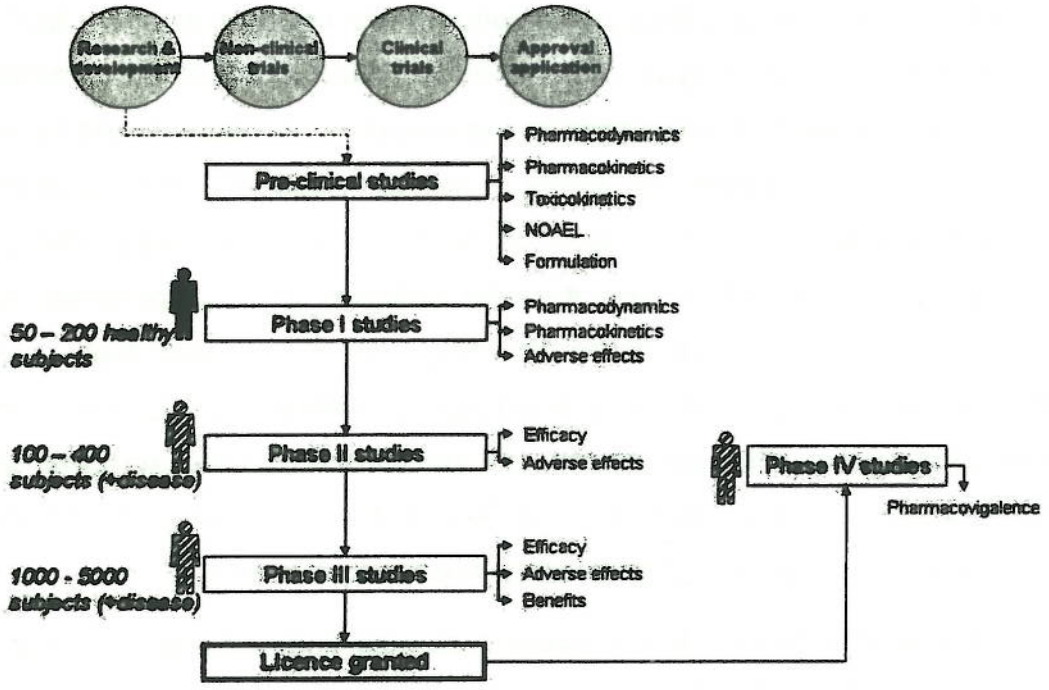

Figure 3.4. The risk assessment process, toxicological and pharmacological studies in pharmaceutical development. The act of Phase IV studies (pharmacovigilance) is controlled by law and ensures the continuous monitoring of unexpected events over a set period of time.

The objectives of the preclinical safety studies are to define both pharmacological and toxicological effects throughout clinical development using both *in vitro* and *in vivo* (animal) studies for characterisation.

Pharmaceuticals that are similar, both structurally and pharmacologically, to an available product may need less extensive toxicity testing. The existing preclinical tests are believed to be adequate due to the high multiple doses used, two animal species, extensive histopathology (on most organs), functional tests (cardiac, neurologic, respiratory, reproductive, immune systems etc) and extended treatment periods (up to 2 years, carcinogenicity).

Preclinical testing must consider the selection of relevant species, age, physiological state, manner of delivery (dose, route of administration, treatment regime) and stability of test material under conditions of use. However, it is recognised that conventional approaches to toxicity testing may not be appropriate for pharmaceuticals due to the diverse structural and biological properties that may include species specificity, immunogenicity and pleiotropic activities.

In vitro assays can be used to evaluate biological activity related to clinical activity. Cell lines or primary cell cultures are used to examine the direct effects on cellular phenotype and proliferation (Barille, 2004). Mammalian cell lines can be used to predict specific aspects of *in vivo* activity and to assess quantitatively the relative sensitivity of various species (including humans). Studies can be used to determine receptor occupancy, receptor affinity, and pharmacological effects to assist in the selection of an appropriate animal species for further *in vivo* pharmacological and toxicological tests. *In vivo* studies assessing the pharmacological activity (including defining mechanisms) are often used to support the rationale of the proposed use of the product in clinical studies. The results from both *in vitro* and *in vivo* studies assist in the extrapolation of the findings to humans.

In vivo tests should include two relevant species and both genders of animal, unless otherwise indicated. The route and frequency of administration used is as close to that proposed for clinical use. The biological activity together with species or tissue specificity of pharmaceuticals, determine the species required for toxicity testing. A relevant species is one in which the test material is pharmacologically active due to the expression of the receptor or an epitope.

The pharmacokinetics and bioavailability of the product in the animal species will help to determine the amount and volume that can be administered to the test animals. If the product is eliminated faster in the animal species, then the frequency of administration will be increased in order to compensate. The route, formulation, concentration and administration site must also be related to that of the expected use. The dosage levels are selected to provide information on a dose-response relationship, including a toxic dose and no observed adverse effect level (NOAEL).

Clinical trials allow the safety and pharmacokinetic data on humans to be collected, therefore it is possible to compare the biological properties of the product as predicted from studies in animal models and the data gained from humans. Therefore the risk assessment involves not only the extrapolation of data across species from studies in animals in relation to the potential toxic effects in humans but also the evaluation of human data. In these cases the safety assessment is not based on the application of a standard uncertainty factor to the NOAEL from animal studies but the findings from such studies are important in assessing the adequacy of the safety assessment based on the results of clinical trials.

The clinical trials start with Phase I exploratory investigations, using a small number of (normally) healthy human volunteers (below 200 subjects) to determine the initial safety of the substance and the dose range. Phase II trials involve a larger number of volunteer patients with the target disease/conditions (100 to 400 subjects) and are used to investigate the safety and efficacy of the substance. Phase III studies involve extensive investigations of safety and efficacy in more than 1000 patients with the target disease. If the substance is satisfactory in terms of quality, safety and efficacy, then an MA is applied for. If granted, further Phase IV studies to monitor the product in order to identify rare and unanticipated adverse effects (pharmacovigilance).

The use of nanoparticles and nanotechnology in medicines are numerous (Chan, 2006). Of particular interest, and use, is the increased surface area to volume ratio of nanoparticles, which in turn increases the particle surface energy (Ozin and Aresault, 2006; Gogotsi, 2006) and may make the particles

more biologically reactive (Oberdörster *et al.*, 2005). The increased biological activity may be beneficial or harmful. However, the same properties that make nanoparticles of medical interest also mean that it is harder to predict the behaviour of a nanoparticle, and therefore its toxicity. There are currently no specific regulatory requirements to test nanoparticles for health, safety and environmental impacts separate to those for bulk materials (discussed later), however it can be argued that the regulatory requirement for the testing of pharmaceuticals are extremely robust, designed to allow cautionary development (as opposed to precautionary), and applicable to the manufacture of nanoscale medicines .

3.2.2. Occupational Risk Assessment

The control of occupational health risks from harmful substances in the workplace is, arguably, the most developed system for the control of chemical exposure. It has been developed due to the long history of the industrial use of chemicals/materials and the resulting incidence of occupational diseases and illnesses, e.g. silicosis from the inhalation on crystalline quartz (Altree Williams and Clapp, 2002; Nij *et al.*, 2003, Nij and Heederik, 2005) and lead poisoning from the inhalation of the dust and fumes from lead and lead-containing compounds (Grimsley and Adams-Mount, 1994; Pierre *et al.*, 2002; Sen *et al.*, 2002). Nowadays, it is mandatory to carry out a risk assessment before allowing any worker to be exposed to any substance. In the UK, this takes place through the Control of Substances Hazardous to Health Regulations (1988 and last consolidated in 2002) enforced by Health and Safety Executive (HSE) and, in the EU, through the Chemical Agents Directive (Chemical Agents Directive, 98/24/EC). In the United States, the Occupational Safety and Health act (1970, last amended 2004) regulates the occupational use of chemicals and within this there are two co-ordinating bodies, Occupational Safety and Health Administration (OSHA; develops and regulates workplace health and safety regulations) and National Institute for Occupational Safety and Health (NIOSH; recommends health and safety standards, and provides information on hazards and prevention; Thorne, 2001).

The routes of exposure for workers in the occupational environment are normally inhalation, dermal or ingestion. Dermal and inhalation monitoring, as well as biomarker monitoring, can be used to characterise the exposure specific workers, e.g. farm workers exposed to pesticides (FAOWHO, 1986; US EPA, 1989). It is unlikely that exposure would be limited to one chemical species however the toxicity of individual substances must be considered initially (EEC, 1988; EC, 1999).

All occupational risk assessments require the employer to assess the substance toxicity (e.g. using material safety and hazard data sheets), the likelihood of worker exposure and exposure of other individuals and, how exposure can be prevented or controlled so as to avoid/minimise risk. Occupational exposure limits (OELs, airborne standards designed to protect health from acute or chronic effects so far as inhalation is concerned) are defined for substances normally as an average over a reference time period (e.g. 8 hours; also referred to as Time Weighted Average; TWA). OELs have been used since 1930's for specific substances (e.g. cotton dust; Topping, 2001). Threshold limit values (TLV) are also used as airborne standards for occupational risk assessment.

In the case of particulate materials, OEL settings have not always been scientifically-based. Historically many particles were regarded as "nuisance" or "low toxicity" dusts, which meant that little attention was given although many workers were exposed. Few dusts/particles produced any systemic toxicity, and the control of exposure was difficult (e.g. in construction, mines and welding). As a consequence, a generic approach to standard-setting was taken for many particulates resulting in a generic inhalable OEL of 10mg/m^3 and a respirable OEL of 4mg/m^3 for many substances (see Table 3.1; IEH, 1999). These were not suitable for particles with a known inhalation or systemic toxicity (e.g. asbestos and lead, respectively) so specific OELs were also determined.

Table 3.1. Particles with generic occupational exposure limits (OEL) of 10 mg/m^3 (inhalable) and 4mg/m^3 (respirable), adapted from IEH, 1999.

Particles with generic inhalable and respirable OEL	
Aluminium metal	Marble
Aluminium oxides	Pentaerythritol
Calcium carbonate	Plaster of Paris
Calciypum silicate	Platinum metal
Cellulose	Portland cement
Graphite	Rouge
Gypsum	Silicon
Limestone	Silicon carbide
Magnesite	Starch
Magnesium oxide	Titanium dioxide
	Zinc distearate
	Zinc oxide fume

Currently OELs are set using all available data (e.g. human, experimental, *in-vivo* and *in-vitro*, physiochemical factors, mechanistic understanding of pathogenicity, inter-species differences and cellular responses). However, over time, epidemiological research (with improved health surveillance) has also shown links between exposure to "low toxicity" dusts and long term illness, e.g. crystalline silica is known to cause silicosis but only recently its links to increased lung cancer have been recognised (Nij and Heederik, 2005), suggesting that the "low toxicity" determination may be over optimistic (IEH, 1999; Fairhurst, 2003) and that species specific long term effects must be considered when setting OELs. Indeed, the US ACGIH have recently defined "low toxicity" particles as Particles Not Otherwise Specified (PNOS; which have no TLV, poor water solubility, and low toxicity). As a result, the ACGIH currently recommend that PNOS have an TLV (TWA 8 hours) of 10mg/m^3 (inhalable) and 3mg/m^3 (respirable), whereas other countries (e.g. MAK Commission in Germany) have lower respirable limits, based on extrapolation from large human occupational groups. These limits reinforce the notion that a simple generic dust standard based on the belief that the main effect is that of nuisance is no longer defensible in view of *in vitro* and *in vivo* investigations demonstrating the importance of particle size, especially surface area, in determining many factors in lung pathogenicity (Oberdörster *et al.*, 1992; Penn *et al.*, 2006).

The establishment of airborne standards for the workplace in the EU currently comes under COSHH and REACH (WATCH, 2006). As part of COSHH, legal basis have been given to the occupational exposure standard (OES) and the

maximum exposure limit (MEL). The OEL ensures a minimum level of safety, which can be exceeded as long as steps are taken to reduce exposure as soon as reasonably practical, whereas MEL is used to maintain safety levels for workers (the MEL must not be exceeded; Topping, 2001). REACH requires that the manufacturer or importer of substances must determine the safe operating conditions and appropriate risk management for the substance, whereas, in COSHH, it is the employer who must assess the risk of a substance and cover all work activities at that site (e.g. production, application and disposal). REACH (a directly-acting EU Regulation) applies, without prejudice, to workplace health and safety legislation, which means that currently EU employers have to comply with both REACH and COSHH.

The occupational exposure of workers to ultrafine particles has been a well studied area (e.g. IEH, 1999b), and ultrafine particles are considered an aerosol particle in the nanoscale range (e.g. diesel exhaust particulates). However, the occupational risk assessment of nanomaterials is less well characterised (Balbus *et al.*, 2007a; Boccuni *et al.*, 2008). The Health and Safety Executive (HSE) in the UK considers there to be three main sources of industrial activities likely to cause exposure to nanoparticles; nanotechnology research and development (in Universities, research centres, and companies), existing ultrafine manufacturing processes (carbon black, titania, alumina manufacturing) and powder handling processes (e.g. manufacture of dyes, pigments, and pharmaceuticals; HSE, 2004). The added complications of particle size, surface modification, particle morphology and the possibility of translocation within the body has concerned scientists, engineers, risk assessors and regulators alike (RS/RAEng, 2004) with many calling for the development of risk assessment strategies for novel particles and, in particular, nanomaterials where surface area and surface properties may be important factors (Atiken *et al.*, 2004). If such a testing strategy is to be used in risk assessment application for particles in the occupational setting, it can also be used in the development of risk assessment methodology for particles in the environmental and consumer products setting. All that will have to be added for the latter two scenarios is likely human exposure (measured or

modelled) and the choice of uncertainty factor if an airborne standard is to be set as part of any the risk management system.

3.2.3. Chemicals risk assessment framework

As previously discussed (Section 1.2) the majority of regulatory risk assessment guidelines have "triggers" that determine whether a prospective risk assessment is required by a manufacturer or operator and the quantity and type of information required within that risk assessment. This is normally the weight of the chemical manufactured or imported per year (i.e. 12 calendar months).

The initial risk assessment trigger in the majority of countries shown in the table is 1 tonne/year (except New Zealand where the act of importing or manufacturing the chemical is the initial trigger). The chemical categories excluded from the risk assessment frameworks for industrial chemicals include polymers (which are considered separately), radioactive materials, medicinal products, and food stuffs. Intermediates, by-products and incidentally-produced chemicals (e.g. contaminants). Naturally-occurring biological chemicals are also generally excluded from the risk assessment framework, and are considered separately by the regulators.

International risk assessment frameworks for chemicals consider both the physiochemical characteristics of the chemical as well as the toxicological effects and environmental effects. Although the exact requirements differ slightly between countries, all expect some degree of hazard identification and assessment. These have been discussed further in Section 2.2, but include:

- Physiochemical properties – detailing melting/boiling point, relative density, vapour pressure, water solubility, flammability, partition coefficient (n-octanol/water), state;
- Toxicological information – evaluation of skin irritation/corrosion, eye irritation, skin sensitisation, mutagenicity (bacterial and mammalian cell studies), acute toxicity studies (route dependant on physical state of chemical), short term repeated dose toxicity study, reproductive study,

developmental toxicity study, two-generation reproductive toxicity study, toxicokinetics; and

- Ecotoxicological information – short term toxicity testing (Daphnia and fish), growth inhibition study on algae, long term toxicity testing (Daphnia and fish), degradation (biodegradability), hydrolysis (as function of pH), bioconcentration (fish), adsorption/desorption screening, effects on terrestrial organisms and micro-organisms.

Regulation of chemical substances in the EU under REACH is based on the (precautionary) principle "that industry should manufacture, import or use substances or place them on the market in a way that, under reasonably foreseeable conditions, human health and the environment are not adversely affected" (ECC, 2000; ILGRA, 2001; ECHA, 2007). Therefore the emphasis is on the manufacturer or importer to collect or generate the data on substances and to assess the risks involved.

Within REACH, there are several "triggers" for specific information requirements (see Figure 3.6). The initial trigger of more than 1 tonne/annum requires the assessor to submit a Chemical Safety Assessment (CSA) i.e. information about the physiochemical properties of the chemical and some toxicological information. Further triggers at 10, 100 and 1000 tonnes/annum require a Chemical Safety Report (CSR) to be submitted with more detailed information on toxicological, ecotoxicological and carcinogenicity required.

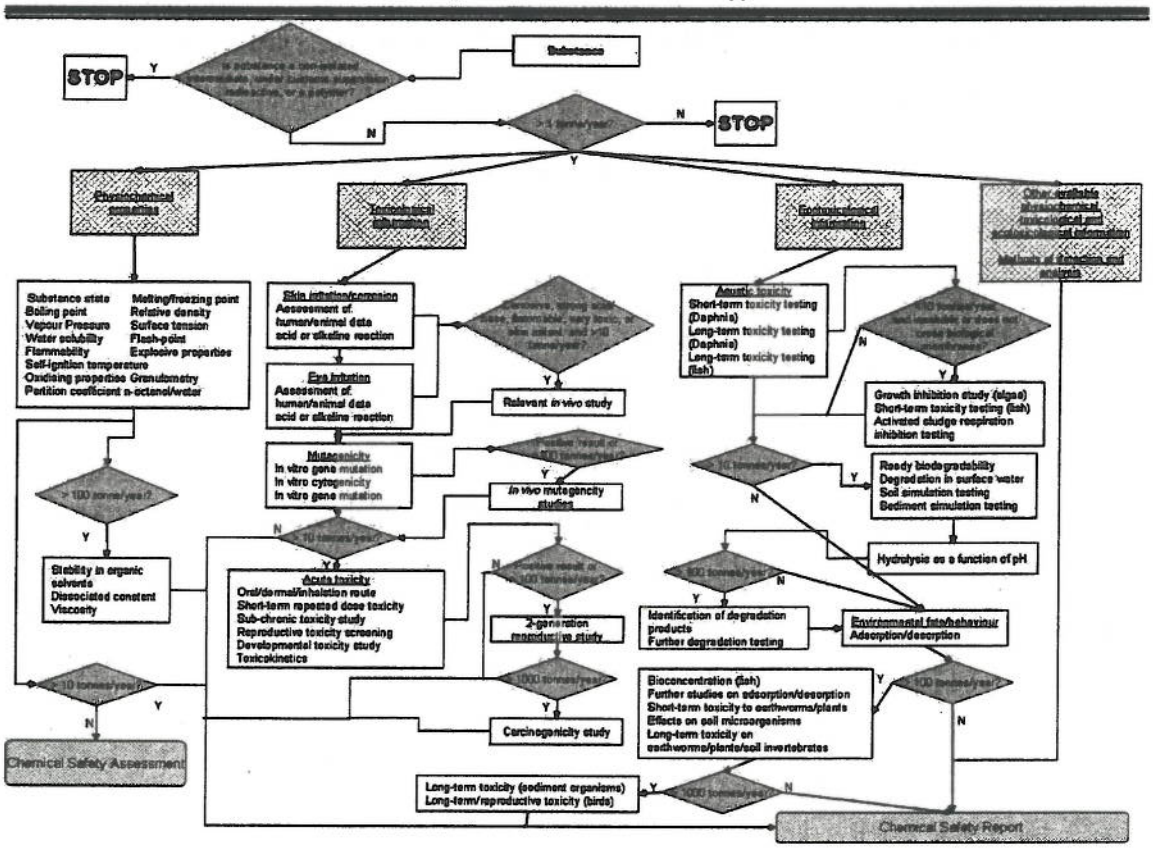

Figure 3.6. Overview of risk assessment by REACH showing information triggers

With the requirement to reduce, replace and refine animal testing, the amount of animal data and experiments required must be monitored and every step taken to ensure that the testing scheme is not replicated unnecessarily. However, the data must also be evaluated to ensure that the regime used was reliable and sufficient for requirements. The physicochemical data previously collected is used to determine the likely route of human exposure (i.e. oral, dermal or inhalation) for the experimental design. However there is a general reliance on oral administration routes for initial toxicity testing.

3.3. Risk Assessment Tools

The risk assessment process can be helped by the use of risk assessment tools.

Table 3.2 Number of published articles or websites that were found due to searches on specified search engines using the search terms listed.

	supporting tools	risk assessment	nanomaterials	supporting tools & risk assessment	supporting tools & nanomaterials	nanomaterials & risk assessment	all
Google	285000	9800000	1240000	12700	218	68300	93
Scopus Article	294	207535	5073	3	0	59	0
Scopus Web	10592	1083586	206676	800	42	7947	36
Google Scholar	9310	869000	53400	382	3	830	0
Science Direct	89	9718	1895	1	0	5	0
ISI Web of Knowledge	27	>10000	493	3	0	54	0
CAB Abstracts	20	15733	54	1	0	1	0
Pubmed	19	95868	15760	0	0	80	0
Environmental Sciences and Pollution Management	11	30234	263	0	0	20	0
Aqualine	2	1958	14	0	0	0	0
Toxline	1	129	21536	0	29	0	0

There are a large number of publications that use or evaluate risk assessment tools (and methods; as shown in Table 3.2). These publications have also elaborated on the mathematical equations used in the evaluation process. In general risk assessment tools are mathematical programmes that factor in uncertainty and safety factors in order to estimate exposure limits for regulatory decisions (van Leeuwan and Vermiere, 2007). A selection of risk assessment tools are presented below. However, the accuracy of the input data and the interpretation of the result are infinitely more important than the risk assessment tool itself. Therefore, the decision was taken to concentrate on the accuracy and inventory of evidence collected as well as the strength and weight of such evidence rather than the mathematical tools that can support decision making in risk assessments.

3.3.1. Human health risk assessment tools

CATREG

CATREG (US EPA, 2000a, b) is the categorical regression analysis on toxicological data after it has been assigned to severity group (e.g. no effect, adverse effect, severe effect) and calculates the probabilities of the different severity categories over the difference exposure variables (up to two, e.g. concentration and duration). It quantifies variables using optimal scaling and results in ain optimal linear regression equitation for the transformed variables. The variables can be given mixed optimal scaling levels and no distributional assumptions about the variables are made. The programme was designed to support the exposure-response analysis for human health and allows the data to be described in terms of effect severity. The programme is available to download on the internet (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=18162).

LEADSPREAD

The LEADSPREAD programme is a Lead Risk Assessment Spreadsheet to evaluate lead exposure and potential for adverse health effects resulting from environmental exposure to inorganic lead (via dietary intake, drinking water, inhalation, dermal exposure, ingestion of soil and dust). Each pathway is represented by an equation relating blood lead incremental increase to medium concentration. A multi-pathway exposure situation is used to determined an estimation of median blood lead concentration. The programme is available to download on the internet (http://www.dtsc.ca.gov/AssessingRisk/leadspread.cfm).

RISK ASSISTANT

Risk Assistant is a programme developed by the Environment Agency which is no longer in operational use. It evaluates exposure and human health risks from chronic exposure to chemicals by measuring or estimating the

concentration of a chemical in air, surface water, groundwater, soil and/or biota (Hampshire Research Institute, www.hampshire.org).

3.3.2. Environmental risk assessment tools

EUSES

EUSES allows assessments of the general risks posed by substances to man and the environment and is intended for initial and refined risk assessments rather than comprehensive assessments. The system is based on the EU Technical Guidance Documents on Risk Assessment for New Notified Substances, Existing Substances and Biocides and uses the IUCLID database as the data source for calculations. The documentation and the program can be downloaded from ECB Website (http://ecb.jrc.it/Euses/).

RISK PRO

RISK PRO estimates the fate and transport of a chemical for a risk-based soil and ground water evaluation using the EPA's unsaturated zone model called SESOIL (models long-term pollutant fate and migration) as well as a ground water model. It predicts environmental risks via multimedia/multipathway environmental pollution systems using measurements of pollutants in soil, water and air and evaluates receptor exposure from these environmental contaminants. It is accessed from (http://www.groundwatersoftware.com/software/soilclean/riskpro/riskpro_demo.htm)

3.4. Reported opinions on the appropriateness of current risk assessment frameworks for application to nanomaterials

There are a number of reported opinions on the suitability of current risk assessment approaches for nanomaterials. These have been incorporated to the document, however the key points of each are summarised below.

A. Royal Society/Royal Academy of Engineering (2004)

The Royal Society/Royal Academy of Engineering (RA/RAEng) considered the need to manage potential risks to environment and human health in the report entitled 'Nanoscience and nanotechnologies: opportunities and uncertainties'. The experts from the Royal Society (RS) and the Royal Academy of Engineering (RAEng) presented a number of recommendations for Government which would ensure an appropriate control framework for nanotechnologies.

The overall conclusions of the RS and RAEng were:

i. That life cycle analysis was carried out for applications and products arising from nanomaterials ensuring that the decreased resource consumption is not superseded by increased use in manufacturing or disposal

ii. That there is interdisciplinary consideration as to the toxicology, epidemiology, persistence, bioaccumulation and exposure pathways

iii. The release of nanomaterials into the environment is currently avoided and that they should be treated as hazardous waste, and that free (i.e. not bound into a carrier matrix) nanomaterials should be prohibited until the benefits of use are shown to outweigh the concerns

iv. The release of nanomaterials are assessed through out their life cycle

v. Scientific advisory committees should consider to whether the screening tests and toxicity tests are suitable to assess nanomaterials, whether the regulation is appropriate, what regulatory gaps are currently present and the application of regulation to future uses

vi. Nanomaterials should be considered as new substances under REACH, but the advisory committees should consider whether the product level triggers are appropriate for use with manufactured nanomaterials

vii. The appropriateness of the regulatory limits for the use of manufacture nanomaterials should be considered

viii. A full review of the safety of nanomaterials before they are used in consumer products should be undertaken, with details of methods and how the nano-scale material differs from that of the bulk should be made available. The products should also be clearly labeled that they contain nanomaterials

ix. The ethical issues surrounding the manufacture and use of nanomaterials should be considered.

B. VDI Technologiezentrum GMbH (2004)

The Future Technologies Division of VDI Technologiezentrum GMbH considered the chances and risks associated with the industrial application of nanomaterials. The report concluded that nanomaterials were likely to form a large portion of commercial development and revenue in the future and therefore the effects of such materials need to be considered. Dry nanomaterials were considered to have more potential health risks as they can easily form aerosols during production and handling which would increase the exposure, and would be likely to cause acute and chronic health effects (e.g. those associated with ultrafine particles). However, they also suggested that engineered nanomaterials usually form aerosols as particle aggregates in the form of micro-scale particles. The report recommended:

i. That basic research was necessary to study particle interactions at the nanoscale and development of modeling tools for production and handling of nanomaterials

ii. The measurement (and metrics) of nanomaterial exposure needed to be established

iii. Workplace exposure of workers to nanomaterials need to be measured and risk management methods developed

iv. The development of *in vitro* (low cost, high throughput) assays to supplement or substitute animal testing

v. Investigation into the action of nanomaterials in the human body and environment, including adequate measurement techniques

C. Institute of Occupational Medicine (2005)

The Institute of Occupational Medicine (IOM) considered the identification of hazard data to address the risk assessment of nanomaterials. Their research suggested that the physicochemical properties and composition of nanomaterials were likely be the source of toxic effects (including oxidative stress, inflammation, fibrogenicity and genotoxicity), although there was limited data about the nature of the hazard, the toxicokinetics or the effects on target organs. The ecotoxicological, human challenge and epidemiological potential of nanomaterials were also investigated. The outcome of the report was that the (ideally) interdisciplinary research needs to be guided by the economical importance of the material as well as the likelihood of exposure. The main recommendations were that

i. A knowledge base of nanoparticle research, development and manufacture needs to be formed and kept current
ii. The methods for measuring nanoparticles in relevant environments (e.g. air and water) need to be improved and made fit for purpose
iii. Reference materials (e.g. well-characterised nanoparticles) need to be established to enable the validation and standardisation of research methods and findings
iv. Appropriate epidemiological methods and prospective study of cohorts of exposed workers should be agreed
v. Research should be funded to study the deposition, toxicokinetics and *in vivo/in vitro* effects of selected relevant nanomaterials
vi. Research should be funded to aid development of agreement on appropriate methods for characterising ecotoxicological exposures and end-points.

D. Nanotechnology Research Co-ordination Group 1st Report (2005)

The Nanotechnology Research Co-ordination Group (NRCG) coordinates publicly funded research into the potential risks presented by nanotechnology products and applications. The first report built on the findings of RS/RAEng and described the research objectives and to characterise the potential risks posed by engineered free nanomaterials. The report identified areas for further research including:

i. The need to develop a risk management framework for nanoparticles
ii. The need to identify and classify the properties, characterisation and metrology, including standardisation, of nanomaterials;
iii. The need to identify and measure human and environmental exposure
iv. The need to identify and assess the hazard to human health and the environment
v. The need to understand the societal and ethical dimensions of nanotechnologies as they arise.

Encompassing all of these is the need for the development of and international agreement on nomenclature and definitions.

E. Scientific Committee on Emerging and Newly Identified Health Risks (2005)

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) is an EU committee reporting on the assessment of new technologies. Their first report (2005) was on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies and they were asked to consider whether the existing methodologies were appropriate to assess the risks associated nanomaterials, how the existing methodologies should be adapted, and what the major knowledge gaps were in risk assessment of nanomaterials. The committee concluded that, whilst the existing toxicological and ecotoxicological methods were appropriate to assess the hazards of

nanomaterials and nanotechnologies, the tests may not address all the hazards and will need to be supplemented by additional tests. The particular concern with the toxicity testing methods were that the mode of delivery didn't reflect the relevant exposure, the dose needed to be carefully considered as mass concentration would not be suitable and that monitoring equipment was not fit for purpose.

i. The routine toxicity testing needs to be supplemented, with the elucidation of the physicochemical properties of nanomaterials included in testing regimes. Some conventional methods are suitable, but many need adaptation for use with nanomaterials, other expected effects of nanomaterials (e.g. translocation) will need novel methods to be developed and adopted. *In vitro* tests would be useful but are not currently available

ii. Equipment for the routine measurement of nanomaterials in various media is needed to measure the environmental exposure

iii. The possibility that nanomaterials may exacerbate pre-existing medical conditions must be investigated

iv. Knowledge gaps

    a. characterisation of mechanisms and kinetics of the release of nanomaterials from a wide range of production processes formulations and uses of products

    b. actual range of exposure levels to nanomaterials (man and environment)

    c. extent to which it is possible to extrapolate from the toxicology of non-nanomaterials and other physical forms (see Figure XXX, e.g. fibres of the same substance to the toxicology of nanomaterials and between nanomaterials of different size ranges and shape)

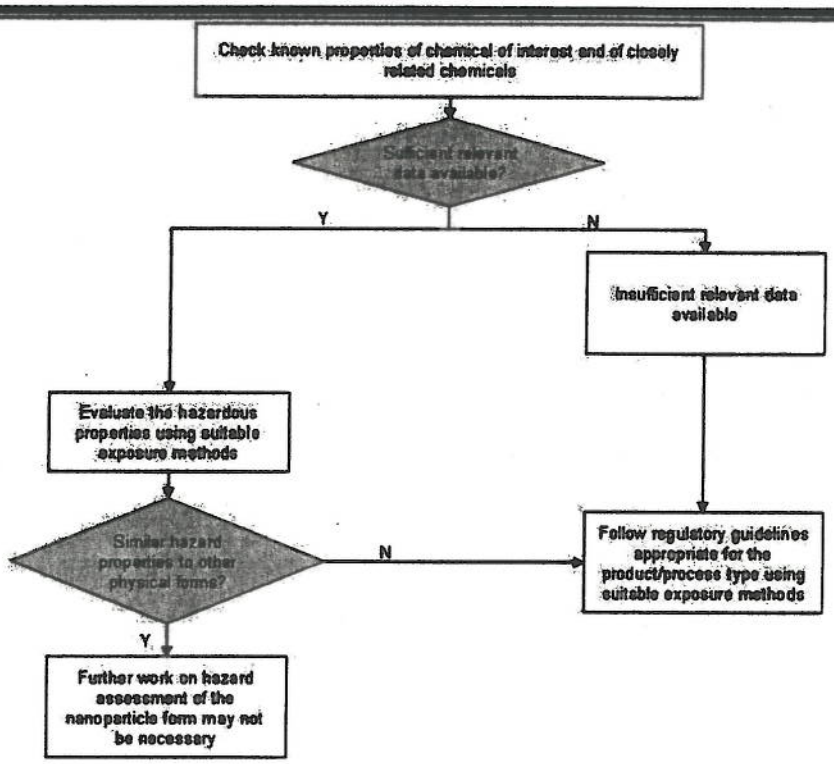

Figure 3.7 Approach to determine whether the hazards of nanomaterials differ from other forms of material (SCENHIR 2005).

d. toxicokinetic data following exposure, to identify target organs and determine doses for hazard assessment

e. information from occupational exposure and associated health effects on workers involved in the manufacture and processing of nanomaterials

f. fate, distribution and persistence and bioaccumulation of nanomaterials in the environment and environmental species including microorganisms

g. the effects of nanomaterials on various environmental species, in each of environmental compartments and representative of different trophic levels and exposure route

h. investigation of the fundamental properties of nanomaterials, including the ability to act as vectors of chemicals, microorganism and interactions with other stressors.

F. Environmental Defense – DuPont Nano Partnership (2007)

The Environmental Defense – DuPont Nano Partnership published a Nano Risk Framework for use in assessing nanomaterials involving a multidisciplinary team (including experts biochemistry, toxicity, environmental sciences, occupational health and safety, environmental law, product development and engineering). The Partnership aimed to develop a framework for the responsible development, production, use and disposal of nanomaterials that identified potential hazards and risks to human health and the environment, evaluate potential release and exposure and manage the arising risks. The recommended data set for the risk assessment of manufactured nanomaterials can be summarised (Table 3.3).

Table 3.3 Summary of recommended data set suggested for Nano Risk Framework (Environmental Defense and DuPont, 2007)

Physicochem Data	Health Hazard Data	Environmental Hazard/Fate Data	Safety Hazard Data	Exposure Data
Technical and commercial name	Short term toxicity 28 day inhalation study (90 day observation period)	Acute aquatic toxicity Fish Invertebrates Aquatic plants	Flammability	Manufacture
Common form	Single dose instillation study (90 day observation period)		Explosivity	Processing
Chemical composition (including surface coating)	28 day repeated dose oral study (90 day observation period)	Terrestrial toxicity Invertebrates Plants	Incompatibility	Use
Molecular and crystal structure		Physicochemical properties (including list) Adsorption-desorption coefficients Aggregation or disaggregation in media	Reactivity	Distribution/storage
Physical form/shape (at room temperature and pressure)				
Particle size, size distribution and surface area	Skin sensitisation/irritation		Corrosivity	Environmental releases
Particle density	Skin penetration	Persistence potential screen Biodegradability (organic based) Photodegradability/photo transformation Stability in water Bioaccumulation		Post-use management
Solubility (in water and biologically relevant fluids)	Genetic toxicity tests			
Dispersability	Additional Data	Additional Data	Additional Data	
Bulk density	Biological fate and behaviour	ADME on aquatic organisms	Stability	
Agglomeration state	Chronic inhalation/ingestion	Chronic toxicity (aquatic, terrestrial, microorganisms)	decomposition	
Porosity	Chronic dermal irritation/sensitisation	Additional species	Polymerisation	
Surface charge	Developmental and reproductive	Avian toxicity testing	Photoactivity	
Surface reactivity	Neurotoxicity	Population/ecosystem-level studies		
	Extensive genotoxicity studies	Activated sludge respiration-inhibition test		
	Focused toxicity studies (susceptibility studies; allergenicity and immunotoxicity organ-function bioassays)	Microorganism toxicity		
		Persistence potential		
		Transformations via oxidation/reduction reactions		
	Endocrine disruption studies			

The base set of measurements were designed to determine the hazards and risks associated with manufactured nanomaterials with additional data also recommended. The triggers for obtaining the additional data were:

i. Potential triggers for obtaining additional data

   a. High exposure potential (related to manufacture and production)

      i. Number of workers or population

      ii. Magnitude of environmental release

iii. High production volume

b. High potential for chronic human or environmental exposure related to sue disposal or recycling

i. Repeated or continuous release

ii. High volume of material used in application

iii. Detection in environment or biota

iv. Wide ranging uses

v. Proximity of receptors to exposure source

ii. Signification change in production, processing or use

iii. Uncertain or high inherent hazard potential

a. Similarity to analogous material that was evaluated to be hazardous

b. Physicochemical properties indicate the potential for dispersion in environment

c. Evidence of toxicity at lowest dose tested

d. Uncertainty (conflicting results for same endpoint, disparity of results

iv. Compensating for incomplete base set of either hazard or exposure data

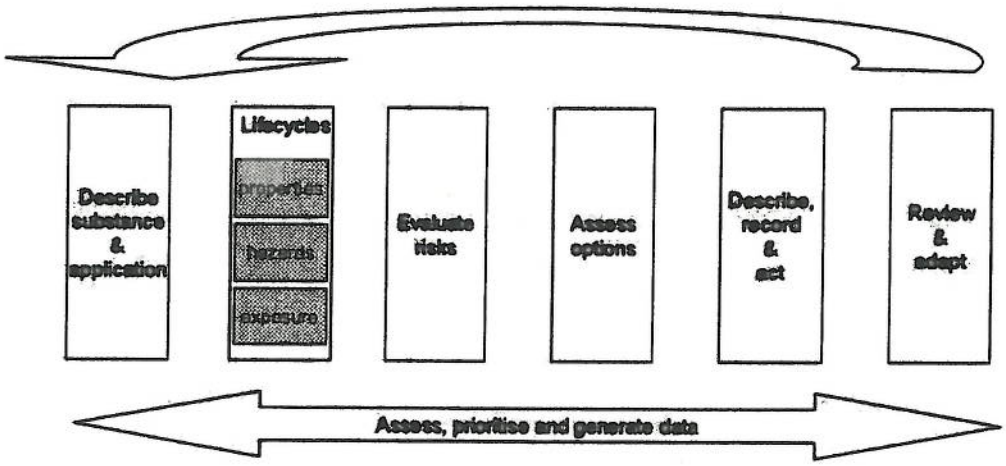

Figure 3.8 Schematic showing the Nano Risk Framework (Environmental Defense/Dupont, 2007)

The overall Nano Risk Framework can be summarised as the description, profile, evaluation and management of risk (Figure 3.8)

G. Nanotechnology Research Co-ordination Group 2nd Report (2007)

Further to the first NRCG report, the investigation into the characterisation of the potential risks posed by engineered nanoparticles was split into five areas covering metrology (characterisation, standardisation and reference materials), exposures (sources, pathways and technologies), human health, environment, and social and economic considerations.

The main overarching requirements for all of the task areas were:

i. The need to be able to measure and characterise nanomaterials in a range of environments (e.g. air, soil, water), requiring the development of appropriate methods and instrumentation to be able to differentiate manufactured materials from naturally occurring nanoparticles in the environment

ii. The need to understand which physicochemical properties of nanomaterials are important for toxicological effects

iii. The need to identify a set of 'reference' nanomaterials for testing (which may differ for occupational exposure, product exposure, and environmental exposure) and to establish the potential hazards to health and the environment

iv. The requirement that methods used in hazard assessment of chemicals and nanomaterials (e.g. OECD test guidelines, or equivalents) are fit for purpose for use

v. The requirement for a review of current risk assessment approaches and associated methods (for chemicals) to ensure that they are suitable for nanomaterials

vi. To understand the economic, social and ethical implications of nanomaterials and nanotechnology.

The report also suggested that the nomenclature and characterisation/measurement methods for nanomaterials were in need of elucidation.

H. Nanosure™ for Nanotechnologies (Arnold, 2007)

Additional dimensions of risk that need to be incorporated into the evaluation of a new product containing nanotechnology (including nanomaterials).

i. Environmental toxicity and persistence. As nanomaterials can be degraded rapidly or slowly throughout the products intended life cycle and at the end of product life, the environmental behaviour and fate of a material must be considered.

ii. Human toxicity. Nanomaterials can be toxic or non-toxic through all routes of exposure. The potential for translocation within a body or environment, or for the (e.g. teratogenic) effect to transfer down genetic lines, is also possible therefore enabling the nanomaterial to have a toxic effect on other systems, locations and generations.

iii. Human exposure. Whilst the manufacture of nanomaterials may occur in a highly-controlled environment and with controlled amounts, it is also possible that the material will be produced in larger quantities for use in consumer and environmental situations. During the life of the product, there is also potential for exposure.

iv. *In vivo* biopersistence. Nanomaterials may accumulate and not be removed from the body. The nanomaterials may also be accumulated into biological structures (e.g. within the protein matrix in membranes) due to their size.

v. Auto-activity. Nanomaterials may activate on response to, and in order to change, the environment.

vi. Mobility. Nanomaterials can be permanently immobilised within the carrier matrix, however they may also be released as a result of intended use or as accidental during the life cycle of the product.

I. Scientific Committee on Emerging and Newly Identified Health Risks (2007)

Following on from the first SCENHIR opinion (2005), the overall conclusions were that the risks of nanomaterials needed to be assessed on a case by case basis. The second opinion considered the appropriateness of the Technical Guidance Documents to determine the hazards of nanomaterials, the improvements to risk assessment methodologies, and how risk assessments can be performed. In general, they concluded:

i. The exposure and dose-effect models of nanomaterials may need to be adapted to take into account the changing physicochemical properties of nanomaterials over time (e.g. agglomeration, degradation)

ii. The experimental dose of nanomaterials should be measured as surface area or particle number per volume as well as (or instead of) mass concentration

iii. The uptake, distribution, clearance and effects of nanomaterials are not known, and the TGD may not be appropriate to measure and determine such effects. Therefore it is likely that the methods will need to be adapted or supplemented to gain this information. A tiered approach to hazard identification may be appropriate

iv. Ecotoxicology will require both acute and chronic exposures to mimic the duration of environmental exposure

v. The characteristics of nanomaterials should be measured in the most relevant dispersed state and should be measured under conditions that mimic those of the potential environments

J. US Environmental Protection Agency (2007)

The US EPA produced a Nanotechnology White Paper to inform and communicate the science needs associated with nanotechnology. Their recommendations included:

i. Research should be supported to understand environmental applications, chemical and physical characteristics, identification,

environmental fate, detection and measurement, potential releases, exposure, human health effects assessment and ecological effects assessment of nanomaterials

ii. Case studies should be conducted of industrial nanomaterials to further identify unique risk assessment considerations for nanomaterials.

iii. Resources should be used to support and develop approaches promoting pollution prevention and sustainable resource use in the production, use and end of life management of nanomaterials

K. Defra (Crane and Handy, 2006)

Crane and Handy produced a report assessing the regulatory testing strategies and methods for characterising the ecotoxicological hazards of nanomaterials in which they considered the technical guidance documents for ecotoxicological effects and how they may be supplemented or adapted for use to determine the environmental hazards of nanomaterials. Their overall recommendations were:

i. Research to develop test strategies and methods should focus on defining realistic worse case exposure scenarios for nanomaterials in environments, considering the fate and behaviour in the environment with and without the presence of natural substances and conditions that may influence the aggregation state

ii. Development of a set of rapid, cost-effective tests to demonstrate that a nanomaterial has similar hazard properties to other physical forms of a substance. These should include tests to identify overall toxicity and to identify specific modes of toxicity (unique to nanomaterials)

iii. If nanomaterials do not exhibit similar hazard properties to other physical forms of the material, the chronic effects of nanomaterials should measured in a limit test design

iv. A minimum base set of measurements for characterising nanomaterials should be produced including

    a. Nomenclature information

b. Concentration of the material (mass concentration as well as particle number concentration or surface area)
c. Electron micrographs of the material in solution
d. Particle size distribution (in solution)
e. Determination of agglomeration or aggregation of material
f. Determination of dispersion of the nanomaterial
g. Identification and measurement of impurities in nanomaterials

3.5 Summary

The knowledge gaps identified by the expert opinions in general were

1. The classification of nanomaterials (both physicochemical properties and chemistry).
2. The toxicology endpoints within toxicity tests are not sufficient to determine the systemic effects of nanomaterials
3. The experimental exposure and dose of nanomaterials needs to be clarified and an appropriate dose and duration of exposure used in experiments
4. The current triggers for risk assessments are not suitable and should be replaced
5. The uncertainty surrounding risk assessments of nanomaterials need to be clarified further
6. Rapid screening tests, related to physical or chemical properties should be developed to ensure that hazardous nanomaterials are readily identified
7. The risk management of nanomaterials should be further considered to ensure that the appropriate responses are in place
8. The risk communication surrounding nanomaterials to non-expert communities should be developed

There have been some efforts to overcome these knowledge gaps.

1. nanomaterials classification – attempts have been made to standardise the vocabulary used to describe nanomaterials and the associated terms (BSI, 2005) with other publications address the labeling of products containing manufactured nanomaterials and the terminology used in applications (including cosmetics, sunscreens and medicinal products; BSI, 2007a-g) whilst other publications offer good practice guidance to specifying nanomaterials (BSI, 2007h) and the safe handling and disposal of nanomaterials (BSI, 2007j).
2. Whilst the toxicological endpoints within toxicity tests are not sufficient to determine the systemic effects of nanomaterials nor the presence of nanomaterials, developments in analytical techniques may enable the systemic effects of nanomaterials to be shown. The use of electron microscopy to show the translocation of nanomaterials has already been a success (for example, Poland et al 2008), the use of additional spectroscopic techniques, such as EDX and XPS, will enable the nanomaterial to be indentified by chemical structure as well as shape. The systemic effects of nanomaterials are likely to be observed only with long term studies, therefore the duration of toxicity testing must be considered. However, if reference nanomaterials are developed and the mechanism of action determined, then such tests may not be necessary.
3. The experimental exposure and dose of nanomaterials needs to be at an appropriate level to mimic that of expected exposure or worse case scenario. This is currently possible and technical guidance should be given in this respect. The duration of exposure must also represent the likely actual exposure, therefore acute toxicity testing results for nanomaterials may not be as important as chronic toxicity testing results.
4. The current triggers for risk assessments are not suitable as they are based on weight concentration. Whilst it may not be possible to assess

every separate type and shape of nanomaterials that enter into production, the determination of important physicochemical characteristics and the consideration of the bulk materials' toxicity will become necessary in order to make initial assumptions as to the hazards associated with specific nanomaterials. The Environmental Defense-DuPont Partnership (2006) suggest a testing regime for nanomaterials, but do not suggest an appropriate trigger for the initiation of the risk assessment process. Other expert opinions (RA/RAEng, 2004) suggest a cautionary approach with the risk of every manufactured nanomaterial being determined before their use. This is not appropriate for industrial growth, however it the potential related risks do need to be considered before manufacture begins.

5. The uncertainty surrounding risk assessments of nanomaterials (such as appropriateness of testing methods, the selection of testing methods, the use of solvents, the detection and distinction of nanomaterials, and the use of potential *in vitro* screening methods) must be fully considered for each nanomaterial. Whilst general statements as to the suitability of testing methods are possible, the requirements and circumstances of each nanomaterial should be taken into consideration.

6. Whilst the development of rapid screening tests (possibly *in vitro* toxicity testing) should be developed to ensure that hazardous nanomaterials are readily identified, the use of physicochemical data is likely to be more important in the classification of nanomaterials and their group toxicity effects. Rapid screening tests will only identify the predicted toxicological reactions and can not be used to determine the potential interaction between biological and manufactured nanomaterials which may be more responsible for toxicological effects.

7. The risk management of nanomaterials is currently well developed in many industries, however the possibility for accidental release and the unknown consequences of that release is still present. Whilst there are no formal regulations on the manufacture of nanomaterials, there are several voluntary schemes (e.g. Nanotechnologies Industry

Association) which encourage and develop industrial responses to nanomaterials regulation.

8. Risk communication to non-expert communities is an important area of the ethical and social issues surrounding the production of nanomaterials.

However, the accuracy of the scientific techniques used to determine the properties of nanomaterials and the interpretation of such results are more important than the tests themselves. The combination of materials science, toxicology and exposure awareness needs to occur in the risk assessment of manufactured nanomaterials in order to ensure that an appropriate regulatory response is taken. Therefore, the decision was taken to concentrate on the accuracy and inventory of evidence collected as well as the strength and weight of such evidence, and in devising an appropriate method to support risk assessment decisions for manufactured nanomaterials.

Section 4

Workshop outcomes

4.1. Overview

An expert workshop was held at Cranfield University on 15th May 2008 to gather further intelligence about the appropriateness of current risk assessment methods to assess manufactured nanomaterials. The workshop considered the evidence, strength of evidence and weight of evidence required for risk assessment (as discussed in Section 3). A summary of the discussion for each section is presented below, with the overall outcomes of the workshop.

4.2. Issues considered

4.2.1. Inventory of evidence

Consider (1) are all the relevant, discrete lines of evidence captured, (2) are the lines of evidence properly categorised (source of hazard, exposure pathway and receptor effects), and (3) how the evidence relates to nanomaterials and other structures.

The delegates were given a copy of an example table (see Table 4.1) showing the possible distinction between hazard, exposure and receptors that may be applicable for the risk assessment of nanomaterials. The delegates were asked to discuss the table to ensure that the above points were covered and that they agreed on the amount, distinction and classification of lines of evidence that should be presented when considering the risk assessment of nanomaterials.

Table 4.1. Lines of evidence that may be relevant to the risk assessment of nanomaterials – table presented to workshop delegates

Hazard (Property)	Availability (Exposure)	Sensitivity (Receptor)
<100nm (one diameter) Solids Morphology Surface reactivity Surface area Chemical toxicity of bulk chemical Solubility Density/ mobility Particle size distribution (uniform or highly distributed) Aerodynamic diameter Step changes (band gap) Surface coating Aggregation/agglomeration Charge	Use Wet/ dry state Manufacture scenario Predicted use Unintended use Load/ amount Tonnage Route (absorption/ distribution/ metabolism/ excretion) Occupational Environmental Consumer Translocation Personal protection equipment Local/regional	Asthmatics Blood clots Nucleation Genetic polymorphism Chronic obstructive pulmonary disease Cardiovascular Plants Bottom/ sediments feeders Soil organisms Carbon/ nitrogen cycle

The points that the workshop delegates raised were:

- The physical properties should be categorised further, including surface reactivity (chemistry, amount of reaction on surface), surface porosity (which will affect surface area), surface composition, solubility or suspension formed (dissolved fraction or nanosuspension), explosive nature (e.g. metal nanomaterials), stability, size, agglomeration, aggregation with environmental nanomaterials, aspect ratio of non-spherical nanomaterials.
- The exposure distinctions should include point of use, release (during which stage), differentiation from environmental concentration and/or nanomaterials, distance from exposure, translocation potential (split into environmental fate and behaviour, mechanism of absorption, long range transport), durability in organisms (adsorption, distribution, metabolism, excretion), environmental hazards and consequences, bioaccumulation, biomagnification, and effects of nanomaterials in mixtures.
- The receptors will be determined by the exposure (e.g. aquatic and aerosol release will have different receptors), life cycle assessment,

extrapolation of known material exposures to nanomaterials, whether there are appropriate environmental models currently to determine exposure.

- The "effects" and "sensitivity to effects" need to be considered separately, however these will vary with each separate nanomaterial.
- The current triggers for chemical risk assessment are not appropriate for nanomaterials (i.e. 1 tonne/annum), and it should be considered whether there is enough evidence to determine what the triggers should be for the risk assessment of nanomaterials.
- Whether there is the potential for significant exposure of susceptible receptors at the amounts currently used/manufactured and whether the toxicity testing considers long enough durations.
- Intelligent testing for risk assessment is required to ensure that the most significant nanomaterials are given priority and that risk assessment takes into account the priority lines of evidence.
- Whether correlation could be drawn from the known hazards of the bulk material or the material at a different particle size.
- Whether the data set suggested by the Environmental Defense/DuPont Partnership covers the potential hazards posed by all manufactured nanomaterials

The delegates recognised that there was a need for a significant amount of information to ensure an accurate assessment of the risks of one individual nano-scale material. However concerns over the appropriateness of toxicological endpoints and outcomes (e.g. LC_{50}) were raised as the amount of the dose required to obtain these outcomes was considered to be highly unlikely in normal or likely exposure. The possibility of systemic effects being missed in initial toxicity studies was also raised.

Summary

The main points and opinions collected under the lines of evidence debate were:

i. a desire for more definition and structure within each column (i.e. the lines of evidence provided were headings to which more detail should be added)

ii. whether it was possible to prioritise (or rank) the list to provide a hierarchy of evidence

iii. whether the main risk was to exposed groups, or whether a residual/secondary risk also was prevalent

iv. whether a benchmarking or "class" approach could be taken with the lines of evidence to enable the hazard of a specific nanomaterial to be predicted

v. assumption that the chemical reactivity forms the basis of the toxic effect (e.g. surface chemistry/reactivity) whilst the size of the material could be the determining factor

Table 4.2. Lines of evidence that may be relevant to the risk assessment of nanomaterials – altered table

Hazard	Exposure	Receptor
Size Solid Morphology – aspect ratio Surface reactivity Surface area Surface composition Porosity Chemical toxicity (bulk) Solubility Density/ mobility Particle size distribution Bioaccumulation Aggregation (with other materials) Agglomeration Charge Stability Explosive nature	Manufacture scenario (point of use) Point of release (during manufacture) Unintended use Load/ amount Tonnage Route Bioaccumulation/magnification Toxicokinetics Translocation potential (environmental fate/behaviour, mechanism of absorption, long range translocation) Exposure model Variation from background concentrations Durability in organisms (ADME) Distance from exposure source Effect in mixtures	Sensitivity to effects Sensitivity to route of exposure Sensitive groups Critical groups Worse case scenario Relative to exposure Appropriate environmental models Life cycle assessment (to identify receptors)

4.2.2. Strength of evidence

Consider (1) the individual strength of lines of evidence, (2) which characteristics/experiments/receptors are important, and (3) which characteristics/experiments/receptors will change for different materials.

The workshop delegates considered whether the individual lines of evidence could be placed into a hierarchy in order to prioritise the measurements required for risk assessment.

The comments that arose from this discussion were that the basic methods (and therefore strength of evidence) are suitable for application to manufactured nanomaterials, but that the testing of the material must be done in terms of exposure. This would cover experimental conditions such as duration, route, amount and mixture (with chemicals and particle size distribution). Scientific evidence would need to be additionally collected on the likely exposure of individuals or environment, which would drive the selection of exposure mode for toxicity testing. It was also suggested that a Direct Toxicity Assessment (DTA) may be suitable for the estimation of environmental release of nanomaterials. However, the measurement and detection of environmentally released nanomaterials would be difficult in air, and unrealistic in aqueous samples, suggesting that a model of exposure would be required. Concerns were also raised that the risk assessment will cover specific particles within a selected fraction of the particle size distribution, but will not take into account the likely effects from other sizes within the manufacturing sample. Therefore the experimental situations should mimic "real life" or worse case scenario as much as possible.

General concerns over the quality of data presented, good laboratory practice, peer review, and quantity of evidence presented were discussed with the proviso that data collected for toxicological reviews should fulfil these criteria. The degree of concurrence between data, either disparate or aligned, was also discussed and the general need for distinction between supporting data and anomalies was identified. It was suggested that the ranking or scoring of data (e.g. using Klimisch criteria) would help to clarify this situation and that this was not unique to the risk assessment of nanomaterials. Questions were

raised as to whether the Klimisch criteria can be applied to nanomaterials as well as exposure assessment and measurement, or whether the criteria could be used to form a "banded strength of evidence" for application to risk assessment frameworks (e.g. REACH).

The hierarchy of relevance of collected data was established as an individual study (specifically designed for nanomaterials) was more relevant than a general human study (epidemiology), which was more relevant than an animal study (e.g. *in vivo* rodent), which was more relevant than *in vitro* studies.

There was also concern raised about the relevance of the data currently collected under the toxicity testing structures and whether they support mechanistic understanding of the effects observed. As the manufactured nanomaterials are unlikely to exist in a pure (unadulterated) sample, there were concerns raised as to whether the toxicity of mixtures would be more important to assessing the environmental and human health effects. This would be further complicated by the confusion over the metrology of particles and the possible (wide) particle size distribution.

The workshop delegates felt that the quantification of uncertainty and areas of uncertainty (e.g. metrology, particle size distribution, unknown exposure) would be necessary in order to support the strength of individual lines of evidence. The possibility of using other materials (other sizes or benchmark materials) as analogues was also considered in order to identify the evidence which would be important for risk assessment. These are currently under investigation worldwide (EPA, NPL) and have been previously used in ecotoxicology. Whether specific nanomaterials can be compared to reference particles may be of further issue due to the number of causal characteristics which may be responsible. The application of Bradford Hill criteria (used in epidemiological studies) was suggested to elucidate the relationship between the specific characteristics of nanomaterials and the observed toxic effects.

The need for an expert panel (beyond the scoring and ranking of collected data) was considered in order to bring in individual expertise and knowledge into the assessment of data. Whilst the ranking and scoring of the data

considers the robustness of data collection, the relevance and association of factor and effect must be considered separately by an individual.

The communication of outcome to non-expert groups would also be a potential outcome of the risk assessment, although with limited utility. With the increased public awareness surrounding the use of nanomaterials in industry, a transparent and precise decision process and supporting data would be beneficial. The schematic presentation of strength of evidence would assist in the communication to interested groups, including groups such as manufacturers and assessors. However, there will always be the need for detailed expert evaluation and study.

Supporting reasoning

Bradford Hill's criteria (Hill, 1965) attempted to separate causal from non-causal explanations of observed associations by a number of criteria (defined by Hofler, 2005) including:

1. strength of association (a strong association is likely to have a causal component)
2. consistency (reproducibility)
3. specificity
4. temporality (effect succeeds action or factor)
5. biological gradient (dose response)
6. plausibility (biological explanations)
7. coherence (agrees with current knowledge)
8. randomised experiments (good study design)
9. analogy (effect has already been shown)

The use of Hill's criteria to determine whether experimental observations are linked to the specific experimental conditions is supported by good study design. For example, the reproducibility of results is required to ensure that artefactual results are not considered indicative of the true result, this is also

true for the analysis of data collected which would be covered by the criteria of biological gradient, plausibility, temporality, specificity and analogy. It can be argued that a similar version of Bradford Hill's criteria should be used to assess all scientific studies for use in risk assessments.

Klimisch and colleagues (1997) developed a systematic approach of evaluation of the quality of data. The scoring system used to categorise the reliability is:

1 = reliable without restrictions. Where the data was generated according to internationally accepted (or validated) testing guidelines (e.g. OECD) and preferably performed according to GLP or where the test parameters are closely related to a guideline method;

2 = reliable with restrictions. Where the data was mostly not performed according to GLP and where the test parameters do not totally comply with the testing guideline, but are considered sufficient to accept the data;

3 = not reliable. Where there were interferences between the measuring system and the test substance, or in which the test systems were used which are not relevant in relation to the exposure, or were generated using an unacceptable method;

4 = not assignable. The experimental details provided were not sufficient and were only listed in short abstracts or secondary literature.

These evaluation criteria have been applied to many risk assessment methods previously and have proved to be an acceptable method of determining the quality of the data to be assessed. As long as the initial requirements for information (and the quality of that information) are established in defined technical guidance documents, and adopted by bodies such as OECD, then the application of the Klimisch score to collected data is acceptable. However, the information requirements and the analysis of the collected data must be robust and transparent in order to ensure that the Klimisch score is applied correctly and robustly.

The hierarchy of relevance of collected data (stated as individual study>human>animal>*in vitro* during this workshop) is generally accepted (). However, the Klimsch score should also be taken into consideration when the

evidence is considered to ensure the robustness of the risk assessment. This will only be possible if an expert can assess the data. However, the expert does need experience in toxicological endpoints as well as materials characterisation in order to assess the appropriateness of not only the toxic nature of the material, the exposure during manufacture, and the experimental sample. The variation in nanomaterials caused by the manufacture route will not be apparent to toxicologist, whilst the appropriateness of the dose and endpoints will not be apparent to materials scientists. There will therefore need to be a wide range of expert opinions gathered on the same data to ensure that the presented knowledge is reliable from both toxicology and materials view points.

Individual expertise is also required to determine the relevance and association of factor and effect; however the possibility of benchmarking certain lines of evidence to indicate which areas of evidence (or hazard) should be considered further may speed up the decision process. This is currently possible for some chemicals to a certain extent with QSAR, allowing the prediction of toxicological outcomes from the chemical structure of a molecule. If the size or shape of a nanomaterials determines its toxicity, then the relationship is clear and the outcome will only be affected if the environment transforms the nanomaterial (either by physical or biological methods). If there are other factors that also contribute to the inherent toxicity of the material, for example the surface chemistry, then the need for specific information becomes clear (including information on the aerodynamic diameter, route into body and potential for agglomeration).

The Direct Toxicity Assessment (DTA) measures the hazard of industrial effluent (whole effluent) discharged into waters. It determines the overall toxic effect of the contaminants in an effluent sample using standardised aquatic ecotoxicological assays and can be used in conjunction with substance-specific assessment to identify, characterised and control the ecotoxicity of effluents. Whilst a DTA integrates the acute effects of all of the substances present, it does not assess the chronic toxicity of an effluent or identify the causative agents within the effluent.

Summary

The main points and opinions collected under the strength of evidence debate were:

i. uncertainties need to be clarified (both with collected data and with testing methods)

ii. the hierarchy of evidence will depend on the nanomaterial and which characteristics prove to be more important for toxic effects

iii. the Klimisch criteria and Bradford Hill criteria will both apply to collected data, however individual expertise will also be required

iv. relevant conditions should be used in toxicity testing, e.g. experimental dose, route and duration.

4.2.3. Weight of evidence

Consider (1) overall weight of evidence considering complementary and contradictory evidence of varying strengths and (2) presentational clarity.

The distinction between the risk assessment of new (nano-scale) and existing (bulk) material needs to be legally clarified. Whilst REACH (in the UK) covers all new materials, the possibility of new questions and data required to assess the risks of nanomaterials must be considered. Manufactured nanomaterials are covered under the existing legislation (e.g. industrial chemicals, pharmaceuticals, agricultural products, and food additives) however there are no guidelines for the assessment of specific toxicological data. Therefore the weight of evidence needs to be considered; for instance is the data collected from one line of evidence stronger, and therefore more important, than that collected for another line of evidence and how does this compare to the other data collected.

It is likely that some nanomaterials will produce unexpected novel effects and non-intuitive effects, for instance effects or processes that are not anticipated and cannot be predicted. These are likely to only be discovered after the initial testing of the material. In pharmaceuticals, transparent methods of reporting and vigilance after the manufacturing licence has been granted

mean that there is more testing and therefore more control and potential to find adverse effects. As chemicals are not routinely tested for specific toxicity the risk assessor is not routinely looking for every toxic effect in every species. The consideration for regulators is whether there is an obligation to report an adverse effect after the initial risk assessment and, if so, what new data needs to be presented.

Supporting reasoning

Whilst the toxicity tests are generally suitable for use with manufactured nanomaterials, with some adjustments as previously described in Section 2, guidelines are required for preliminary risk assessments by manufacturers and users as currently the amounts of nanomaterials produced are not sufficient to provoke risk assessment under EU legislation.

A scheme for preliminary risk assessment of nanoparticle materials has been suggested previously (Howard and de Jong, 2004, for Oxonica, UK; Figure 4.1).

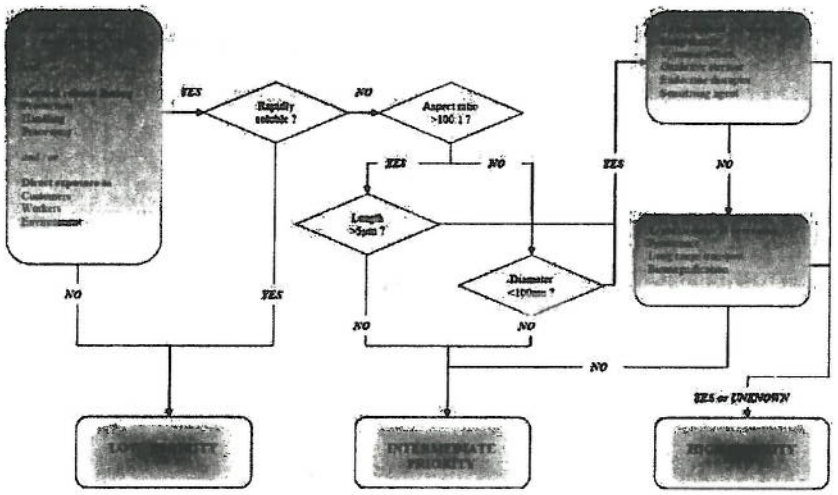

Figure 41. Performa scheme for a preliminary risk assessment of nanoparticulate materials (Howard and de Jong, 2004).

The scheme uses the initial concerns of potential release, exposure and size to trigger further investigation and to determine whether a substance will be of low, intermediate or high priority for further assessment. The initial assessment is based on a number of parameters including production volume, exposure potential, solubility and aspect ratio. The numerous varieties of

nanomaterials mean that the determination of "reference" nanomaterials will be difficult and will not encompass the range of toxicological endpoints possible.

4.3. Significant knowledge gaps

The significant knowledge gaps identified by the workshop attendees were:

i. assumption that the chemical reactivity of the nanomaterial (or surface coating of the nanomaterial) was responsible for the toxic effect;

ii. obscure language used to refer to same properties, a "novel" language needs to be defined to ensure that the scientists and engineers using/manufacturing/assessing nanomaterials are speaking about the same properties (BSI, 2006);

iii. the distinction between the solubility of nanomaterials or the formation of a suspension in liquids needs to be determined, and whether the distinction between them is significant needs to be investigated;

iv. whether agglomerated nanomaterials will undergo a delayed release in the environment, whether this will occur at a rate where the exposure should be measured (e.g. bioaccumulation/biomagnification) and whether this will occur quickly or not;

v. whether agglomerated or single nanomaterials will undergo enzymatic digestion and will breakdown to release toxic chemicals;

vi. whether the bulk material can be used as an indicator of the likely toxicity of the nanomaterial form, and whether it is appropriate to use the toxicity of the bulk material as a starting point for the risk assessment of nanomaterials;

vii. whether there is an incremental residual risk of released nanomaterials above the background concentration of environmental nanomaterials;

viii. whether manufactured nanomaterials will behave differently to "background" environmental nanomaterials;

ix. whether it is possible to have standard nanomaterials in order to benchmark the toxicity/actions of nanomaterials;

x. whether the likely impurities of manufactured nanomaterials will contribute more to the toxic properties than the parent chemical;

xi. whilst the regulation is currently in place, whether the amount of information requested in the risk assessments is enough to determine the risk of manufactured nanomaterials

xii. whether specific characteristics of nanomaterials can be indicative of toxic effects and the relative importance of these characteristics

xiii. whether generic ranking and scoring (e.g. Klimisch score) can be applied to collected data where the testing criteria are not clearly defined

xiv. whether the dose/duration in toxicological testing is appropriate to assess the toxic nature of nanomaterials

xv. whether *in vitro* testing is appropriate for nanomaterials where translocation and systemic effects may be more significant than target organ toxicity

Section 5

Summary

The overall knowledge gaps that were identified by the project team and invited experts were:

1. a general assumption that the chemical reactivity rather than the shape or size of the nanomaterial is responsible for the toxic effect. This will be further elucidated by current research projects (NERC funded; EPA, 2008);
2. confusion over terminology and classification used, which needs to be standardised. The BSI have published recommendations on this subject and it is hoped that all interested parties will consider these terms;
3. the potential for delayed release of agglomerated nanomaterials in the environment, whether this will occur at a rate or site where the exposure is measured;
4. whether the bulk material can be used as an indicator of the likely toxicity of the nanomaterial form, and whether it is appropriate to use the toxicity of the bulk material as a starting point for the risk assessment of nanomaterials. Again current research projects and risk assessments (EPA, 2008) are investigating this knowledge gap;
5. whether there is an incremental residual risk of released nanomaterials above the background concentration of environmental nanomaterials and whether manufactured nanomaterials will behave differently to "background" environmental nanomaterials;
6. the possibility of reference or standard nanomaterials in order to benchmark the toxicity/actions of nanomaterials;
7. whether the likely impurities of manufactured nanomaterials will contribute more to the toxic properties than the parent chemical;

8. whilst the regulation is currently in place, whether the amount of information requested in the risk assessments is enough to determine the risk of manufactured nanomaterials
9. the current toxicological tests (OECD TG) are generally fit for use, however there are concerns over whether the dose/duration is appropriate to assess the toxic nature of nanomaterials and the interaction between the manufactured nanomaterial and its surroundings.

Further advances in scientific understanding will help to elucidate the knowledge gaps identified in this project. However the general need to have a thorough understanding of the nature of the material as well as the potential toxicological effects is necessary for individuals undertaking the risk assessment of nanomaterials. The appreciation of the strength and weight of evidence provided within the regulatory guidelines becomes more important when further knowledge is provided about the general toxicological mechanisms of manufactured nanomaterials. The Environmental Defense-DuPont Partnership's Nano Risk Framework has introduced the idea that the development of further toxicity tests and physicochemical determination may be necessary when distinctive physicochemical properties are noted. However the need to be able to factor in uncertainties into the frame work is missing. The authors believe that the development of a risk assessment supporting tool to identify required information for different types of nanomaterials will be necessary in order to ensure a safe interpretation of the data collected.

Section 6

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Section 7

Abbreviations

Aerodynamic diameter – diameter of a spherical particle with a density of 1000kg/m^3 that has the same settling velocity as the particle under consideration; related to the inertial properties of aerosol particles.

Agglomerate – group of particle held together by relatively weak forces, including Van der Waals forces, electrostatic forces and surface tension.

Aggregate – heterogeneous particle in which various components are not easily broken apart.

Article – an object composed of one or more substances or preparation which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does

Bottom-up nanotechnology – mainly related to chemical synthesis, structure creation by connecting molecules.

Carbon nanotubes (CNT)– tiny tubes about 10,000 times thinner than a human hair – consist of rolled up sheets of carbon hexagons

CMR – substances that are carcinogenic, mutagenic, toxic for reproduction

CNS – central nervous system

CSA – chemical safety assessment

CSR – chemical safety report

EC – European Community

EDX – Energy Dispersive X-ray

Effective particle size – measure of a particle that characterises its properties or behaviour in a specific system.

Engineered nanoparticles – nanoparticles between 1nm and 100nm manufactured to have specific properties or composition

EPA – Environmental Protection Agency

EPR – electron paramagnetic resonance

Epithelial – type of cells in close proximity to and which line the surface of an organ or hollow internal structure without the need for connective tissue.

Equivalent diameter – diameter of a sphere which behaves like the observed particle relative to or deduced from a chosen property.

ERMA – Environmental Risk Management Authority

EU – European Union

Fibrosis – abnormal formation or development of excess fibrous connective tissue as a reparative or reactive process.

GAC – Generic Assessment Criteria

GLP – good laboratory practise

GM – genetically modified

HSNO – Hazardous Substances and New Organisms

Hydrodynamic diameter – effective diameter of a particle in a liquid environment

MMR - measles, mumps and rubella

Mobility diameter – diameter of a spherical particle with the same mobility as the particle under consideration

Monomer unit – the reacted form of a monomer substance in a polymer

Multi-walled carbon nanotubes (MWCNTs)– carbon nanotubes which consist of more than one nanotube completely contained within another.

Nano – 10^{-9} or 0.000000001

Nano-aerosol – a collection of nanoparticles suspended in a gas

Nanocrystal – diameter of between 1nm and 10 nm and has fundamental properties depending strongly on their size

Nanoengineering – the construction of nanostructures and their components

Nanomaterial – material which is either a nano-object or is nanostructured

Nanoparticles (NP) – particles having at least one dimension (length, breadth or width) measuring less than 100nm (also see ultrafine particles)

Nanopowder – dry nanoparticles

Nano-object – material confined in one, two or three dimensions at the nanoscale.

Nanoscale – 1 to 100 billionths of a metre

Nanospheres – spheres in nanoscale

Nanostructures – nanometre sized objects

Nanotoxicology – the study of adverse effects of nanoparticles on health and the environment

Nanotubes – nanometre-sized tubes composed of various substances

Nanowires – molecular wires

NDSL – Non-Domestic Substances List

NICNAS – National Industrial chemicals Notification and Assessment Scheme

OECD – Organisation for Economic Co-operation and Development

Particle size – size of a particle as determined by a specified measurement method

PBT – substances that are persistent, bioaccumulative and toxic

Permissible exposure limit (PEL) – OSHA (USA) guideline/standard for maximum workplace exposure over an 8 hour time weighted average (TWA) exposure

PMN – Pre-Manufacture Notice

Polymer – a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to difference in the number of monomer units. A polymer comprises of a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; b) less than a simple weight majority of molecules of the same molecular weight.

Preparation – a mixture or solution composed of two or more substances

Quantum dots – nanometre-sized fragments of semiconductor crystalline material

REACH – Registration, Evaluation, Authorisation and Restriction of Chemical substances

SDS – safety data sheet

Semiconductor – material whose conductivity is normally in the range between that of metals and insulators and in which the electric charge carrier density can be changed by external means

Sequestration – the action or process of making unavailable without destroying or inactivating

SIEF – substance information exchange forum

Specific surface area – ratio of the surface area to the mass of a nanopowder

Substance – a chemical element and its compound in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

Time weighted average (TWA) – the average exposure to a contaminant to which workers may be exposed without adverse effect over a specified time period

Top-down nanotechnology – engineers taking existing devices, such as transistors, and making them smaller.

TSCA – Toxic Substances Control Act

Ultrafine particles – an anthropogenic or natural form of nanoparticles which is usually derived from combustion processes – distinguished by large variations in size and composition

vPvB – substances that are very persistent and very bioaccumulative

Workplace exposure standard (WES) – Australian Safety and Compensation Council (ASCC) guideline/standard for maximum workplace exposure over an 8 hour time weighted average

XPS - X-ray photoelectron spectroscopy

XRD - X-ray Diffraction