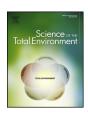
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# Where do uncertainties reside within environmental risk assessments? Expert opinion on uncertainty distributions for pesticide risks to surface water organisms



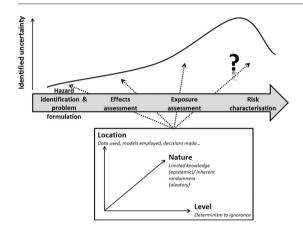
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#### HIGHLIGHTS

- Expert elicitation described uncertainty associated with risk assessment tasks.
- The highest uncertainty level noted within the risk characterisation phase
- The typology and associated use enables analysts to identify where uncertainties reside.
- The typology output allows prioritisation of tasks by uncertainty potential.

#### GRAPHICAL ABSTRACT



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# ABSTRACT

A reliable characterisation of uncertainties can aid uncertainty identification during environmental risk assessments (ERAs). However, typologies can be implemented inconsistently, causing uncertainties to go unidentified. We present an approach based on nine structured elicitations, in which subject-matter experts, for pesticide risks to surface water organisms, validate and assess three dimensions of uncertainty: its level (the severity of uncertainty, ranging from determinism to ignorance); nature (whether the uncertainty is epistemic or aleatory); and location (the data source or area in which the uncertainty arises). Risk characterisation contains the highest median levels of uncertainty, associated with estimating, aggregating and evaluating the magnitude of risks. Regarding the locations in which uncertainty is manifest, data uncertainty is dominant in problem formulation, exposure assessment and effects assessment. The comprehensive description of uncertainty described will enable risk analysts to prioritise the required phases, groups of tasks, or individual tasks within a risk analysis according to the highest levels of uncertainty, the potential for uncertainty to be reduced or quantified, or the types of location-based uncertainty, thus aiding uncertainty prioritisation during environmental risk assessments. In turn, it is expected to inform investment in uncertainty reduction or targeted risk management action.

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## 1. Introduction

The primary objective of an environmental risk assessment (ERA) is to estimate the magnitude or level(s) of risk posed to environmental receptors by sources of potential harm (Department for Environment, Food and Rural Affairs [Defra], 2011). Confidence in the risk estimate can be lowered by uncertainties in the ERA, which can weaken, or stall, the basis for risk management. Whilst risk analysts recognise uncertainty should be considered (Funtowicz and Ravetz, 1990; Costanza et al., 1992; Handmer et al., 2001), many ERAs still fail to identify uncertainties (EEA, 2007; Hart et al., 2007; Dale et al., 2008). This paper introduces an approach to aid uncertainty identification and prioritisation within ERAs.

Uncertainty in environmental systems is investigated through its constituent dimensions (Walker et al., 2003); namely, its location (where the uncertainty is manifest in the various stages of a risk assessment), its nature (due to the incompleteness of knowledge or the inherent variability of natural systems), and its level (the severity of the uncertainty, ranging from determinism to ignorance). Ideally, the location of the uncertainty must be known, since without this, no action to reduce it can be implemented. The nature of the uncertainty dictates the extent to which it can be managed; knowledge-based uncertainties can be quantified, reduced, and potentially removed; whilst those that reflect the randomness of natural processes can only be quantified (Kelly and Campbell, 2000). Finally, the level of uncertainty informs selection of an appropriate management technique (Refsgaard et al., 2007). In order to manage uncertainty effectively, it is essential that reasonable attempts to identify all dimensions are made (Walker et al., 2003; Janssen et al., 2003; Refsgaard et al., 2007; Knol et al., 2009).

The identification of uncertainties relies on risk analysts compiling lists of potential uncertainties with their analyses. These commonlytermed uncertainty typologies aim to define and communicate the important features of uncertainty. When complete, typologies provide reliable characterisations of uncertainties for ERAs. However, the differing abilities and experiences of ERA practitioners results in typologies being used inconsistently (Gillund et al., 2008; Knol et al., 2009). Some typologies deploy terminology that is contradictory; communicate frequencies and dimensions of uncertainties that can be unclear; and they can deploy source information from limited data sets and that cannot be applied, on an individual basis, to ERAs to characterise the wide range of uncertainties (Skinner et al., 2014a). Critically, an approach for describing uncertainty comprehensively - with specific guidance regarding the identification of uncertainties in ERAs than is found in a typology - is lacking (Sigel et al., 2010). This paper introduces such an approach, based on validated maps of the risk assessment process as a decision system, supported by structured expert elicitations. Here, the approach is illustrated through application to the domain of agricultural pesticide risks to surface water organisms, a subject that has attracted the wide attention of environmental risk assessors.

# 2. Methods

# 2.1. Overview

The methodological process began by creating and validating a template (a risk assessment process map) containing the key stages of a generic ERA. For the topic of agricultural pesticide risk to surface water organisms (the risk 'domain'), our 'case study', an evidence base of ERAs was assembled from the prior art from which a dominant risk relationship was selected as the focus. A case study version of the ERA template was created, using information from the gathered ERAs, and validated. Following this, an elicitation was designed using the information within the generic and case study ERA templates, and completed using case study experts selected from their publication of relevant ERAs. The elicitations were combined to describe the levels, natures, and locations of uncertainties within ERAs for the case study. The method is explored in detail below.

#### 2.2. Generic ERA template

An examination of peer-reviewed and regulatory literature allowed collation of the important features of ERAs, constructed for this study as a generic ERA template, version 1 - in short, a generalised risk assessment framework comprised of the accepted stages of analysis. Validation of this template was performed in two rounds using the opinions of ERA experts who were asked whether they recognised and could confirm the key stages of an ERA as expressed by the generic process in the template. Experts were sourced using Scopus™, which covers a wide journal range (including academic and industrial trade journals; Falagas et al., 2008), using search terms joined by Boolean connectors 'risk assessment (in article title) AND ecological OR environmental OR human (in keywords)'. Results were limited to the last 10 years, so to identify experts active in ERA. The location of the experts was not defined, allowing worldwide input. In-built filtering within Scopus™ was used to remove non-relevant literature, with further filtering to ensure the returned sources related to ERAs, performed using the information within titles and abstracts. Filtered records were ordered by decreasing citation count, and the contact details of the first 2000 records exported. This threshold was set to allow for a 50% redundancy in records (due to outdated contact details, duplicates, or retired individuals), and a 5–10% response rate from the remainder (Speirs-Bridge et al., 2010), resulting in 50–100 responses. The email addresses of the corresponding authors were extracted from each record, and duplicate addresses removed.

For the first round of validation, the generic ERA template version 1 was sent to every other contact in the compiled list (i.e. all odd entries) with explanatory information on the research and details of the validation request. Experts were asked to validate the risk assessment phases (e.g. problem formulation), sub-phases (e.g. defining the conceptual model), and individual technical tasks (e.g. identifying sources or stressors, pathways, and receptors) within the generic template. A response time of four weeks was offered, after which the views of the experts were collated, and alterations to the generic ERA template, version 1, made, for suggestions where two or more experts agreed. This exercise yielded the generic ERA template, version 2. The procedure was repeated for a second round of validation, with the generic ERA template, version 2 sent to the remaining experts in the contacts list (i.e. all even entries). Completion of the second validation yielded generic ERA template, version 3, which was then used as the structure for the case study ERA template. To an extent, version 3 of the generic ERA template represents a practitioner consensus on the phases, sub-phases and individual tasks of an environmental or ecological risk assessment.

# 2.3. Case study ERA template

Next, a domain-specific version of the validated generic ERA template version 3 was constructed for the case study. A new evidence base of peer-reviewed ERAs was compiled from Scopus™, using the search term 'risk assessment (in keywords) and pesticide (in keywords) and water (in keywords)'. Results were not restricted temporally (e.g. the last 10 years), but assessed for relevance using the procedure described above. The returned ERAs were analysed, with all risk relationships (connections of sources, pathways, and receptors; S-P-Rs; Pollard et al., 2002, 2006) recorded. A single S-P-R risk relationship was selected on the basis of the most frequently occurring set of S-P-Rs, and the evidence base updated to contain the corresponding ERAs only. For this case study, the risk relationship explored was the chemical risk (consequence) posed to surface water macroinvertebrates (receptor) as expressed by direct exposure (pathway) to agricultural pesticides (source). Information within the ERAs was used to populate the generic ERA template version 3, so creating a case study ERA template for the specific risk relationship. Following validation, information within the case study ERA template was used to devise an uncertainty-based expert elicitation.

### 2.4. Uncertainty-based expert elicitation

Elicitations were performed (Slottje et al., 2008; US EPA, 2009; Knol et al., 2010) following a seven-step procedure derived from published methodologies (Knol et al., 2010).

#### 2.4.1. Step 1: characterisation of uncertainties

The elicitation used a characterisation of uncertainties based on 171 peer-reviewed ERAs (Skinner et al., 2014a) which consisted of three types of uncertainty within the nature dimension (epistemic, aleatory, and combined) and seven types of uncertainty across the location dimension (data, language, system, variability, extrapolation, model, and decision). Sub-types of location-based uncertainties (Skinner et al., 2014b) were not included. The level of uncertainty was expressed as a range of integers (where zero represents a deterministic understanding of the uncertainty and 10 represents total ignorance to it), consistent with Krayer von Krauss et al. (2004).

# 2.4.2. Step 2: scope and format of the elicitation

Elicitations deployed a questionnaire implemented in Microsoft Excel 2007 (Microsoft Corporation, Redmond WA) using controls and macros, distributed to experts via email, completed remotely and returned before a set deadline. Experts were approached as individuals.

#### 2.4.3. Step 3: selection of experts

The experts selected to participate were the same as those invited to validate the domain-specific ERA templates, unless they stated a wish not to, and were considered to be subject-matter experts drawn from academia, industry, and regulatory agencies. The credentials of an expert who completed an elicitation were checked to ensure recent and extended involvement in the relevant domain.

#### 2.4.4. Step 4: design of the elicitation protocol

The elicitation was organised according to the phases, groups of tasks, and individual tasks within the validated generic ERA template, all of which were contextualised for the case study ERA template. Experts were asked to assess four aspects for every task within each ERA phase:

- using tick-box controls, whether the task was deemed necessary in an ERA of the case study domain, thereby providing an extra validation of the elicitation contents. If deemed unnecessary, experts were able to move to the next task;
- 2) using slide bars, the level of the uncertainty associated with performing the task (on a scale of zero to 10, as above);
- 3) Using tick-box controls, the nature of the uncertainty associated with performing the task (epistemic, aleatory, or combined); and
- using tick-box controls, the location(s) of the uncertainty associated with performing the task (data, language, system, variability, extrapolation, model, or decision).

The maximum number of tasks evaluated by an expert during the elicitation was the same as the total number of tasks contained within the validated case study ERA template.

To ensure experts understood uncertainty concepts, they were asked to complete a practice exercise prior to elicitation, based on the introduction of a DNA vaccine into aquaculture (Gillund et al., 2008). The practice task, which consisted of five questions, followed the same format as the main elicitation, so to familiarise the experts with the structure. The answers provided, relating to the level and nature of uncertainty, were compared to the 'control' set from the published elicitation (Gillund et al., 2008) in which the location of uncertainty was not assessed. Experts were considered to understand, and be able to assess the level of uncertainty (i.e. not be overly optimistic or pessimistic when faced with a scenario) if their averaged results were within  $\pm\,50\%$  of the control group. With regard to the nature of the uncertainty, experts were expected to agree with the control group to a minimum level of

60% (i.e. three out of five questions). Provided these two criteria were met, their judgements within the corresponding elicitations were deemed valid. A thorough written or verbal communication was held with experts who failed to complete the practice exercise, to satisfy that they understood the associated uncertainty-based concepts.

## 2.4.5. Step 5: preparation of the elicitation session

The distribution of the case study ERA template to all potential experts, for the purpose of validation, ensured their proper preparation. Both the validated generic ERA and case study ERA templates were provided for experts to view as part of the introductory information within the elicitation system.

# 2.4.6. Step 6: elicitation of expert judgements

The elicitation was organised into three sections: an introduction, with an elicitation overview and background on uncertainty dimensions and the ERA process; instructions on how to complete the elicitation, including the method used to assess the levels, natures, and locations of uncertainty, as well as the pre-elicitation practice exercise; and the main elicitation, separated into the four ERA phases.

# 2.4.7. Step 7: possible aggregation and reporting

Due to the stringent selection criteria above, the responses of all experts were considered of equal importance, with equal weighting methods selected as the basis for combining results (Clemen and Winkler, 1999; Slottje et al., 2008). Specifically, the responses for the levels of uncertainty were aggregated using measures of central tendency, with the natures and locations of uncertainty combined into occurrence rates (the following sub-section contains more information about the types of data gathered).

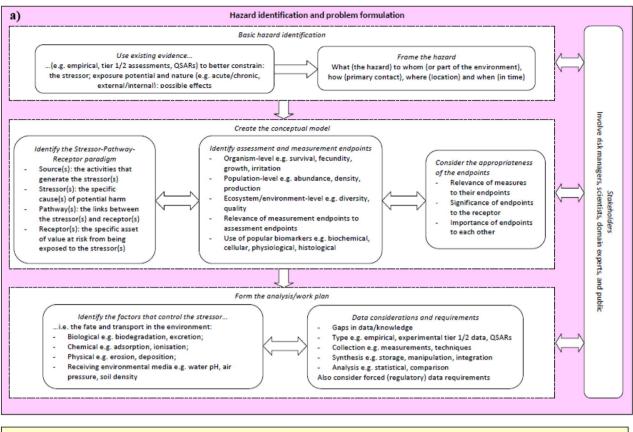
#### 2.5. Data analysis

ERA tasks within the elicitations had two kinds of data associated with them: (i) the level of uncertainty (measured using slide bars) was represented through integer values in the range zero to 10; whilst (ii) the nature and location of uncertainty (measured using tick box controls) were treated as binary values. The data from completed elicitations were extracted to a spreadsheet and assigned an expert identifier. With respect to the level of uncertainty associated with each ERA task, relationships were evaluated using central tendencies, variations from central tendency, and the high-low ranges of responses. Suitable parametric (mean and standard deviation) or non-parametric (median and inter-quartile range) measures were applied, as highlighted in the results below, based on an assessment of their normality. Binary data does not need to be assessed for normality, and was considered to be non-parametric due to the small size of the datasets analysed. All binary data relating to each category within the nature and location dimensions were converted to occurrence rates (%) describing the degree to which that category was selected by experts during the elicitations.

# 3. Results

# 3.1. Generic ERA template creation and validation

The generic ERA template, version 1 was created from several academic and grey literature sources (US EPA, 1992, 2003; Suter, 1996; US EPA, 1998; Fairman et al., 1998; DETR/EA and IEH 2000; DHA, 2002; Landis, 2005; Beer, 2006; Briggs, 2008; Defra, 2011). The 35 experts (21 from academia, 4 from industry, 10 from regulatory agencies) in the first validation provided 111 comments (28 in problem formulation, 22 in exposure assessment, 35 in effects assessment, and 26 in risk characterisation) on the correctness and completeness of this template; 23 of which were implemented (8 in problem formulation, 4 in exposure assessment, 7 in effects assessment, and 4 in risk characterisation. Thirteen experts (9 from academia, 2 from industry, 2 from regulatory



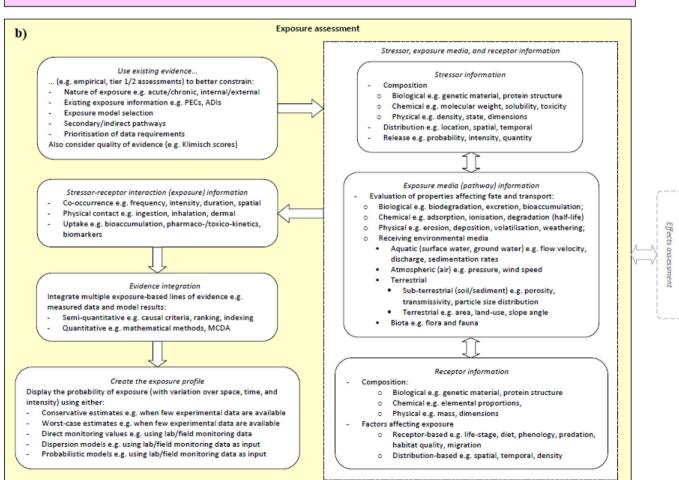
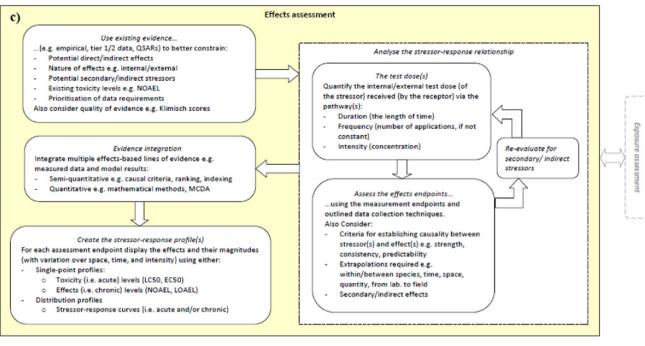


Fig. 1. The generic ERA template, version 3, created through the expert validation of versions 1 and 2, describing the important aspects within the phases of: a) hazard identification and problem formulation; b) exposure assessment; c) effects assessment; and d) risk characterisation.



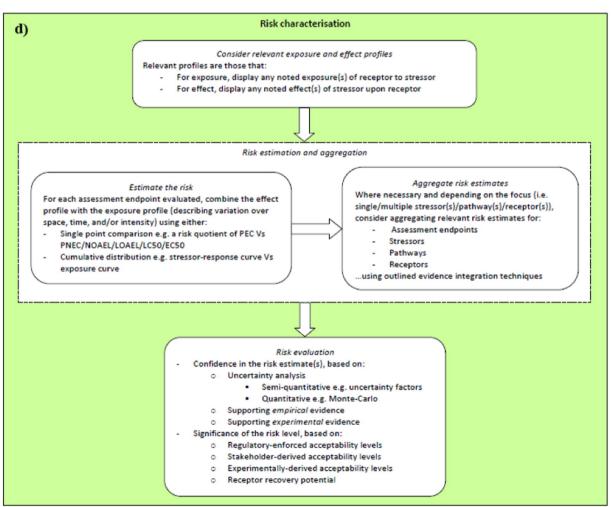


Fig. 1 (continued).

agencies) in the second validation provided 37 comments (11 in problem formulation, 10 in exposure assessment, 11 in effects assessment, and 5 in risk characterisation), 3 of which were further implemented (1 in problem formulation, 1 in exposure assessment, 0 in effects assessment, and 1 in risk characterisation. Implementation resulted in generic ERA template, version 3 (Fig. 1); organised by its phases, sub-phases, groups of tasks, and individual tasks (Table 1).

## 3.2. Case study risk relationship (S-P-R)

The literature searches, after filtering and relevance-checking, returned 127 peer-reviewed articles, reduced on the basis of missing information within the articles to a pesticides evidence base of 49 ERA articles. This was analysed for risk relationships, the most frequent of which (n = 5) were 'potential agricultural chemical pesticide risk to surface water macroinvertebrates' and 'potential agricultural chemical pesticide risk to surface water quality'. With dominant parameters described for the source categories (agricultural and chemical, respectively), but less so for the receptor category (macroinvertebrates and water quality, respectively), several receptor parameters were combined (multiple organisms, algae, crustaceans, and macroinvertebrates), establishing a defined risk relationship (n = 13; Cuppen et al., 2000; Mastin and Rodgers, 2000; Palma et al., 2004; van Wijngaarden et al., 2004; Wan et al., 2006; Schuler and Rand, 2008; Siemering et al., 2008; van den Brink et al., 2009; Vryzas et al., 2009; Burgert et al., 2011; Damásio et al., 2011; Guy et al., 2011; Vryzas et al., 2011) of 'potential agricultural chemical pesticide risk to surface water organisms', which was as specific as defensible and selected as the risk relationship for the case study. This allowed the detailed examinations of uncertainties for this case study ERA.

#### 3.3. Case study ERA template creation and validation

The generic ERA template version 3 was populated with relevant information from 13 peer-reviewed articles to form the agricultural chemical pesticide risk to surface water organisms ERA template, version 1. Experts (n=22) provided 119 comments (46 in problem formulation, 37 in exposure assessment, 20 in effects assessment, and 16 in

risk characterisation) regarding the correctness and completeness of this template, 32 of which were implemented (14 in problem formulation, 7 in exposure assessment, 8 in effects assessment, and 3 in risk characterisation), enabling the creation of the case study ERA template, version 2. Experts were from academia (n = 15), industry (n = 3), and regulation (n = 4), and resided in Argentina (n = 1), Belgium (n = 1), Canada (n = 4), China (n = 1), Denmark (n = 1), France (n = 2), Netherlands (n = 5), Portugal (n = 1), Serbia and Montenegro (n = 1), Switzerland (n = 1) and the USA (n = 4).

#### 3.4. Case study expert elicitation exercise

Nine experts participated in the elicitation, assessing 102 ERA-based tasks (31 in problem formulation, 36 in exposure assessment, 21 in effects assessment, and 14 in risk characterisation) for the levels, natures and locations of uncertainty. Experts were drawn from academia (n = 3), industry (n = 1), and regulation (n = 5), and resided in Canada (n = 2), France (n = 1), Greece (n = 1), Netherlands (n = 2), Spain (n = 1), Switzerland (n = 1) and the UK (n = 1). ERA tasks 16, 36 and 80 from the generic ERA template were not included since they did not appear in case study ERA template, version 2. Data relating to the level dimension were treated as non-Gaussian after assessment of the mean, median, and mode values; central tendency and spread were measured using median values and inter-quartile ranges (IQRs). Shapiro-Wilk normality test (Shapiro and Wilk, 1965) was applied, where significance values for 16 out of the 102 datasets evaluated (i.e. the ERA tasks) fell below the 0.05 significance threshold, confirming a non-Gaussian dataset. The median level of uncertainty across the tasks in problem formulation was 3.0, in the range of statistical uncertainty (Fig. 2a). The group of tasks considering the appropriateness of endpoints had the highest median level of any group in this phase (6.0; group 5). Experts agreed to a moderate extent, with a median IQR of 3.0 across all tasks in this phase. The nature of uncertainty was deemed to consist of a combined epistemic and aleatory category, with a median occurrence rate of 67% across the tasks in this phase (Table 2). However, there were six tasks for which no dominant nature was apportioned, due to occurrence rates of below 50%. Four locations of uncertainty

**Table 1**Summary of the 105 ERA tasks in the generic ERA template, version 3, organised by ERA phase, sub-phase, and task-group, to be potentially included in the case study expert elicitation exercises (individual tasks are listed in Table S1).

ERA phase	ERA sub-phase	ERA task group	ERA task number
Problem formulation	Preliminary hazard identification	1. Use available evidence to better constrain	1-4
		2. Framing the hazard	5-9
	Define the conceptual model	3. Identify the S-P-R paradigm, including	10-13
		4. Choose assessment and measurement endpoints	14-21
		5. Consider the appropriateness of the endpoints	22-24
	Form the analysis/work plan	6. Identify the factors controlling fate and transport of the stressor	25-28
• • • •		7. Identify data considerations	29-32
Exposure assessment	Use available evidence to better constrain	8. (Use available evidence to better constrain)	33-37
	Stressor, exposure media, and receptor information	9. Collect information about the stressor's composition	38-40
		10. Collect information about the stressor's distribution	41-42
		11. Collect information about the stressor's release	43-45
		12. Collect information about properties affecting fate and transport	46-53
		13. Collect information about the receptor	54-57
	Evaluate stressor-receptor contact	14. Evaluate co-occurrence for	58-60
		15. Evaluate	61-62
	Integrate multiple LOEs using	16. (Integrate multiple LOEs using)	63-64
	Create the exposure profile(s) using	17. (Create the exposure profile(s) using)	65-69
Effects assessment	Use available evidence to better constrain	18. (Use available evidence to better constrain)	70-74
	Analyse the stressor-response relationship	19. Determine the test dose for the	75-77
		20. Assess effect endpoints	78-85
	Integrate multiple LOEs using	21. (Integrate multiple LOEs using)	86-87
	Create stressor-response profile using	22. Single point or distribution methods showing	88-91
Risk characterisation	Select relevant profiles	23. (Select relevant profiles)	92-93
	Estimate and aggregate risk	24. Estimate risk using	94-95
		25. Aggregate risk estimates for	96-99
	Evaluate risk levels	26. Assess confidence in the risk levels using	100-101
		27. Assess the significance of the risk levels using	102-105



Fig. 2. The level of uncertainty communicated by the experts (n = 9) across the 102 assessed ERA tasks, organised into the ERA phases of a) problem formulation, b) exposure assessment, c) effects assessment, and d) risk characterisation, and described using median values (red crosses), inter-quartile ranges (boxes), and low-high range values (dashed lines) on a 0 (representing determinism) to 10 (representing total ignorance) scale. The ERA tasks are separated into the groups listed in Table 1. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

**Table 2**Median occurrence rates (%) for the individual natures and locations of uncertainty provided by experts (n = 9), organised by ERA phase and showing the highest rates (of at least 50%) for the nature (shaded blue) and location (shaded red) of uncertainty associated with each ERA phase.

	Nature of uncertainty (%)			Location of uncertainty (%)						
ERA phase	Epistemic	Aleatory	Combined	Data	Language	System	Variability	Extrapolation	Model	Decision
Problem formulation median	22	11	67	67	11	56	56	56	44	11
Problem formulation mode	22	0	67	67	0	67	56	56	56	11
Exposure assessment median	33	11	56	67	0	3	50	39	22	11
Exposure assessment mode	33	11	44	56	0	33	56	44	22	11
Effects assessment median	22	11	67	67	0	44	56	33	44	0
Effects assessment mode	11	0	67	67	0	56	67	33	56	0
Risk characterisation median	0	11	89	39	0	56	56	78	78	33
Risk characterisation mode	0	11	89	33	0	44	67	78	78	33
Overall median	22	11	67	67	0	44	56	44	44	11
Overall mode	22	11	67	67	0	33	56	56	44	11

had median occurrence rates of at least 50% in this phase, namely data (67%), system, variability and extrapolation (all 56%; Table 2).

The median level of uncertainty in exposure assessment was 4.0, in the range of scenario uncertainty (Fig. 2b). The set of tasks with the highest median level involved collecting information about the distribution of the source term (5.0; group 10), whilst several groups contained similarly low median levels (3.0; groups 9, 11 and 12). Experts showed a high degree of agreement in this phase, with an overall median IQR of 2.0. Half of the 32 assessed ERA tasks in exposure assessment did not have a primary nature of uncertainty associated with them, with the other 16 tasks associated with the combined category (Table 2). The phase median for the latter was 56%, the lowest for the combined category in any phase of the case study. Data uncertainty was the most frequent location based uncertainty, with a median occurrence rate of 67% across the tasks in this phase (Table 2). The high level of uncertainty communicated above for group 10 was shown here to manifest primarily through data-based uncertainty, which had a particularly high median rate of 100%.

Effects assessment had a median level of uncertainty of 4.0, in the range of scenario uncertainty (Fig. 2c). Group 22, involving the creation of stressor-response profiles, contained the lowest median levels of uncertainty (3.3). Experts showed large disagreement about the values of the individual tasks, with a median IQR of 5.0. This phase was again dominated by the combined nature category, with a median occurrence rate of 67% (Table 2). However, task 70, using available evidence at the beginning of the phase to better constrain the potential effects of the source term on the receptor, contained the only example of one of the other two categories occurring more frequently. As for the previous two phases in this case study, effects assessment consisted primarily of data uncertainty, with a median occurrence rate of 67% (Table 2). The uncertainty was also found to exist in the form of variability, but to a lesser extent (56%).

Risk characterisation contained the highest median level of uncertainty of the four phases (6.0; Fig. 2d), although was still in the range of scenario uncertainty. Specifically, groups 25, aggregating risk estimates, and 27, assessing the significance of the risk levels, had the highest associated values, of 6.0. The median levels across the 14 tasks all fell within the range of 5.0 to 7.0, but despite this, the median IQR for this phase was 3.0, highlighting the variation in responses. All 14 tasks in this phase were deemed to consist of the combined category, with an overall median rate of 89% (Table 2). The locations of extrapolation and model uncertainty were the most frequent, with median levels of 78% across this phase (Table 2), making risk characterisation the only phase in which data uncertainty was not the primary location-based concern.

The overall case study median level of uncertainty was 4.0, in the range of scenario uncertainty. Experts consistently communicated that the uncertainty seen was both epistemic and aleatory in nature. Data was the highest location-based uncertainty with a median rate of 67%.

## 4. Discussion

#### 4.1. Uncertainty within an ERA in the case study domain

#### 4.1.1. Case study selection

Agricultural chemical pesticides, including insecticides, herbicides, and fungicides, have proven benefits including improved yield, quality, nutritional value, and cosmetic appearance (Damalas and Eleftherohorinos, 2011). However, the persistence and transport of chemical pesticides can cause wide-ranging adverse effects across different environmental compartments (Chèvre et al., 2006). Regulatory authorities, such as the United States Environmental Protection Agency (US EPA) and the Chemicals Regulation Directorate in the UK, recognise the potential risks of chemicals in pesticide formulations, and oversee strict licensing processes for which environmental risk assessments are key to informing risk management and regulatory control

(Schwarzman and Wilson, 2009). In the context of this research, a suitable risk domain is one which: has a large amount of associated empirical evidence; where ERAs are prevalent throughout and where environmental uncertainty is present.

## 4.1.2. Uncertainty across the phases of an ERA in the case study domain

We are interested in where uncertainties are distributed in ERAs and their extent because decisions on whether to manage risk must rely on risk estimates with which decision-makers have confidence. Decisions about whether to refine the ERA further, or act now based on a knowledge of attending uncertainty, depend on knowing where uncertainties reside in the risk assessment process, how large they are, and whether they are resolvable or not. In turn, this influences the degree of precaution decision-makers are prepared to tolerate. The median levels of uncertainty communicated across the ERA phases for the case study were found to lie in the range of statistical or scenario uncertainty. However, these median values had relatively high IQRs. A high IQR is the result of a stretched distribution resulting from disparate values (Manikandan, 2011), which equates here to disagreement amongst experts. A potential explanation for disagreement is the risk relationship selected as the focus, into which several potential types of agricultural pesticide, multiple environmental pathways, and a multitude of aquatic organisms could still feasibly fit. Experts may be drawing from slightly different interpretations of the risk relationship, basing their responses on past experiences and knowledge as well as on the information presented (Knol et al., 2010); therefore high IQRs may also be the result of disparate experiences. However, they may also result from inherently different attitudes to assessing uncertainty, since the experts involved in this case study provided varied responses to the level-based questions during the practice exercise, with an average variance of 27% to the control group.

Regarding the location of uncertainty, of note is the extrapolation category which returned high median values, especially during risk characterisation (Table 2). Several articles from the pesticides literature discuss the concerns of extrapolating from, for example, predicted noeffect concentrations (PNECs) and no observed adverse effect levels (NOAELs) to expressions of risk (primarily quotients; Palma et al., 2004; Chèvre et al., 2008), as well as basing PNECs and NOAELs on questionable data during effects assessment (Uricchio et al., 2004). For more specific observations to be made, these patterns must be investigated at the ERA task level.

#### 4.1.3. Uncertainty across the tasks of an ERA in the case study domain

Framing uncertainties in the context of specific ERA tasks not only provides more granularity than at the ERA phase level, but allows for more specific and targeted guidance on the selection and implementation of potential techniques to manage the uncertainty. The ERA tasks with the lowest levels of uncertainty (Table S1, presented in Supplementary Material) predominantly reside within the problem formulation phase; just under 50% of the 20 tasks with the lowest levels were found elsewhere. The sub-phases of defining the conceptual model (with four entries) and forming the analysis/work plan (with five entries) are areas in which experts had most confidence. The lowest levels of uncertainty seen in the case study were 1.0. According to the experts, uncertainty was present in all 102 tasks and should be considered throughout. The natures of these low-level uncertainties cannot be described for eight of the 20 tasks with the lowest levels, since their occurrence rates were below 50% (i.e. they occur less frequently than they occur), similarly for just one of the 20 locations (task 10). Of the locations that do feature, data uncertainty dominates with an occurrence rate of above 50% in 15 of these 20 tasks. These observations demonstrate the difficulty in providing detailed descriptions of uncertainty for tasks where levels and occurrence rates are low.

Of the 20 ERA tasks with the highest median levels of uncertainty (Table S1, presented in Supplementary Material), 50% are found in the risk characterisation phase, despite its smaller size (n=14 tasks)

compared to the other phases, with seven in problem formulation, and three in effects assessment. None of these 'most uncertain' tasks occur in the exposure assessment phase. The two tasks with the highest level of uncertainty appeared in the problem formulation phase, for this case the inclusion of the primary production and nutrient cycling endpoints (task 21), and the evaluation of the relative importance of the endpoints to each other (task 24). The former is difficult to measure and often omitted from ERAs (Barnthouse, 2008), and the latter reflects the large number of endpoints for consideration (n = 7). These early-stage uncertainties are the exceptions, with tasks from risk characterisation more commonplace, such as aggregating risk estimates for multiple stressors (task 97) and pathways (task 98) and assessing the significance of these risk estimates using thresholds derived through experimentation (task 101) or regulation (task 102).

Across the 20 tasks with the highest median levels of uncertainty, the nature of uncertainty was exclusively communicated as being epistemic and aleatory combined, and there was representation from five of the seven locations of uncertainty, with language and decision not appearing. These results show that where uncertainty is present, especially at the 'deep' levels (i.e. recognised ignorance) seen in these tasks, it is essential that all aspects of uncertainty are considered and potentially managed (Walker et al., 2003; Kandlikar et al., 2007; Refsgaard et al., 2007; Knol et al., 2009).

Increased levels, natures, and locations of uncertainty allow for informative descriptions and management guidance to be provided, but also highlight the extent of the uncertainty for the analyst to manage. The results from the case study may be considered useful for analysts based in this specific research domain, but there are some potentially influential aspects that should be considered.

#### 4.2. Potentially influential methodological aspects

The method of creating and validating (risk assessment) process maps as the basis for expert engagement, so to elicit views about risks and uncertainties, is gaining in popularity within the risk research community (Krayer von Krauss et al., 2004; Gillund et al., 2008; Krayer von Krauss et al., 2008; Ravnum et al., 2012; Smita et al., 2012; Zimmer et al., 2012). Here, every effort was made to ensure the templates were as complete and correct as possible, using amassed evidence, before being distributed to experts for validation. However, in sourcing reference materials, there is the chance of an influential source being overlooked. The majority of validation suggestions corresponded to domain-specific terminology and across the templates the number of alterations made was small.

The scope and format of expert elicitations can be greatly influenced by the resources available to the researcher (Knol et al., 2010). In this case, it was beneficial to conduct remote elicitations. Remotely-executed elicitations have benefits over face-to-face formats, including that they are less expensive, their content and structure can be standardised easily, and experts can complete them at their leisure (US EPA, 2009; Knol et al., 2010). With a remote-elicitation format, experts were approached as individuals rather than as groups; hence, the views of experts were considered to be theirs alone and not that of a collective, as is the case with Delphi methods, for example. The types of experts included was also a consideration. Three types of experts are noted: generalists, who have substantial knowledge in a discipline connected to the elicitation, and a solid understanding of the elicitation context itself; subject-matter experts, who hold detailed knowledge in the subject of the elicitation and are considered by their peers as an authority in the field; and normative experts, who have knowledge or experience that can aid the elicitation process, such as statistical or psychoanalytical skills (Kotra et al., 1996; Loveridge, 2004; Knol et al., 2010). Experts participating in the elicitation process were required to be subject-matter experts with appropriate levels of domain-expertise, in order for a range of balanced and valid opinions to be communicated (US EPA, 2009).

The phrasing of questions and the language used can significantly affect the responses of experts (Meyer and Booker, 1991). To avoid this influence, all questions (namely the ERA tasks) within the elicitations were worded in a consistent manner, using the validated common terminology within the generic and case study ERA templates. Furthermore, potential bias in responses was reduced by providing the experts with personal and professional anonymity throughout. Suggested participant numbers vary depending on the subject, format and budget of the elicitation, and the availability and willingness of experts to participate (US EPA, 2009). The inclusion of a minimum of five or six experts is considered sufficient to cover the breadth of scientific opinion on a given topic, with little benefit in including additional experts beyond 12 (Clemen and Winkler, 1999; Cooke and Probst, 2006). This research aimed for participant numbers of between five and 12, in order for results to be considered representative.

Typically, tests such as Shapiro and Wilk (1965) or Kolmogorov-Smirnov (Daniel, 1990) are used to determine whether a distribution can be classified as normal (Gaussian), and by extension as parametric or non-parametric (Rees, 2000). However, these tests can be unreliable when performed on small datasets (of less than five and seven values for Kolmogorov-Smirnov and Shapiro-Wilk, respectively), since outliers can easily skew otherwise consistently-distributed data. Furthermore, they are not designed for datasets with high frequencies of duplicate values, as seen here. In such circumstances, a more appropriate method, adopted in this research, is to compare the mean, median, and mode, where consistently similar values for each denote normally-distributed data (McCluskey and Lalkhen, 2007). Whilst these constraints have a potential to affect the approach described in this research, they should not be considered prohibitive to repeated executions within the case study domain, or elsewhere. Having noted these aspects, it is also appropriate to discuss the potential merits of the approach.

#### 4.3. On the identification of uncertainties in ERAs

The primary method for identifying uncertainties in ERAs is application of one or more uncertainty typologies by risk analysts (Morgan et al., 1990; van Asselt and Rotmans, 2002; Knol et al., 2009). The differing abilities and experiences of ERA practitioners results in these typologies being used inconsistently (Gillund et al., 2008; Knol et al., 2009), which allows uncertainties in ERAs to go unidentified (EEA, 2007; Hart et al., 2007; Dale et al., 2008) and sometimes, arguably, treated in a rather token fashion. Some attempts have been made to turn the traditional typology format (i.e. a list of organised uncertainties and their related definitions) into a more useful tool for uncertainty identification. For example, Walker et al. (2003) introduced an uncertainty matrix, reproduced by Janssen et al. (2003), that contained blank sections the analyst was encouraged to complete using qualitative or quantitative information relevant to the system under study. However, in this approach it was still the sole responsibility of the analyst to locate the defined uncertainties, since no specific system-related guidance was provided. The matrix approach was extended to include aspects of systems in which the different dimensions of uncertainty may have been present (e.g. data uncertainty relating to measures of population exposure; Refsgaard et al., 2007; Knol et al., 2009). However, these aspects, drawn from the domains of environmental modelling and burden of disease assessments were not representative of the full range of potential aspects that would require consideration in such systems. Furthermore, analysts conducting ERAs were not significantly aided by this guidance, due to the limited cross-over between the research domains, and were in a similar position as when equipped with a typology or blank uncertainty matrix. More guidance was offered by Knol et al. (2009) who suggested their uncertainty typology should be used to:

- 1) identify sources of uncertainty, by either:
  - a. analysing each step of the assessment and relating uncertainties from the typology to those steps; or

- considering the uncertainties in the typology and explaining where in the assessment these uncertainties may occur;
- 2) prioritise each uncertain element within the assessment according to their relative importance; and
- select one or more suitable uncertainty management techniques (UMTs) to further analyse the identified uncertainties.

Thus, should the analyst have been capable of using the typology or matrix to identify all relevant uncertainties within the system under study, they would still be required to prioritise those uncertainties – according, for example, to a chosen significance metric, or temporal and financial restrictions – before one or more UMTs could be implemented. Guidance related to the selection of one or more UMTs, as noted by Knol et al. (2009), is sufficiently good. If an analyst requires guidance on managing identified uncertainties, it is reasonable to assume that they also require guidance on identifying those uncertainties in the first place. Up to now, this guidance has been lacking, and uncertainty identification has remained a weakness of the uncertainty management process.

Our method, results and observations equip environmental risk analysts with guidance on the locations, natures and levels of uncertainties that are associated with all aspects of the ERA process, for the case study domain. The observations from this research reduce the reliance on the analyst to identify and prioritise uncertainties before they can be managed. The researchers are in the process of applying the method to more case study domains in order to aggregate results and create a generic system for identifying uncertainties within ERAs. This will make the results and associated observations relevant to a larger proportion of environmental risk analysts, when compared to the subset involved in assessing potential agricultural chemical pesticide risk to surface water organisms.

# 5. Conclusions

A reliable characterisation of potential uncertainties is critical for ERAs. Without this, decisions about refining a risk assessment, or acting on the available evidence now, are difficult to make. In the extreme, paralysis over this dilemma could delay time-critical risk management efforts and exacerbate harm to the environment. However, the typologies for uncertainties currently in use can be implemented inconsistently. There is a requirement for an approach which both comprehensively describes uncertainty and offers specific guidance regarding the identification and prioritisation of uncertainties in ERAs.

- (i) This research developed an approach based on the results of nine structured elicitations, for agricultural chemical pesticide risks to surface water organisms, in which subject matter experts validated aspects of ERA templates for three dimensions of uncertainty: level; nature; and location. The elicitations describe the uncertainty associated with 102 distinct tasks across four phases of an ERA in this domain; 31 in problem formulation, 36 in exposure assessment, 21 in effects assessment, and 14 in risk characterisation.
- (ii) The risk characterisation phase contained the highest median level of uncertainty of 6.0 (on a scale from deterministic understanding of the uncertainty at 0.0, to total ignorance of the uncertainty at 10.0), which was specifically associated with estimating (tasks 94 and 95), aggregating (tasks 96 to 99) and evaluating (tasks 100 to 105) risk estimates. Exposure assessment and effects assessment contained the joint-second highest median level at 4.0, whilst problem formulation returned the lowest median level of uncertainty at 3.0. The median nature of uncertainty across the 102 ERA tasks was almost exclusively a simultaneous combination of epistemic and aleatory. Regarding the locations in which uncertainty was manifest, data uncertainty was

- dominant in problem formulation, exposure assessment and effects assessment, and had median occurrence rates of at least 50% in 77 out of 102 tasks, followed by variability (54 out of 102), extrapolation (47), system (43), and model (39), with extrapolation and model the dominant locations during risk characterisation.
- (iii) This comprehensive description of uncertainty enables risk analysts based in the case study domain to prioritise ERA phases, tasks, and groups of tasks according to either the highest levels of uncertainty (the level dimension), the potential for the uncertainty to be reduced or only quantified (the nature dimension), or the associated types of location-based uncertainty (the location dimension), which further allows one or more appropriate tools for managing the uncertainty to be selected.

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