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Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law

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The precautionary principle was formulated to provide a basis for political action to protect the environment from potentially severe or irreversible harm in circumstances of scientific uncertainty that prevent a full risk or cost-benefit analysis. It underpins environmental law in the European Union and has been extended to include public health and consumer safety. The aim of this study was to examine how the precautionary principle has been interpreted and subsequently applied in practice, whether these applications were consistent, and whether they followed the guidance from the Commission. A review of the literature was used to develop a framework for analysis, based on three attributes: severity of potential harm, standard of evidence (or degree of uncertainty), and nature of the regulatory action. This was used to examine 15 pieces of legislation or judicial decisions. The decision whether or not to apply the precautionary principle appears to be poorly defined, with ambiguities inherent in determining what level of uncertainty and significance of hazard justifies invoking it. The cases reviewed suggest that the Commission's guidance was not followed consistently in forming legislation, although judicial decisions tended to be more consistent and to follow the guidance by requiring plausible evidence of potential hazard in order to invoke precaution.

KEY WORDS: Environment; European Union; health; legislation; precautionary principle

1. INTRODUCTION

The aim of this research was to investigate how the precautionary principle has been applied in practice in European Union (EU) legislation and legal decisions, and, in particular, whether the applications were mutually consistent and followed the guidance of the European Commission.[1] It focused on questions around the nature of the hazard, the standard of evidence for which it is appropriate, the nature of the precautionary action, and the provision for gathering further evidence. The remainder of this introduction summarizes some of the statements of the precautionary principle in international affairs, leading to its formal incorporation into EU law. It also highlights some of the attributes often considered when invoking the precautionary principle that will form the basis of the theoretical framework used to analyze the cases.

In a discussion of the tensions between "scientific" evidence-based risk assessments and precautionary approaches to risk, Löfstedt[2] noted that "[d]ifferent guidelines and legal cases are being agreed upon without a clear and coherent policy as to when the Commission should be using risk assessments, let alone the precautionary principle" and identified the need for "a thorough academic analysis of the present use of the precautionary principle" leading to recommendations to ensure that its future use will be "evidence-based and risk-informed." There have been a few studies on the use of the precautionary principle, notably some exploring its application in different jurisdictions. Zander[3]

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compared Sweden, one of the first to adopt the principle with the United Kingdom, where EU membership has influenced its adoption, and the United States, often said to be less precautionary. Vogel[4] examined the history of regulation in the EU and the United States, and found, for the issues he considered, a general trend for the EU to have become more precautionary and the United States less so, although there were exceptions in both jurisdictions. Wiener *et al.*[5] compared the approaches to regulation of 100 risks in the EU and the United States and found that both jurisdictions were selective in the use of the precautionary principle, with neither consistently more precautionary than the other. Another study[6] considered 88 alleged "false positives," mainly from the United States and Europe, where the precautionary principle was applied, but later found to be unwarranted. It concluded that all but four were actually "real risks" or cases where "the jury is still out," and that "fear of false positives is misplaced and should not be a rationale for avoiding precautionary actions where warranted." In contrast to these studies, this article focuses on practices observed in a sample of EU legislation and case law.

The most widely recognized early statement of the precautionary principle in international environmental policy was Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development (the "Rio Declaration"):

> In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[7]

The Rio Declaration contains three attributes: (1) a potential future harm—in this case, "serious and irreversible damage"; (2) an implicit or explicit requirement for a real basis for concern—"threat" not speculation; and (3) action to prevent harm before scientific certainty has been achieved.

There have been many formulations of the precautionary principle since the Rio Declaration; indeed, Sandin[8] identified 19 different versions. A prominent example, which extended the application of precaution, was the Wingspread Statement, formulated by a conference of scientists, philosophers, lawyers, and environmental activists.[9] This extended the scope of the precautionary principle to "threats of harm to human health or the environment" and notably removed the qualifier of the severity of the harm being considered. It also contained an explicit reversal of the burden of proof onto the proponent of the activity.

The status of the precautionary principle within international law is still debated. Although it is widely cited in international agreements, there is disagreement as to whether it can now be considered to be part of customary law.[10] Within the EU, however, it has an explicit place in environmental law, enshrined in Article 174(2) (previously Article 130R) of the Maastricht Treaty in 1992:[11]

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the Precautionary Principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

The precautionary principle is not expressed explicitly in the Treaty; nevertheless, it is considered an autonomous principle inspired by the constitutional traditions in EU member states. It further developed as a general principle of Community law in the early 2000s, and was formally articulated by the European Commission's Communication on the Precautionary Principle,[1] and endorsed by the Council of Ministers' Nice Resolution.[12] This version stated that the precautionary principle is justified

> where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are "reasonable grounds" for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection. (p. 10)

The Commission Communication[1] was intended to give guidance on the nature of precautionary action, and in so doing advised that measures should be:

- proportional to the chosen level of protection;
- nondiscriminatory in their applications;
- consistent with similar measures already taken;
- based on an examination of the potential benefits and costs of action or lack of action;
- subject to review, in light of new scientific data;
- capable of assigning responsibility for producing the scientific evidence necessary for a comprehensive risk assessment.

The first three points placed the precautionary principle within the broader EU legal framework. The fourth point made it clear that decisions on its application should not be based solely on assessment

of the potential hazards. The last two points developed the idea that use of the precautionary principle is contingent on future data (which could either reinforce or contradict the need for protection) and that it is desirable to move toward a full evidence-based risk assessment. Unlike the Wingspread Statement, it did not necessarily place the burden of proof on the proponent.

Both the EU version and the Wingspread Statement (and other formulations) contain the same three attributes found in the Rio Declaration: potential future harm, basis for concern, and anticipatory action before full certainty is achieved. They differ in the definition of the harms to which it is applicable and the robustness of evidence, or degree of uncertainty, required as a basis for concern. The Wingspread Statement adds the reversed burden of proof to the consideration of the evidence, and the Commission Communication includes more explicit contingency of continued action on future data. These attributes are explored further below to form part of the basis of the subsequent assessment.

The following section is a brief review of some of the critiques of and academic debates over the precautionary principle, which develop some of the attributes described above. Subsequently, the methodology is described and applied to examine a sample of EU legislation, Council and Commission decisions, and Court of Justice of the European Union (ECJ) judgments to assess how consistent or otherwise they were in their use of the precautionary principle.

2. CRITIQUES AND ATTRIBUTES OF PRECAUTION

Since its initial formulation, and especially as it has achieved prominence in EU policy, the precautionary principle has been widely debated in both academic and informal literature, attracting strong support and harsh criticism. The literature is extensive and only a few examples can be included here. As a legal principle and a basis for legislation, its critics have claimed that it is vague and incoherent[8,13,14, pp. 14–15] and lacks a single accepted formulation,[8] which risks inconsistency in its application.[15] It has been suggested that the precautionary principle emphasizes hazard rather than risk, so tends to focus on worst cases,[14] rather than rational analysis of risks and benefits.[16] It is argued that, by concentrating on unknown risks and ignoring benefits, it distorts priorities or prevents beneficial developments, with potentially harmful consequences,[17] and stifles innovation.[13,18] Proponents counter that the disbenefits are hypothetical,[19] that the protection of the environment and human health is an overriding priority, and that the costs of the consequences of a lack of precaution may also be large.[20] They also point to research that suggests that the application of regulation may stimulate innovation in technology, products, and processes.[20,21]

The precautionary principle has also been defended, especially for extreme risks (i.e., those with extremely severe consequences), as providing "an ethical, normative principle for dealing with an uncertain future, where, given the complexity and interconnectedness of the natural and social systems in which we live, catastrophic black swans are more likely to occur."[22] It has also been argued that "objective risk" does not exist independently of the preferences, beliefs, and moral choices of people and society.[23] In a democracy, this implies that public opinion about risk is a legitimate consideration for the formulation of policy. Gee[24] also argues for wider use of the precautionary principle, both as a basis for timely actions and to trigger a broader debate about "technical pathways to the future." However, he adds that there is a need for sound scientific and stakeholder processes, considering both risks and benefits, and using a clearer definition of the principle than many of the standard versions.

In response to this lack of consensus, several authors have attempted to clarify the philosophical basis for the precautionary principle and develop a more formal understanding of when it should be applied, especially the degree of "epistemic" uncertainty that justifies precaution.[25–27] They thus address the second of the attributes identified in the introduction: the basis for concern, and the tension between evidence and uncertainty. O'Riordan and Cameron[28] suggest that the most common understanding of the precautionary principle is to act "prudently" when there is "sufficient" evidence and where action may be justified on "reasonable judgments" of costeffectiveness and where inaction could lead to potential irreversible or demonstrable hardship to the defenders and future generations. There is an implication that grounds more substantial than mere speculation are required for the precautionary principle to be invoked. All formulations of the precautionary principle are based on anticipatory

action before "full scientific certainty" (or similar state) is reached; it seems to be understood, certainly in the Commission Communication,[1] that there is a point at which evidence is sufficient to apply the tools of risk assessment.

The need for a minimal evidentiary base before invoking the precautionary principle has been emphasized by other authors. A review of risk assessment in EU food and safety law[29] concluded that precautionary measures should not be based on "purely hypothetical or academic considerations" founded on "mere superstitions, which are not yet scientifically verified." Rather, it is closely connected to risk assessment and should be preceded by a comprehensive evaluation of possible risk to human health and the environment, based on the most recent scientific information. Belvèze[30] also placed the precautionary principle as an integral part of a risk assessment framework. Crawford-Brown and Crawford-Brown[31] expanded on this, suggesting that it is untenable to make claims about risks until evidence accumulates to a minimal level, referred to as an "epistemic threshold." The requirement for a minimum standard of evidence is embodied in the Commission Communication,[1] but it has been argued that it has not been applied consistently by the courts.[32]

There is thus a range of uncertainty, between the lower bound of evidence required before the precautionary principle should be considered and the upper bound where the evidence reduces the uncertainty to the level where risk assessment is feasible and appropriate. Unfortunately, the positions of these bounds are unclear, and subject to variations in interpretation in practice.

Once the precautionary principle has been invoked, the important considerations relate to the third attribute: the nature of precautionary action and the provision for review in the light of further evidence. In general, actions with varying levels of stringency are possible, depending on the severity of the harm being avoided, the strength of the evidence, and the attitude to precaution. The Commission Communication[1] established a requirement to review measures after their introduction in the light of new scientific evidence, and it implied that it is desirable to collect evidence for a full risk assessment, for which responsibility might be assigned to any party, including the regulator, in contrast to the Wingspread Statement. In general, it has been noted that the lower epistemic threshold to establish a threat of harm does not bear the same stringent conditions of scientific proof used in risk assessment,[33] thus increasing the burden that is transferred to the proponent of the potential "risky" activity to prove that it is safe.

The three attributes discussed above formed the basis for the assessment in this study: severity of potential harm, degree of epistemic uncertainty (conversely quality of evidence), and the precautionary measures taken, including the provision for review. These present various defining attributes of the precautionary principle, where differences in interpretation mean that precautionary actions tend to be invoked differently, as what triggers implementation is often unclear.

Some authors have made distinctions between a "weak" and "strong" application of the precautionary principle, which have fueled debates over how stringent government regulation should be, what margin of safety should be built into it, and what conditions often prompt precautionary action (Table I).[3,31,34–36] Weak application of the precautionary principle is characterized by a relatively high epistemic threshold and a preference for risk management. Uncertainty about the consequences of an activity may justify regulation, if there are plausible grounds for believing that it may be harmful. There may be an emphasis on gathering evidence about the chance and severity of harm. Strong application tends to have a lower epistemic threshold and tends toward risk prevention. Uncertainty about an activity may in itself be seen as necessitating stringent actions, such as prohibition, even if there are only weak grounds for believing that it may be harmful. The burden of proof is often reversed, so that the proponent is required to provide proof of a high level of safety. Moderate application assumes that uncertainty justifies action, providing that it can be established that a sufficiently serious threat exists. Controls that include building in larger safety margins and setting up emergency plans may be justified, and extensive investigation into the cause–effect relationship is pursued to reduce uncertainty, possibly to relax the controls if the activity is later proven safe.[3,31,35,36] Clearly, reducing several factors to a single dimension risks oversimplification, but the weak–strong spectrum may be useful, if used carefully. In these terms, the Wingspread Statement represents a stronger approach to precaution than the Rio Declaration[7] and the Commission Communication.[1]

Table I. Interpreting the Strength of Application of the Precautionary Principle

Attributes used to assess the strength of application of the the precautionary principle	Weak precaution: "uncertainty does not justify inaction"	Moderate precaution: "uncertainty justifies action"	Strong precaution: "uncertainty justifies shifting the burden and standard of proof"
Severity of potential harm prompting precautionary action as referenced in international legislation and regulation	Rio Declaration suggests that regulation is permitted to avoid ***"serious and irreversible damage"***	The Commission Communication on the precautionary principle suggests the use of regulation proportional to the risk level, following preliminary objective scientific evaluation to avoid ***"potentially dangerous effects"***	The Wingspread Statement conveys that clear responsibility lies with the proponent in proving an activity is safe even if the cause and effect relationship cannot be determined scientifically to avoid ***"threats of harm"***
Degree of epistemic uncertainty/quality of evidence prompting precautionary action	Regulation is permitted in the absence of full scientific certainty; significant precautionary action may be invoked under uncertainty	Research is needed to establish cause and effect (reduce uncertainty) upon which regulatory decisions are based; until then, precautionary action includes setting regulatory standards with large margins of safety built in through application of uncertainty factors	Uncertainty necessitates forbidding the potentially risky activity until the proponent of the activity demonstrates that it poses no (or acceptable) risk; and is sufficiently safe
Nature of precautionary action/measures taken and provision for review	Presumption of risk management; banning very rare	Underlying presumption of risk management; banning possible, but is a last resort; measures are provisional or subject to review when new information or scientific evidence emerges	Presumption of risk avoidance; banning is likely

Sources: Crawford-Brown and Crawford-Brown[31], Zander[3], Sachs[34], Löfstedt[35], and UK-ILGRA[36]

3. METHODOLOGY: CASE STUDY APPROACH

A key objective of the research was to examine how the precautionary principle has been applied in practice in EU legislation and legal decisions. As a basis for this, there was an exploration of the practice-guiding interpretations of the precautionary principle, which reflect an explicit or implicit basis for taking precautionary action. The aim was to understand and explain differences in precautionary thinking, reflecting on the particular context of the decision (i.e., subject, degree of harm, availability of evidence, and action taken) in order to identify how the Commission and the European courts have interpreted, and subsequently applied, the precautionary principle in practice, whether these applications were consistent, and whether they followed the guidance from the Commission.[1]

A multiple case study approach based on a "theoretical replication" design was adopted to examine how the precautionary principle has been used in the regulation of environmental, health, and consumer safety issues (Fig. 1). A review of several case studies addressed questions around how the precautionary principle has been interpreted, articulated, and subsequently applied through European legislation and regulation, and how its meaning has been developed and clarified through case law.

There were four main steps in the research: (1) design of the study and development of a theoretical framework on which to base subsequent case analysis, (2) a search of the EUR-Lex database (http://eur-lex.europa.eu/) to identify relevant cases for study, (3) selection of cases from the search results, applying a "theoretical" sampling technique, and (4) analyses of cases.

3.1. Study Design and Theoretical Framework

Multiple case studies were used to explore the contextual conditions around decisions to invoke the precautionary principle and, in some disputed cases, decisions taken to revoke its use. The multiple case study approach is an empirical form of inquiry appropriate for qualitative studies,[37] where the goal for this study was to describe the characteristics of

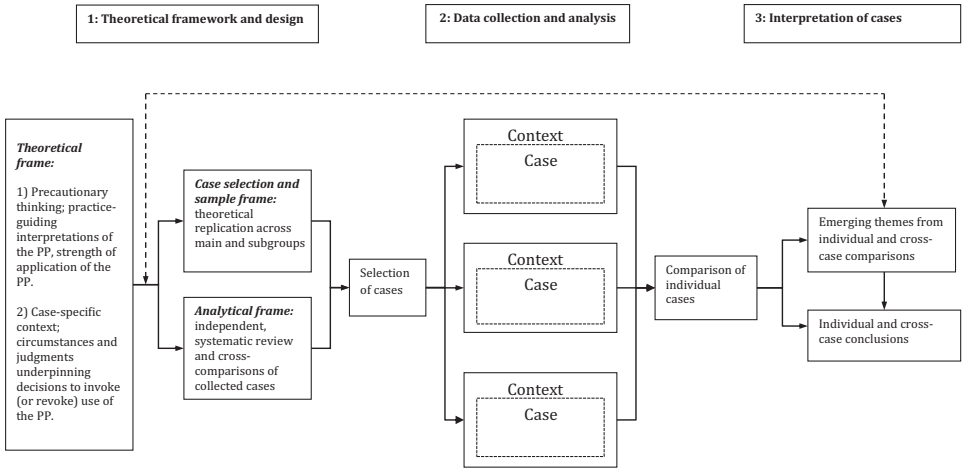

Fig. 1. Multiple case study design (based on Yin[37]).

the cases (i.e., how the precautionary principle is interpreted and subsequently applied) and the context surrounding each case (i.e., circumstances and judgments underpinning decisions to invoke or revoke the precautionary principle).

A theoretical framework was developed from the review of the academic literature around the precautionary principle (Table II). Questions and analytical factors were defined and subsequently used to review each case systematically in order to gather evidence around the three attributes discussed above. The cases were then assessed to determine the extent to which precautionary thinking and actions were replicated in different situations. This allowed for an exploration of differences in practice, and positioning of the cases along a continuum from weak to strong application of the precautionary principle.

3.2. Search Procedures and Results

To find the set of relevant legislation, the EUR-Lex database was searched for documents in "Domain = Legislation" containing the phrase "precautionary principle." Separate searches were carried out for directives, regulations, and regulatory decisions. The searches of EU legislation found 40 directives, 32 regulations, and 41 decisions that explicitly used the search phrase. Of these, seven directives and 17 regulations included the phrase outside the recitals (introductory text). Health, environment, and food were the most frequent topics, with fewer pieces of legislation related to consumer protection.

A similar procedure was followed to find cases in the ECJ that referred to the precautionary principle. The search of court cases included both the judgments of the court and the opinions of the Advocates General, which often gave more detailed information on the interpretation. There were 109 judgments containing the phrase "precautionary principle," but the selection was restricted to 35 cases between member states and the EU to explore the contrasts between national and EU views. Although the full set covered the same range of topics as the legislation, the majority of informative judgments were found in the areas of public health and consumer protection.

3.3. Sampling Procedure

Replication designs are common in multiple case studies that aim to understand how a concept or theory manifests across several cases. When selecting cases, these designs typically use "theoretical" or systematic sampling based on a judgment logic, rather than random or stratified sampling, as the aim is to observe the state of development of a phenomenon and not to measure its incidence or prevalence in the cases.[37] With theoretical sampling, "cases are selected because they are particularly suitable for illuminating and extending relationships and logic among constructs."[38]

During case selection, emphasis was placed on deriving a sample that covered the broad spectrum of issues within EU legislation, including directives and regulations, judicial cases, and regulatory disputes addressing environment, health, and consumer safety

Table II. Theoretical Framework for Reviewing the Case Studies

Context for Analysis	Questions for Interrogating the Data	Theoretical Construct
Trend of principle application in the EU (sectoral application or general Community law) Indicators that characterize the interpretation, and subsequent application of, the precautionary principle in practice in the EU	How and when did the precautionary principle come into play? How is it applied? How is its use justified? What was the outcome for regulation based on the precautionary principle? Has this been upheld, overturned, or superseded?	Strength of application: Trend of application of the precautionary principle (weak–strong spectrum), based on: (1) Severity of potential harm (2) Standards of evidence and degree of uncertainty (3) Nature of precautionary action and provision for review

issues. An important consideration in this study was the context in each case that offered rival explanations of how parties understood and applied the precautionary principle. When selecting court cases, representative cases were chosen from some of the common topics, excluding topics in the sample of Council and Commission decisions. As a result, none of the selected cases was purely environmental, though some covered both environmental and health concerns (e.g., genetically modified organisms—GMOs). The selection took account of the number of references to the precautionary principle (the "relevance" order in the search) and whether it was important to the case or mentioned in passing. Some of the secondary sources (e.g., Marchant and Mossman[15]) had identified judgments that were particularly pertinent, which were considered for review, but used with caution, because of potential selection biases.

Fifteen case studies were selected for analysis: four directives, four regulations, three regulatory decisions by the Council or Commission, and four ECJ cases between states and the Commission.

3.4. Review and Assessment of Cases

The selected cases were examined to assess what reference was made to the precautionary principle and the extent to which they allowed for an examination of conditions for invoking (or revoking) the precautionary principle. Some were explicit in their application of the precautionary principle, while there was some question around whether other cases actually reflected the precautionary principle or were based on preventative action or well-founded science as part of a more risk-based approach. In each case, an analysis was made of the nature of the hazard and inherent uncertainties, and the standard of evidence that was deemed appropriate for application of the precautionary principle.

Assessing the strength of application of the precautionary principle relied on the attributes derived from the academic literature and from the Commission Communication:[1] the severity of possible harm, standards of evidence and degree of uncertainty, including the burden of proof, and the type of action taken, including provision for review (Table I). The review of each case sought to gather evidence around these three attributes to reveal what indicators characterized the interpretation and subsequent application of the precautionary principle, and the strength of application of the principle implied in each case. Evidence found in some of the cases was used to support an argument (or general findings), while the evidence from all other cases was summarized in supplementary tables to ensure traceability of the data and greater transparency of the process.

Conclusions drawn from the case studies were compared to understand the reasons for differences or similarities across the cases, reflecting on the strength of application of the precautionary principle and the trends observed. These cross-case conclusions offer insight into the conditions for invoking or revoking the precautionary principle, and provided a basis for illuminating, extending, or revealing contrasting arguments in the literature around the use of the precautionary principle in practice in the EU.

4. FINDINGS: STRENGTH OF APPLICATION OF THE PRECAUTIONARY PRINCIPLE

In most of the cases reviewed, the precautionary principle was taken as a general duty to act under

uncertainty to avoid serious or irreversible risks. The application of the precautionary principle usually concerned a hazard in the form of a current or proposed activity that might be harmful. However, there was usually sufficient uncertainty about the exposure pathway, and hence the risk, or the severity of the harm to prevent a reliable risk assessment. The discussion that follows highlights the ambiguities inherent in determining what level of uncertainty and significance of hazard justifies invoking the precautionary principle.

4.1. EU Directives and Regulations

The directives and regulations reviewed showed that the precautionary principle in EU law was applied differently with very little consistency across cases regarding the conditions for taking precautionary action and the basis for imposing regulation (Table III).

Three applications were assessed to be strong with a relatively low standard of proof and no clear indication of the basis for invoking the precautionary principle. For example, Directive 2001/18[39] establishes a prior approval mechanism for the deliberate release of GMOs into the environment, where all member states are consulted and consensus gained before a GMO and its products are allowed on the Community market: "No GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing…." The Directive stipulates the potential risks posed to human health and the environment should be assessed on a case-by-case basis. Where a GMO and its products are released to the market, subsequent monitoring of its impact (including cumulative effects) must be assessed to ensure it remains safe. This provides a basis for challenging the release of GMOs, should monitoring reveal a future threat to human health or the environment.

The emphasis on field testing places a heavy burden of proof on the proponent of a GMO to show that it is safe. The requirement for a consensus among all member states, whether or not the GMO will be used in their territory, further raises the standard for "proof of safety," which is consistent with a strong interpretation of the precautionary principle. The resulting action is equally strict: prohibition, rather than restriction to maintain a high level of protection, as observed in other cases reviewed (Table III). While it is implicitly understood that the burden of proof is transferred to the proponent to demonstrate a product or activity is "safe," there is no guidance provided on level of proof or margin of safety required to establish this.

Three applications were assessed to be moderate, since products were provisionally restricted based on scientific evidence of potential harm, but subject to review once new information about the risks emerged. For example, Directive 2011/65[40] restricts the use of certain hazardous substances in electrical and electronic equipment (EEE) and specifies precautionary measures to avoid risks:

> As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including…[nanomaterials], which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives, which ensure the same level of protection of consumers, should be examined.
>
> … a review, based on a thorough assessment, and amendment of the list of restricted substances… shall be considered… and periodically thereafter on its own initiative or following the submission of a proposal by a Member State…

Provisions in the Directive put emphasis on the development of safer substances, and it places the burden of environmental protection on the producers of equipment, which may also help to stimulate innovation. However, broad restrictions on substances (e.g., nanomaterials) have come under criticism, with industry claiming that health and environmental concerns are prioritized over innovation in the performance and functionality of EEE.[41] Industry bodies support a more risk-based approach, where restrictions are only made after a full scientific analysis.[42]

Some of the pieces of EU legislation reviewed make provisions to review precautionary measures once new scientific evidence and information is revealed. However, there are nuances in the language used that implicitly suggest what basis justifies a review, and subsequent modification, of measures. Directive 2011/65/EU[40] suggests measures be reviewed "based on thorough assessment, and amendment of the list of restricted substances." Regulation (EC) No 178/2002, laying down the basis for food law,[43] suggests measures "be reviewed within a reasonable period of time, depending on the nature of the risk to life and health." Other legislation is more explicit about the provisional nature of action under the precautionary principle and the need for review:

Table III. Strength of Application of the Precautionary Principle: Examples of EU Law

Case	Subject(s) of Protection	Severity of Potential Harm	Evidence for Threat: Standard of Proof	Nature of Regulation	Strength of Application
Directive 2001/18/EC (GMOs)	Environment/ human health	Severe	Relatively low	Products to be proved safe through field testing at R&D stage in potentially affected ecosystems	Strong
Directive 2009/127/EC (Pesticide machinery)	Human health/ environment/ consumer safety	Severe	Relatively low	Product bans imposed where available scientific evidence is insufficient for accurate risk assessment	Strong
Regulation (EC) No. 1946/2003 (GMOs)	Environment/ human health	Severe	Relatively low	Duty to prevent significant adverse effect on the conservation and sustainable use of biological diversity, taking into account risk to human health	Strong
Directive 2011/65/EU (Restriction of hazardous substances)	Human health/ environment	Severe-to-moderate	Moderate/high	Substances "provisionally" restricted, subject to review of new evidence; technical and economic feasibility of options considered, including alternatives	Moderate
Regulation (EC) No. 178/2002 (Food safety)	Human health/ consumer safety	Severe-to-moderate	Moderate/high	Products "provisionally" restricted, subject to review of new evidence though depends on severity of risk; technical and economic feasibility and impact on trade also considered	Moderate
Council Regulation (EC) No. 708/2007 (Alien aquatic species)	Environment	Severe-to-moderate	Moderate/high	Restrictions imposed on basis of scientific evidence, though review is possible where new evidence materializes	Moderate
Directive 2013/30/EU (Offshore safety)	Environment	Severe	High	Avoidance of major accidents, damage rectified at source, considering effectiveness, costs, and benefits of action	Weak
Regulation (EC) No. 1334/2008 (Use of flavorings)	Human health/ consumer safety	Severe	High	Restrictions imposed with firm scientific evidence of potential harm to consumers; social, economic, ethical, and other factors considered	Weak

> … in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.[44]

The emphasis placed on setting "provisional" measures implies that any restriction placed on trading food responds to a probable and serious potential health impact, but action is temporary until such a time that sufficient evidence is gathered about the potential risk. The burden of proof is transferred to the proponent, though there is no guidance in the cases reviewed (Table III) on the nature of information that would justify a reexamination of the potential risk.

Two applications of the precautionary principle were assessed to be weak, each with a high standard of proof set out for invoking the principle, where firm scientific evidence, a weighting of costs and benefits,

and some consideration of the effectiveness of measures play a role in approving regulation. For example, in Directive 2013/30[45] on offshore safety regulations: "[Operators are expected to] reduce the risk of a major accident as low as reasonably practical, to the point where the cost of further risk reduction would be grossly disproportionate to the benefits of such reduction." An assessment of the "appropriateness" of action through consideration of the effectiveness, costs, and benefits of measures to achieve the desired level of precaution is implicit within the directive.

Where similar standards are imposed for health and consumer legislation (e.g., Regulation No. 1334/2008 on use of flavorings[46]), a wider range of issues, including societal, economic, ethical, and environmental factors, is considered in approving regulation. In these cases, firm scientific evidence of potential harm to the consumer is needed to justify precautionary action and may serve to protect against the use of product bans that impede free movement of goods within the Community market: "[Flavorings] must be safe when used, and certain [types] should, therefore, undergo a risk assessment [where possible, determining any negative consequences for vulnerable groups] before they can be permitted in food."

In the cases reviewed (Table III), there appear to be differences around the burden of proof. A requirement to justify that a product is safe (stronger applications; e.g., Directive 2001/18/EC on the deliberate release of GMOs) carries with it a higher reversed burden of proof, while proving a product may potentially cause harm (weaker applications; e.g., Regulation (EC) No. 1334/2008 on use of food flavorings) necessitates demonstrating some plausible cause and effect relationship. The fear is that a higher reversed burden of proof may require proponents to establish safety beyond "reasonable levels," which may have cost implications.

4.2. Regulatory Decisions and Court Judgments

The review of regulatory decisions and court judgments showed a more consistent approach to considering what conditions warrant recourse to the precautionary principle and the way in which it was applied. Five cases were assessed to be weak applications, one weak-to-moderate, and one moderate-to-strong (Table IV). This consistency came in part from the practice of drawing precedents from previous case law when reaching decisions.

A weak application of the precautionary principle was evident in the court's decision in most judicial cases reviewed. In most instances, a high standard for scientific proof was established for invoking the principle with a broad spectrum of precautionary action proposed with regard to food safety and public health. A key point in these cases was the minimum standard of evidence required to apply the precautionary principle and, to a lesser extent, the standard at which risk assessment became more appropriate. In most disputed cases, the court required a high standard of proof for invoking the precautionary principle by setting out requirements for firm scientific evidence, a weighting of costs and benefits, and some consideration of the effectiveness of the measures as a basis for approving regulation:

> A proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research.[47]

> The introduction of new national provisions must be based on new scientific evidence relating to the protection of the environment or working environment ….[48]

> Further research [is needed] on the likelihood of the emergence of susceptibility to antimicrobial substances, and the possibility of their resistance to therapeutic antibiotics and other antimicrobial agents.[49]

A presumption of risk management is inherent in these statements, which was the underlying basis for refuting the interpretation by the Kingdom of Netherlands authorities of provisions that presumed a strong application of the precautionary principle: "prohibiting the addition of nutrients, vitamins and minerals to foods, unless there is a nutritional need for these substances in the population." The Commission challenged the interpretation of the precautionary principle in this case, and in reference to precedent set in a similar judgment,[50] suggested that a high standard of proof was needed to impose restrictions on the sale of the vitamin-fortified products, which must be assessed on a case-by-case basis.[47] The Commission suggested that such restrictions constituted unjustified obstacles to intra-Community trade and required credible evidence of the threat of serious harm before imposing such a ban. The court ruled against the Netherlands government, thus establishing further precedent for use of high standards of proof, as observed in other cases reviewed (Table IV).

Table IV. Strength of Application of the Precautionary Principle: Examples of EU Regulatory Decisions and Court Judgments

Case	Subject(s) of Protection	Severity of Potential Harm	Conditions for Precautionary Action: Standard of Proof	Nature of Regulatory Action	Strength of Application
United Kingdom v. Commission: C-180/96 (BSE)	Human health	Severe	Relatively low-to-moderate	Product ban upheld; hazard considered "sufficiently severe," despite uncertainty about the causal link	Moderate-to-strong
Commission Decision 1999/832/EC (Netherlands, creosote)	Environment/ human health	Severe-to-moderate	High	Product ban upheld; "credible evidence" of a threat of harm, where local circumstances warrant precautionary action	Weak-to-moderate
Commission Decision 2003/653/EC (Austria, GMOs)	Environment/ human health	Moderate-to-low	High	Product ban rejected; insufficient evidence around a "local or geographic-specific" risk of potentially "dangerous effects"	Weak
Council Decision 2009/121/EC (antimicrobials)	Human health/ environment	Low	High	Product ban rejected; lack of sufficient evidence around "likelihood of occurrence and severity of consequences"	Weak
Commission v. Denmark: C-192/01 (fruit juice)	Human health	Low	High	Product ban rejected; insufficient scientific data to substantiate "real" threat to public health	Weak
Germany v. Commission: C-512/99 (mineral wool)	Human health/ consumer safety	Low	High	Reclassification of carcinogenic potential of product rejected; lack of a definitive scientific position on potential for harm	Weak
Commission v. Kingdom of the Netherlands C-41/02 (breakfast cereal)	Human health	Low	High	Product ban rejected; insufficient scientific data to substantiate "real" threat to public health	Weak

Conversely, a moderate-to-strong application of the principle was evident where there was deemed to be a risk of severe consequences for public health. For instance, the Commission imposed stringent precautionary measures in the form of product restrictions on U.K. trade, banning the movement of animals, meat, and derived products possibly exposed to bovine spongiform encephalopathy (BSE):

> Although there is no direct evidence of a link, on current data and in absence of any credible alternative the most likely explanation at present is that these cases are linked to exposure to BSE before the introduction of the [specified bovine offal] ban in 1989. This is a cause for great concern.[51]

Despite the lack of definitive evidence, the potential impact on human health necessitated enforcing "a high level of protection of human life and health." The effect on trade and U.K. agriculture were deemed relatively unimportant compared with preventing the spread of the disease, the protection of public health, and the maintenance of public confidence in European beef. Recourse to the precautionary principle was presumably justified on the

basis that the associated consequences were too severe to allow even the slightest chance of occurrence.

A weak-to-moderate application of the precautionary principle was deemed more appropriate in less extreme cases (those unrelated to human mortality). In such cases, a serious human health hazard may still be enough to invoke strong precautionary measures, but these provisions are not usually based solely on conjecture or a hypothetical causal link. For example, a relatively low standard of proof was apparent in the Commission Decision 1999/832/EC[52] (Table IV) in which the Commission approved a proposal by the Netherlands government to establish more restrictive regulations on the use of creosote. However, the Netherlands proposal was based on new scientific evidence relating to the possibility of an environment and health risk heightened by the local circumstances. The Commission approved the national provisions because a potential health risk was substantiated by credible evidence of harm in the prevailing conditions in the member state. This conveyed a strong message that the risk claim must be substantiated in order to justify stricter national provisions.

5. CONCLUSION

The decision whether or not to apply the precautionary principle appears to be poorly defined, with ambiguities inherent in determining what level of uncertainty and significance of hazard justifies invoking the precautionary principle.

The sample of cases reviewed in this study suggests that the Commission's guidance for invoking the precautionary principle was not followed consistently in forming legislation, although ECJ decisions tended to resist this trend by requiring plausible evidence of potential hazard in order to invoke precaution. These findings support those of Löfsted[32] for legislation, while differing for court cases, probably due to a different selection of cases for consideration. Exploring trends in the application of the precautionary principle across a weak–strong spectrum revealed that weaker applications demand firmer evidence of harm, and economic considerations may encourage measures that include regulating with minimal controls. On the other hand, stronger applications require proponents to bear the burden of proving an activity is safe, even if a cause–effect relationship cannot be determined scientifically, to avoid "threats of harm." In stronger applications, the tendency is to pass the cost of implementation to proponents of the potentially harmful activity or product (*United Kingdom v. Commission*[39]).

While some formulations of the precautionary principle shift the burden of proof toward the proponent of the potentially harmful activity, the ECJ and regulatory decisions have often placed the initial burden on the opponent to provide credible grounds. However, once invoked, the burden of proof usually falls on the proponent.

The different standards of proof for invoking the precautionary principle, established in EU directives and regulations, suggest that grounds for invoking the precautionary principle may be dependent on what is at stake. Extension of the application of the precautionary principle from prevention of environmental damage to protection of human health and consumer safety has changed the nature of the hazards considered and the types of evidence available. The cases reviewed revealed a trend toward requiring less evidence of harm where there was a severe threat to human health. Some member states appeared to accept a lower standard of proof than the ECJ would accept. In cases where possible consequences of an activity were sufficiently severe (human mortality in *United Kingdom v. Commission*[39]), it was entirely feasible that the standard of proof would be lowered from an "absence of full scientific certainty"[7] to "reasonable grounds for concern,"[1] and that precautionary measures would include preventive action.

Commentators on the precautionary principle suggest that the vagueness of its definition is evident in the lack of guidance on the level of precaution to adopt in practice.[3,14,19,53] Precautionary measures tend to vary from those prohibiting an activity to others that place an obligation on a manufacturer or operator to find methods to deliver a high level of protection. In some European legislation, the language used implies a default to preventative measures in the absence of full scientific certainty, which often requires an operator or manufacturer to prove an activity is safe (e.g., Directive 2001/18[39]). While this may have the effect of stimulating innovation,[20] broad restrictions (e.g., early attempts to ban the use of nanomaterials) have been criticized on the basis that they could impede progress.

Judgments on proposed precautionary measures often include economic and legal factors, but rarely the full consideration of costs and benefits recommended by the Commission Communication.[1] Recourse to the precautionary principle and the application of safeguard measures is based around

varying degrees of scientific uncertainty about the potential impact on human health. In some cases, strict measures are proposed to eliminate or control potential hazards where there are gaps in scientific theory and a general inability to bridge information gaps, for example, in a dose–response model (e.g., *Commission v. Kingdom* of Netherlands[47]) and unknown effects of cumulative, multiple, or interactive exposure. Such cases frequently raised concerns about potential economic and commercial consequences, particularly where they affect the production or sale of specific commodities. A common consideration is the impact of national measures on the internal free market: precaution is not allowed to override other basic principles of the EU (e.g., Regulation No. 1334/2008[46]). Where the potential consequences were sufficiently severe, in the case of the ban on exports of British beef during the BSE crisis, economic considerations were overruled.

The Commission Communication[1] states that measures based on the precautionary principle should be periodically reviewed, and amended as necessary, in light of new scientific information. Furthermore, it says that it should be "capable of assigning responsibility for producing the scientific evidence necessary for a comprehensive risk assessment." However, if the scientific information remains incomplete or inconclusive, and the potential hazard is significant in view of the chosen level of protection, then the measures should be upheld. Some legislation (e.g., Directive 2011/65/EU[40]) expresses the provisional nature of precautionary measures arising from the precautionary principle and lays down a requirement for review in the light of new evidence, or a requirement to develop evidence. Although it is not made explicit in all the legislation, it appears that there is an understanding that measures based on the precautionary principle can, and often should, be reviewed when new evidence is available. This allows for assessing whether precautionary action has produced the intended consequences, and checking whether measures put in place need to be modified, taking into account new information or knowledge that may reduce the degree of scientific uncertainty. In the cases reviewed, however, there was no guidance on what conditions justify a reexamination of the potential risk, and who would be responsible for producing the evidence required for risk assessment.

As other authors have pointed out, although the Commission Communication on the precautionary principle[1] provided a framework for its application, the cases reviewed in this study suggest that this is not consistently followed by the institutions of the EU or the member states.

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Multi-case review of the application of the precautionary principle in European Union Law and Case Law

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