



EUROPEAN RISK FORUM - POLICY NOTE 14

PRECAUTION AND REGULATORY DECISION-MAKING AT EU-LEVEL

2009

European Risk Forum

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, cost, benefits, and legitimacy of different policy options (risk management).
- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;
- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);
- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Achieving these goals is, the Forum believes, likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF does not seek to promote any specific set of values, ideologies, or interests. Instead it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERF's work.

EXECUTIVE SUMMARY

For over a century, the concept of precaution, the idea of taking preventative action in advance of harm, has informed the development of strategies used by governments to manage risks to human health, public safety, and the environment. Supported by scientific evidence and an understanding of costs and benefits, the precautionary approach has enabled governments throughout the OECD area to design effective risk management strategies for complex problems that, moreover, take account of differing levels of scientific uncertainty and social acceptance of risk.

In recent years a new form of precautionary risk management has emerged. Based on the concept of a formal “Precautionary Principle”, this approach seeks to institutionalise the use of precaution to manage risks. To many citizens and governments, a Precautionary Principle, as a tool for managing complex, modern risks, seems to be a statement of common sense. The problems lie, however, in implementing it.

The Precautionary Principle is one of the main tools used by the EU institutions to manage potential risks to human health, public safety, and the environment. Evidence from its widespread use in the EU and throughout the OECD suggests that, as a mechanism for ensuring high quality regulatory decisions, it is substantially flawed. Actions taken by the Commission and the ECJ have addressed some of the well-established weaknesses of the Precautionary Principle, but these steps do not go far enough. Possible additional reforms include:

- Undertake an independent evaluation of the use of the Precautionary Principle by the EU institutions;
- Develop additional guidance for the application of the Precautionary Principle by the European Commission focusing on limiting the scope of application and defining clearly the evidential thresholds and standards needed to justify its use;
- Establish new procedures for assessing the plausibility of evidence used to justify the application of the Precautionary Principle;
- Establish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments by the European Commission’s scientific advisers;
- Develop a Commission Communication on the use and implementation of the Proportionality Principle;
- Revise the impact assessment guidelines for risk management decisions, highlighting the costs and limitations of the Precautionary Principle;
- Require all uses of the Precautionary Principle to be documented and included in the Commission’s annual report on law-making;

1. PRECAUTION AND RISK MANAGEMENT

For over 100 years, the concept of precaution, the idea of taking preventative action in advance of harm, has informed the development of strategies used by governments to manage risks to human health, public safety, and the environment. Regulation of food safety, pharmaceuticals, chemical products, and risks posed by emissions from productive processes all encompass major precautionary elements, for instance.

Informed by scientific evidence and an understanding of costs and benefits, the precautionary approach has enabled governments throughout the OECD area to design effective risk management strategies for complex problems that, moreover, take account of differing levels of scientific uncertainty and social acceptance of risk.

Over the last three decades, a new form of precautionary risk management has emerged. Based on the concept of a formal “Precautionary Principle”, this approach seeks to institutionalise the use of precaution to manage health, safety, and environmental risks. Whilst this approach has its origins, it is argued, in environmental law in Germany and Sweden, it is today widely used throughout the OECD area and internationally to manage an extensive range of different types of risk.

A number of factors explain this change in the way in which precaution is used to manage risk. Citizens are becoming increasingly concerned about potential risks, most notably those posed by new technologies, rather than established sources of harm. Alongside this, some influential groups argue that existing risk management tools, based primarily on rigorous, evidence-based processes, are too slow to provide effective protection against emerging threats to health, safety, and the environment. Within this context, the concept of a Precautionary Principle is attractive. It appears to institutionalise preventative action by governments and to promote anticipation of long-term threats, particularly those that may lead to irreversible or catastrophic harms.

To many citizens and governments, a Precautionary Principle, as a tool for managing complex, modern risks, seems to be a statement of common sense. The problems lie, however, in implementing it. Its use as a practical tool to make high quality regulatory decisions that deliver overall net benefits to societies remains controversial.

Most importantly, there is no single agreed definition of the Precautionary Principle or established set of processes, standards, and guidelines for its effective implementation. ‘Mild’ forms of the Precautionary Principle legitimise actions by government to make risk management decisions, even if full scientific certainty has not been achieved. In contrast, stronger forms of the Principle require governments to act if there is any scientific uncertainty. The most aggressive forms of the Principle, however, require governments to ban activities that pose any risk to health, safety, or the environment.

Amongst policy-makers and opinion-formers, a greater understanding of the impact of these structural weaknesses on the effectiveness of the Precautionary Principle as a tool for managing risk is needed, if the concept of precaution is to continue to play an appropriate role in protecting citizens and the environment from harm.

2. IMPLEMENTATION OF THE PRECAUTIONARY PRINCIPLE

Over the last 10-15 years, substantial numbers of risk management decisions have been made using various forms of the Precautionary Principle. These provide important insights into the potential strengths of this approach, and its limitations.

Proponents of the Precautionary Principle argue that its use has resulted in higher levels of protection of citizens and the environment, as well as more equitable regulatory outcomes. These claims are contested. Evidence from the implementation of the Precautionary Principle suggests that it has a number of serious weaknesses that limit its effectiveness. Specifically:

- The costs of “false positives” are overlooked. These include economic losses, restricted freedoms, and the loss of existing health and environmental benefits.
- Decision-makers shift resources away from established problems and towards unproven, but high profile, social concerns, leading to negative effects on health and well-being;
- Used without extensive and rigorous procedural controls, it undermines the evidence-based approach to policy-making, weakening the link between science, evidence, and action, and delivering ineffective regulatory decisions;
- It increases administrative discretion and the politicisation of decision-making, leading to reduced predictability and providing opportunities for “regulatory capture” by interest groups;
- In its stronger and more aggressive forms, it paralyses risk management, halts technological innovation, and, because of unjustified restrictions, triggers the emergence of new, unintended risks (“risk-risk”); and,
- It institutionalises risk aversion throughout regulatory decision-making processes, leading to the use of non-scientific approaches to risk assessment, placing undue emphasis on unsubstantiated harms, and favouring restrictions;

These well-established weaknesses have been recognised by a number of leading governments. In Canada, for example, the use of the Precautionary Principle in risk management decisions is heavily restricted through the use of extensive guidelines and process standards¹. The scope of application of the approach is, for instance, limited to certain types of risk. Moreover, the Precautionary Principle may only be used if there is science-based plausible evidence of a potential problem, derived from a process encompassing peer review. Risk management measures based on the Principle must, moreover, be non-discriminatory, consistent, provisional, and based on a sound understanding of costs and benefits (including the risk-risk problem).

¹ Government of Canada ‘A Framework for the Application of Precaution in Science-Based Decision-making about Risk’ (2003)

3. THE PRECAUTIONARY PRINCIPLE AT EU-LEVEL

The Precautionary Principle is one of the tools used by decision-makers at EU-level to manage risks to health, safety, and the environment. It provides, some commentators argue, an important mechanism for ensuring that the EU is able to meet the demand of citizens for high standards of protection, especially from potential risks. Application of the Precautionary Principle by the EU's institutions is influenced by three institutional factors:

Treaty – the requirement to base environmental protection policies, in part, on the Precautionary Principle is set out in the EU Treaty. Included initially in the 1992 Maastricht Treaty, the scope of application of the Principle was subsequently expanded to encompass human health risks by political decisions at the Nice Summit in 2000 and European Court of Justice (ECJ) case law.

Commission Policy – in 2000, the European Commission set out its policy, along with guidelines, for the use of the Precautionary Principle². In a formal communication, the Commission identifies the Principle as a risk management tool but fails to provide a formal definition. The Communication identifies a wide scope for the application of the Principle, focusing its use on potentially dangerous effects on human animal, or plant health that may be inconsistent with the high level of protection chosen by the Community. Such circumstances should be characterised by scientific uncertainty, and public concern may also be considered by decision-makers. Use of the Principle should be preceded by a scientific risk assessment, and its application should take place within a traditional risk analysis framework. Levels of social acceptance of risk, and final decisions about the use of the Principle, are to be taken politically. Measures based on the Principle should be proportionate, non-discriminatory, consistent, and subject to review. They should also consider costs and benefits, although protection of health or the environment must take precedence over economic concerns.

ECJ Case Law – the EC courts have developed a substantive body of case law dealing with the application of the Precautionary Principle. In general, the ECJ permits the EU institutions considerable discretion in their application of the Principle, accepting regulatory decisions made on the basis of limited evidence. Moreover, the EC courts have failed to define the scope of the application of the Principle or the nature and quality of evidence needed to justify its use. The courts have, however, indicated that risks managed using the Principle should be real and not hypothetical, and that measures should take account of proportionality.

Whilst the EU institutions have taken important steps to ensure that risk management decisions based on the Precautionary Principle are of high quality, there remain major problems. The Principle remains undefined; its scope is extensive; the evidential basis for its application is undefined; the process for assessing the plausibility of the evidence of potential harm is ill-defined; and, there is inadequate understanding of the impact of its application.

² European Commission 'Communication from the Commission on the Precautionary Principle' (2000)
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4. RECOMMENDATIONS

The Precautionary Principle is one of the main tools used by the EU institutions to manage potential risks to human health, public safety, and the environment. Evidence from its widespread use in the EU and throughout the OECD suggests that, as a mechanism for ensuring high quality regulatory decisions, it is substantially flawed. Actions taken by the Commission and the ECJ have addressed some of the well-established weaknesses of the Precautionary Principle, but these steps do not go far enough. Possible additional reforms include:

- **Undertake an independent evaluation of the use of the Precautionary Principle by the EU institutions**, focusing on the scope of application, justification for action, overall negative and positive impacts, and processes;
- **Develop additional guidance for the application of the Precautionary Principle by the European Commission** focusing on limiting the scope of application and defining clearly the evidential thresholds and standards needed to justify its use;
- **Establish new procedures for assessing the plausibility of evidence used to justify the application of the Precautionary Principle**, emphasising transparency, the importance of high quality science, and independent, peer review of assessments;
- **Establish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments** by the European Commission's scientific advisers. These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science.
- **Develop a Commission Communication on the use and implementation of the Proportionality Principle**, ensuring that this is used to counter-balance the application of Precautionary Principle;
- **Revise the impact assessment guidelines for risk management decisions**, highlighting the limited role the Precautionary Principle plays in managing risks, its costs and limitations, and the need for plausible justifications of its application;
- **Require all uses of the Precautionary Principle to be documented and included in the Commission's annual report on law-making**, highlighting the justification for the use of the Principle including an independent assessment of the plausibility of the evidence of harm and nature of the risk to be managed;

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This policy brief was written by Richard Meads, the European Risk Forum's rapporteur, with help from members of the Forum. However, the views and opinions expressed in this paper do not necessarily state or reflect those of the European Risk Forum.