



EUROPEAN RISK FORUM – POLICY NOTE 10

JUDICIAL REVIEW AND RISK MANAGEMENT AT EU-LEVEL

2008

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

Judicial review is a legal concept that describes the power of the judiciary to annul acts of the executive or legislative functions of government. In open, democratic societies it is one of the most important mechanisms for protecting the rights of individuals (including businesses) established by a legal system. Decisions by judges, made through the process of judicial review, can influence the procedures and standards used by governments to make major administrative decisions, including the implementation of primary risk management laws.

In response to a progressive increase in the scope and nature of the risk management responsibilities of the European Union, European Community courts are being increasingly called upon to review legislative and regulatory decisions to manage risks. Traditionally, such reviews have been limited to questions of whether or not regulatory discretion has been exercised in an arbitrary or unjustifiable manner, and have avoided scientific or procedural issues. This approach is changing. Recent cases (vitamins, animal antibiotics, crop protection, and flame retardants) indicate a greater willingness of the EC courts to make assessments of the scientific evidence, and decision-making processes, when making legal judgements.

Action is needed by the Commission and the other EU institutions to respond to these judgments and that ensure that regulatory quality is enhanced, unpredictability reduced, and risk acceptance sustained. Possible reforms include:

- Introduce a Commission-wide policy for new risk management laws designed to improve quality and to limit the scope for ambiguity in implementation;
- Develop an assessment, based on scientific evidence, justifying the use of existing risk assessment and management 'models';
- Draw up mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication");
- Establish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments;
- Require significant risk assessment opinions to be independently peer-reviewed;
- Establish more rigorous procedural standards for the operation of the Commission's Regulatory Standing Committees;
- Ensure that scientific advisers focus only on risk assessment;
- Undertake an ex post evaluation of the operation of the Precautionary Principle by the EU's institutions

1. BACKGROUND

Judicial review is a legal concept that describes the power of the judiciary to annul acts of the executive or legislative functions of government. In open, democratic societies it is one of the most important mechanisms for protecting the rights of individuals (including businesses) established by a legal system.

Decisions by judges, made through the process of judicial review, can influence the procedures and standards used by governments to make major administrative decisions, including the implementation of primary risk management laws.

In the USA, for instance, courts have been instrumental in requiring Federal agencies to undertake rigorous and rational reviews of the risks posed by new products and technologies, and to base risk management decisions on high quality scientific evidence. Until recently, European Community (EC) courts took a different approach. Traditionally, they have tended to permit the EU institutions wide discretion when making risk management decisions, and have avoided detailed involvement in technical and scientific issues.

As a result, the EU's approach to making regulatory decision-making when implementing risk management legislation has tended to be based on a combination of Treaty requirements (such as taking account of scientific information), problem-specific secondary legislation, the comitology process for making implementation decisions, and an emerging group of horizontal decision-making mechanisms (such as consultation and impact assessment standards, and scientific committees). Whilst this approach has a number of well-understood weaknesses (such as the politicisation of implementation decisions and lack of scientific standards), it does, in general, ensure that science plays a role in decision-making, that rules are based on acceptance of risk, and that risk management rules are tailored to deal with specific hazards and exposures.

Recent trends in judicial review by EC courts pose a potential challenge to this approach. Judges have begun to take an interest in scientific and technical issues, and in the way that risk management decisions are taken. Important risk management decisions have been annulled. Criticisms have been made of the procedures used for the collection, assessment, and use of scientific evidence, and of the comitology process. And, moreover, judges have begun to assess the procedures and standards used to determine whether or not specific risks (or risk management measures) are acceptable to citizens.

Action is needed by the EU's institutions in general, and by the European Commission in particular to recognise this process and to help shape its evolution. Without action, it is possible that greater judicial review of the EU's risk management decision-making process could trigger the emergence of institutionalised aversion to risk, and increase regulatory unpredictability. Alternatively, judicial involvement could be used to provide a stimulus towards enhanced regulatory quality.

2. JUDICIAL REVIEW AT EU-LEVEL

At EU-level, judicial review of the administrative actions of the executive and legislative functions is undertaken by the Court of Justice of the European Communities. Often described as the ECJ, this is the judicial institution of the European Community. The ECJ is assisted in its work by the European Court of First Instance (ECFI) and the Civil Service Tribunal.

The ECJ is the highest court of the European Union in matters of European law. Its principal tasks are to ensure uniform interpretation of Community law and to examine the legality of Community measures. To achieve these goals, action can be taken on a number of grounds, including whether a Member State has fulfilled its obligations under Community law; preliminary rulings to help Member States clarify issues of Community law; and annulment of a measure adopted by an EU institution.

The power to annul administrative acts, such as implementing decisions made through comitology, is the principal mechanism through which the EC courts carry out judicial review. Administrative acts can be annulled for a range of reasons, including lack of competence, infringement of essential procedural requirements, infringement of the Treaty, and misuse of powers.

Although access to this process of judicial review is limited, its impact on the way in which the EU institutions implement secondary laws can be substantial.

Competition policy provides a good example. Here is an area where the EU has considerable powers, based on a series of framework secondary laws and implemented on a case-by-case basis through regulatory decision-making processes. Judicial review by the EC courts, although limited to a focus on legality and 'errors', has been used to trigger a major improvement in regulatory quality. A series of high-profile annulments of decisions by EU institutions over the last decade have achieved the following changes:

- Internal decision-making procedures have been reformed substantially;
- Decisions are required to demonstrate compliance with procedural rules, and to provide a clear statement of reasons for action along with proof of facts;
- Appraisals are required to be logical, coherent, and proportionate;
- Standards of proof of potential harm have been toughened up, along with the quality of evidence that must be used to demonstrate the potential for harm;

However, judicial review does not always produce improvements in regulatory quality. The traditional approach taken by the EC courts to risk management decisions, because it allows considerable discretion to regulators, has contributed to regulatory unpredictability and increased political risk for some investments in innovation.

3. EU RISK MANAGEMENT AND JUDICIAL REVIEW

In response to a progressive increase in the scope and nature of the risk management responsibilities of the European Union, European Community courts are being increasingly called upon to review legislative and regulatory decisions to manage risks. A process that is likely to continue, as complex laws with major potential for economic damage, such as REACH, are implemented.

Traditionally, such reviews have been limited to questions of whether or not regulatory discretion has been exercised in an arbitrary or unjustifiable manner, and have avoided scientific or procedural issues. This approach is changing. Recent cases (vitamins, animal antibiotics, crop protection, and flame retardants) indicate a greater willingness of the EC courts to make assessments of the scientific evidence, and decision-making processes, when making legal judgements.

Major legal cases have, for instance, addressed the following issues:

- *Scope and application of the Precautionary Principle*, permitting, for instance, its expansion to include health as well as environmental risks;
- *Scientific evaluation processes*, highlighting process failings such as a lack of written explanations justifying conclusions;
- *Nature of 'admissible' scientific evidence*, highlighting gaps in standards but requiring assessors to consider all suggestions of 'concern';
- *Risk assessment procedures*, requiring assessment of all potential uses, exposures, and hazards, regardless of likely exposures and usage conditions;
- *Risk management options*, requiring additional evidence to demonstrate the potential effectiveness of risk mitigation measures;
- *Comitology and risk management decision-making*, criticising the procedures used by Standing Committees to evaluate and disclose additional evidence;
- *Risk acceptance*, using the precautionary principle to establish a new, "risk averse" standard for risk management decisions;

This emerging trend poses important questions for the development of the EU's approach to managing risk in general, and the use of scientific evidence to support decision-making in particular. Whilst, many of the examples are the result of specific legal circumstances, over time they may begin to influence explicitly the overall approach to managing risk at EU-level. On the one hand, they could lead to a more risk averse and unpredictable approach; as an alternative, they could provide, if properly managed, the basis for major improvements in decision-making procedures and standards.

4. RECOMMENDATIONS

Action is needed by the Commission and the other EU institutions to respond to these judgments and that ensure that regulatory quality is enhanced, unpredictability reduced, and risk acceptance sustained. Possible reforms include:

- **Introduce a Commission-wide policy for new risk management laws designed to improve quality** by improving definitions, reducing ambiguity, highlighting social acceptance of risk, and recognising explicitly that zero risk is unattainable;
- **Develop an assessment, based on scientific evidence, justifying the use of existing risk assessment and management ‘models’.** Public interest benefits should be highlighted and compared to the likely negative impacts of alternative, more precautionary approaches;
- **Draw up mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers.** These should, for example, require written explanations explaining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings.
- **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.
- **Require significant risk assessment opinions to be independently peer-reviewed;**
- **Establish more rigorous procedural standards for the operation of the Commission’s Regulatory Standing Committees.** These should ensure that all scientific evidence taken into account by a Standing Committee is fully disclosed, properly written up, and formally reviewed by experts.
- **Develop new guidance to ensure that scientific advisers focus only on risk assessment.** This should identify risk assessment practices (such as the use of “worst case scenarios”) that embed implicit decisions about risk acceptance.
- **Undertake an ex post evaluation of the operation of the Precautionary Principle by the EU’s institutions,** including its application by the ECJ, and the use, effectiveness, and impact of the Commission’s operational guidelines.

2008

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.