EUROPEAN RISK FORUM – POLICY NOTE 09

SCIENCE AND DECISION-MAKING – EUROPEAN COURT OF JUSTICE (ECJ) AND SCIENCE

MARCH 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 practioners 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.

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EXECUTIVE SUMMARY

Recent judgements by the European Court of Justice (ECJ) in two cases (*Paraquat* and *Metaxyl*) involving crop protection products may pose, if acted on more widely, a potential challenge to the traditional way in which scientific evidence is used to inform EU-level technical regulatory decision-making processes.

The judgements set out new and more precautionary risk assessment requirements (contradicting processes and requirements developed within the context of relevant Directives to manage risks effectively, recognising the real-world situation facing suppliers, citizens, and the environment), as well as potentially limiting the scope of possible risk management options.

Action is needed by the Commission and the other EU institutions to limit the potential wider negative impacts of these legal judgements and to recognise the pertinent criticisms made by the court of the EU's technical regulatory decision-making processes. Possible reforms include:

- Introduce a Commission-wide policy for new risk management laws designed to improve quality;
- Develop an assessment, based on scientific evidence, justifying the use of existing risk 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;
- Establish more rigorous procedural standards for the operation of the Commission's Regulatory Standing Committees;
- Develop new guidance to 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

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1. BACKGROUND

At EU-level, the potential risks posed to citizens and the environment by the substances and technologies used by the crop protection industry are managed using a mix of 'ex ante' and 'ex post' regulatory mechanisms[1]. These include mandatory pre-market approval of new or improved products, post market surveillance, and periodic renewals of existing products. Scientific evidence is used extensively to support specific case-by-case regulatory decisions.

Health, safety, and environmental risks in many other sectors, such as pharmaceuticals, animal health, novel foods, speciality chemicals, advanced medical devices, and biotechnology, are managed using a similar approach. Regulatory problems encountered in the crop protection sector, if linked to the operation of other technical risk assessment and management processes, may be of relevance to other sectors.

Recent judgements by the European Court of Justice (ECJ) in two cases (*Paraquat* and *Metaxyl*) involving crop protection products may pose, if acted on more widely, a potential challenge to the traditional way in which scientific evidence is used to inform EU-level technical regulatory decision-making processes[2].

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2. ECJ DECISIONS

2.1. THE *'PARAQUAT'* CASE (CASE T-229/04, JULY 2007)

In response to a legal challenge from the Government of Sweden, the Court of First Instance, part of the ECJ, overturned a 2003 European Commission decision, made using Directive 91/414, to approve the herbicide *paraquat* for use throughout the EU. It based its judgement on criticisms of the administrative decision-making processes used by the European Commission, as well as a legal interpretation, influenced extensively by the Precautionary Principle, of the adequacy of the steps taken by regulators to assess and manage risks.

[1] 'Ex ante' mechanisms, such as pre-market approval processes or voluntary standards, are used to manage risks before substances or products are placed on the market. This is a precautionary approach but one that presumes a level of risk acceptance. It requires suppliers to demonstrate, without evidence of specific hazards or risks, that their products and substances meet pre-determined safety thresholds, as a pre-condition of market access. In contrast, 'ex post' mechanisms are used to manage the risks posed by substances or products after they have been placed on the market.

[2] Many public risk management objectives are achieved through a complex, multi-stage approach, involving framework primary laws and technical, implementing processes. Primary laws set out in the social goals to be achieved, define the level of social acceptance of risk, and, ideally, specify the principal characteristics of the implementing process, including risk assessment and risk management mechanisms. In turn, the objectives of primary risk management legislation are implemented through "technical regulatory decision-making processes". These are used by governments to make large numbers of complex case-by case decisions efficiently and to adapt rapidly and flexibly to technical progress.

The ECJ's ruling in this case raises a number of important points that, taken together, may be of relevance to the future operation of other technical regulatory decision-making processes. Specifically:

- **Scientific evaluation process** –significant process failures were identified in the judgement, most notably a lack of written explanations justifying the Commission's conclusions, particularly with regard to the acceptance or applicability of specific studies and findings, and the rationale as to why some studies were not considered or some findings were rejected.

- '**Admissible' evidence** – the judgement criticised the Commission's scientific advisers for not including in their risk assessment a review of general literature concerning any alleged health effects or toxicity. Moreover, it argued that such a review should form part of the "current scientific knowledge" and can include material introduced at any time in the process.

- **Comitology and additional evidence** – the judgement criticised the procedures used by the relevant EU Standing Committee to assess additional scientific and technical evidence that had not been reviewed by the Commission's scientific advisers during the formal risk assessment phase. Some pieces of evidence had been supplied orally to the Standing Committee.

  In response to this, the judgement set out informal procedural 'standards' for risk management decision-making. These are designed to ensure that all scientific evidence taken into account by a Standing Committee is fully disclosed, properly written up, and formally reviewed by experts.

- **Safety tests** – over time, the Commission has developed a pragmatic and effective way of assessing likely exposures of citizens, animals, and the environment to crop protection products. It enables regulators to take account of national differences and of real-world circumstances, and involves central assessment, in detail, of a small number of representative uses along with the delegation of certain elements of risk assessment and management to Member States.

  The judgement rejected this approach. It argued that all potential uses, exposures and hazards should be assessed fully, regardless of likely exposures and usage conditions. This is a precautionary approach to risk assessment.

- **Precaution and human health protection** – influenced by the Precautionary Principle, ECJ decided that the Commission should not have approved the use of the product.

  In the general opinion of the court, authorisation should be rejected, on the grounds of protecting human health, if "serious indicators" exist that reasonably allow one to doubt the safety of the substance. In practice, the judgement accepted that such indicators exist because of the results from the use of the substance by a single person in a small-scale (20 person) field study carried out in Central America in the mid-1990s. (Scientific advisers had seen the study and rejected the relevance of its findings.)

On this basis, the judgement suggested that, proving beyond reasonable doubt that a substance is not harmful means that if any doubt exists, no matter how weak the evidence, it may not be approved.

- **Precaution and risk management** – the judgement used the Precautionary Principle to further interpret the original directive and to develop a new test of the legal acceptability of proposed risk management measures. (Plant protection products, along with many other science-based technologies or substances, are often approved for use subject to strict risk mitigation controls over use and handling.)

  Proposed risk mitigation measures must, the judgement argued, establish beyond reasonable doubt that proposed restrictions on the use of a substance will achieve their objectives. This is only likely to be achieved, the judgement explained, if the Commission, the EU-wide risk manager, provides new specific scientific data. In contrast, the expert opinions of scientific advisers, or the delegation of risk mitigation measures to Member States, are unlikely to provide an acceptable guarantee of probable effectiveness.

  Because of a lack of such new scientific evidence, the judgement rejected the risk mitigation measures attached to the approval of the substance, and designed to ensure safe use and to limit risks to animals and people.

- **Legal standing** - the direct involvement of a Member State in the cases is a source of further concern. (The Commission decision to licence *paraquat* for use was challenged directly by the government of Sweden.) If a Member State is involved directly in an ECJ case, this limits opportunities of product owners or investors to appeal judgements or provide additional evidence supporting their property. They have no "legal standing" within the Court, and are unable to defend their property rights.

2.2. THE *'METALAXYL'* CASE (CASE C-326/05)

In this case, the ECJ annulled a Commission decision not to approve *metalaxyl*, a plant protection substance, for use in the EU.

The ECJ criticised the European Commission for applying administrative deadlines rather than focussing on safety, particularly if new scientific evidence was available. Moreover, the ECJ suggested that the Commission should recognise the risks to citizens and the environment if products were de-listed because the application of administrative deadlines led to the exclusion of new studies from risk assessments.

3. 'HORIZONTAL' ISSUES

Whilst all of the problems created by the ECJ's decisions are closely linked to the specific circumstances of each case, the judgements also raise 'horizontal' concerns that

could be of substantial importance for the operation of EU-level technical regulatory decision-making processes affecting a wide range of different sectors.

3.1. INFORMATION QUALITY

The judgements highlight the need for the Commission to establish and enforce information quality standards and guidelines for EU-level risk assessors, including independent Scientific Committees, Rapporteur Member States, and Technical Working Groups. Such standards should define, for instance, quality thresholds for the admissibility of scientific studies and data within risk assessments.

3.2. COMITOLOGY

Gaps and inadequacies in the procedural standards for the operation of the EU's comitology processes are identified by the Court. These undermine the transparency and legitimacy of the work of the Commission's regulatory Standing Committees. There is a need for the Commission to establish, jointly with the other EU institutions, binding procedural standards for the operation of all relevant regulatory committees.

3.3. PRECAUTIONARY PRINCIPLE

Many of the findings of the court have been, on this occasion, substantially influenced by an interpretation of the precautionary principle. It has been used to admit poor quality data into risk assessment; to expand risk assessments so that they include theoretical exposures; to create a risk averse standard for managing health risks, without supporting scientific evidence; and to undermine the use of risk mitigation measures, favouring, by implication, risk removal thorough bans. There is a need for the Commission to undertake an ex post evaluation of the operation of the Precautionary Principle, including its application by the ECJ.

3.4. EU-LEVEL RISK ASSESSMENT 'MODELS'

The judgements challenge established risk assessment models in three ways:

- First, they require safety data for all potential and theoretical applications (and uses) rather than using realistic exposure analyses, placing more emphasis on hazard rather than risk;

- Second, risk assessors are required to use "worst case" assumptions rather than taking a "weight-of-evidence" approach, confusing risk assessment and management by making implicit decisions about social acceptance of risk;

- Finally, risk assessors are required to consider any publicly available data or suggestion of 'concern' as evidence of uncertainty, without regard to scientific quality.

If, as a result of these judgements, this approach is adopted more widely, it undermines explicit requirements set out in secondary legislation and introduces a precautionary, REACH-style risk assessment process for science-based technical regulatory decision-making processes in a wide range of sectors.

3.5. UNCERTAINTY

The judgements create the possibility of a major increase in regulatory uncertainty within the EU's processes for implementing secondary risk management legislation:

- First, an important and novel dimension of these judgements is the extent to which the ECJ has commented directly on the use of science within the risk assessment and management process. In the past, the ECJ's comments have been restricted, in general, to administrative and legal processes.

- Second, the judgements may encourage more Member State challenges of Community decisions.

- Finally, the suggestion that "general literature" can be admitted into the scientific evaluation of risk at any time creates opportunities for delay and confusion. Moreover, it would allow unproven theories to be entered into the risk assessment process, undermining decision-making, and creating uncertainty. In turn, this could provide a basis for some groups to argue that the precautionary principle should be applied more frequently because of the presence of supposedly competing scientific evidence, leading to scientific uncertainty.

3.6. RISK AVERSION

The court has developed an interpretation of a well-established piece of secondary risk management legislation that, influenced heavily by a specific interpretation of the nature and purpose of the Precautionary Principle, creates a new and "risk averse" regulatory decision-making process. In contrast the regulatory process originally designed by the Commission, and accepted by the other institutions, was overtly based on the concept of "risk acceptance". This new approach has been undertaken without any substantive evidence of changes in the level of social acceptance of risk by the EU's citizens or legislative reform, by the EU's Member States and Parliament, of the original statute.

4. RECOMMENDATIONS

Action is needed by the Commission and the other EU institutions to limit the potential wider negative impacts of these legal judgements and to recognise the pertinent criticisms made by the court of the EU's technical regulatory decision-making processes. 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 management 'models'.** Public interest benefits should be highlighted and compared to the likely negative impacts of alternative, precautionary approaches;

- **Draw up mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication").** These should, for example, require written explanations explaining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings, and explaining why some studies were not considered or some findings were rejected.

- **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 and committees (including EU-level risk assessment agencies, Technical Working Groups, and Rapporteur Member States). 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.

- **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.

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- **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 the level of social acceptance of risk.

- **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.

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This background note 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.

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