EUROPEAN RISK FORUM – COMMUNICATION 07

IMPROVEMENT OF RISK ASSESSMENT IN VIEW OF THE NEEDS OF RISK MANAGERS – EUROPEAN COMMISSION CONSULTATION

February 2012

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

A Working Group has been established by the Inter-Committee Co-ordination Group of the Non-Food Scientific Committees serving the European Commission. This group has three objectives: review current risk assessment practices; explore what risk managers and policy managers need from risk assessment; and, identify approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent, and easy to interpret and communicate.

A preliminary review has been completed by the group. The main conclusion of this phase of the study is that the outputs of risk assessment need to be more policy-relevant. This includes describing the outputs of risk assessments in terms of value-relevant impacts on humans and ecosystems.

The European Risk Forum (ERF) welcomes this study and, in general, supports its recommendations. Since its inception, the ERF has argued consistently for greater use of evidence in legislative and regulatory decision-making.

If implemented, these reforms could, along with other improvements, help improve the quality of all forms of risk management decisions taken at EU-level. Specifically, a better integration of the outputs of risk assessments with the needs of officials responsible for impact analyses and risk management could achieve the following: better analysis of the benefits of risk management; enhanced understanding of the extent to which benefits justify costs when making legislative and regulatory decisions; better informed risk governance; improved impact assessment; and, more utilisation of cost effectiveness analysis.

Alongside the excellent recommendations put forward by the working group, the ERF has identified a series of additional ideas that could improve the utility of risk assessment within the risk management process. These include:

- Focus on quantification of outcomes initially, recognising that monetisation poses particular conceptual, technical, and ethical challenges;
- Base quantified estimates of harms and potential benefits on expected outcomes reflecting real world exposures rather than worst case scenarios and/or theoretical exposures;
- Introduce detailed guidelines for quantifying estimates of potential harms;
- Ensure that estimates of the potential economic and social costs continue to be assessed by risk managers rather than risk assessors;
- Establish processes to prevent policy-relevant outcomes of risk assessments stigmatising specific materials or technologies, including developing appropriate risk communication techniques;
- Establish consolidated mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments;
- Expand the proposed guidelines for the presentation of scientific advice to risk managers and policy-makers to require written explanations outlining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings; and
- Require significant risk assessment opinions to be independently and publicly peer-reviewed.

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1. EUROPEAN RISK FORUM

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2. PUBLIC MANAGEMENT OF RISK

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Today, it is most readily associated with government actions to protect people at work and to protect citizens and the environment from harm. But as a core function of government, risk management has been a potent and pervasive form of public policy for more than 200 years. In that period it has been used to support a range of varied policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment; protecting industrial workers from the impacts of economic activity; and protecting citizens and the environment from ruinous risks.

Public risk management can be broadly defined as any government action designed to prevent, reduce, or re-allocate risk. It includes actions to manage risks posed by technologies, economic activity, and lifestyle choices.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their risk management responsibilities. These now encompass issues such as product safety, food safety, pharmaceuticals, chemicals, environmental protection, public health, occupational health and safety, and consumer protection.

EU-level risk management decisions are taken through two distinct and different mechanisms: the creation of new (or the revision of) secondary legislation; and the implementation of existing legislation through technical regulatory decision-making processes (including agencies, specialist advisory or scientific committees, guidelines, and implementing processes, such as 'new' comitology).

Effective risk management policy requires decision-makers to strike a balance between fostering prosperity on the one hand and maximising security and equity on the other – a balance that changes over time. To ensure that risk management policies are successful, the EU's institutions need to be able to make decisions that will deliver intended economic and social goals without major, unintended negative side-effects, whilst also meeting ever rising standards of good governance.

In recent years, achieving these goals has become more difficult. Traditional decision-making models for assessing and managing risks face major challenges, which include declining public trust; increasing dissent; greater uncertainty; and increasing risk aversion. At the same time, policy goals and risk management objectives have become more complex, and new ideas about the best way to manage risks have emerged.

At EU-level, these challenges have triggered a number of major changes. New risk assessment institutions have been set up; new policy objectives have been established; the scope of risk management policy-making has been expanded (to encompass lifestyle risks); and major changes have been made in technical regulatory decision-making processes. Alongside these risk-specific changes, the EU's commitment to improved governance and better quality decision-making ("Better Regulation") has led to the introduction of new regulatory process management tools, most notably consultation and impact assessment.

Over the last decade, the EU's "Better Regulation" initiatives have led to remarkable progress. However, more needs to be done to strengthen the robustness of the tools and the accountability of the processes, as well as sustaining momentum in a number of areas, in particular the collection and use of scientific advice for decision-making, the production of high quality risk assessments, and the role and functioning of European agencies.

3. PROPOSALS

A Working Group has been established by the Inter-Committee Co-ordination Group of the Non-Food Scientific Committees serving the European Commission. This group has three objectives: review current risk assessment practices; explore what risk managers and policy managers need from risk assessment; and, identify approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent, and easy to interpret and communicate.

A preliminary review has been completed by the group. The main conclusion of this phase of the study is that the outputs of risk assessment need to be more policy-relevant. This includes describing the outputs of risk assessments in terms of value-relevant impacts on humans and ecosystems.

Within the report, the group set out a number of initial recommendations. These include:

- **Setting the scope of the risk assessment** – for complex issues a more integrated approach to risk assessment should be taken, ensuring that questions are not framed too narrowly.

- **Alignment of risk assessment and risk management** – risk characterisation within a risk assessment should be made more informative for risk managers. Specifically, this should be achieved by making the following changes:

    - Express effects (endpoints) in terms that are of relevance for protection of ecosystem services and human health;
    - Relate changes in these effects explicitly to changes in exposure, to the extent possible, by calculating attributable risk for populations;
    - Be explicit about how precautionary threshold values might be in terms of the dose-response; and,
    - Be explicit about how variability and uncertainty in effects and exposures.

- **Alignment of risk assessment and risk management** – risk assessment reports should follow a harmonised framework and include:

    - Evaluation of different scenarios or options, including potential risks of inaction;
    - Full characterisation of the whole population at risk, explicitly addressing sub-populations that may be particularly susceptible or more highly exposed;

- Systematic description of the weight of the evidence and identified data gaps;
- Identification and assessment of uncertainties and variability, including the impact of these issues on the conclusions of the risk assessment; and,
- Explicit description and justification of the hypotheses used in the absence of adequate data

- **Improving the dialogue between risk assessors and risk managers** – there needs to be greater interaction between risk assessors and risk managers during the "problem definition" and "options analysis" stages of the policy and legislative cycle. However, this should not compromise the independence of the scientific committee.

- **Further research** – so as to ensure greater utility of risk assessment reports for risk managers, additional research is needed in the following areas:

    - Development of an integrated risk assessment methodology that takes current endpoints used in toxicological or eco-toxicological risk assessment in order to estimate the likelihood and the magnitude of health and ecosystems impacts and translate them into a form that stakeholders, including the general public, understand and regards as important;
    - Expression of risks in probabilistic terms rather than deterministic terms; and,
    - Development of a better understanding of individuals' perceptions of safety

4. GENERAL COMMENTS BY THE EUROPEAN RISK FORUM

4.1. RISK MANAGEMENT AND UNDERSTANDING BENEFITS OF GOVERNMENT ACTION

The European Risk Forum (ERF) welcomes this study and, in general, supports its recommendations. Since its inception, the ERF has argued consistently for greater use of evidence in legislative and regulatory decision-making. It has, moreover, supported other initiatives taken by the European Commission, including the Better Regulation strategy, designed to improve the management of regulatory processes.

If implemented, these reforms could, along with other reforms, help improve the quality of all forms of risk management decisions taken at EU-level. Specifically, a better integration of the outputs of risk assessments with the needs of officials responsible for impact analyses and risk management could achieve the following:

- **Better analysis of the benefits of risk management** – The development of a thorough, evidence-based understanding of the benefits of government action, combined with rigorous measurement, is an essential pre-condition for making high quality risk management decisions. It helps improve effectiveness, highlighting "cause-and-effect" relationships, facilitating comparison of regulatory options, and ensuring that government interventions are likely to be successful. It

strengthens legitimacy by providing credible evidence that the benefits of government action are likely to exceed its costs. Finally, it provides the basis for effective ex post evaluation of regulatory decisions, strengthening further the utility, transparency, and accountability of modern regulatory processes.

Evidence from work by the OECD and others suggests that in too many instances, risk management decisions are based on an incomplete or inadequate assessment of the potential benefits of government intervention. In contrast, high quality decisions ensure that potential benefits, including the reduction of harms through government action, are assessed fully, supported by robust evidence, quantified, and, wherever possible, monetized.

Indeed, there is evidence of substantial gaps and weaknesses in the approach taken by the EU's institutions. Annual reports by the Commission's Impact Assessment Board consistently highlight the lack of quantification of regulatory impacts, especially benefits. A recent report by the European Court of Auditors, focusing on the Commission's impact assessment system, highlighted similar concerns. Specifically, it identified significant weaknesses in the "intervention logic" (the link between policy action and benefits) in too many impact assessments, and a consistent failure to quantify benefits.

- **Enhanced understanding of the extent to which benefits justify costs when making legislative and regulatory decisions** – a more transparent and rigorous identification of potential harms, expressed in policy-relevant ways and based on real world scenarios and expected outcomes (rather than worst case scenarios) will help policy-makers understand the extent to which risk management options deliver the greatest benefits to citizens. Too often, analysis of the potential benefits of government intervention is either incomplete or too optimistic. Evidence from the US OMB and from recent US research, for instance, suggests that there is a strong tendency for regulators to over-claim benefits and costs of government intervention. Failure to provide a full justification for the scale of resources needed to manage specific potential harms increases the risk of regulatory failure and undermines legitimacy.

  Using the approach proposed by the initial report, greater use could also be made of the knowledge and expertise of risk assessors during the "Analysis of Options" stage of the EU's decision-making model. For instance, risk assessors could provide a more informed and rigorous commentary on potential risk-risk threats posed by specific risk management options. If a risk management option creates new risks or increases an existing potential for harm, then these are additional costs of regulatory intervention and should form part of the impact assessment.

- **Better informed risk governance** – risk governance encompasses the selection of risks to be managed by government action; the objectives of risk management policy; the level of social acceptance of risk; the way in which risks should be managed; and, the processes by which risk management decisions are made. Risk assessments that provide policy-relevant information about potential harms will facilitate the development of a more open and better informed debate at EU-

level about the appropriate allocation of social resources to manage particular harms.

- **Improved impact assessment** – expression of the outcomes of risk assessments in terms of policy-relevant measures will have two beneficial consequences for the European Commission's impact assessment process. First, it will make the "Problem Definition" phase more rigorous and credible. Evidence from the Impact Assessment Board's regular reports suggests that, in too many cases, officials fail to justify adequately why government action is needed, and what public policy can achieve. Second, these reforms will help facilitate more transparent comparison of risk management options in the later stages of the impact assessment process, improving the balance between the costs and benefits of regulatory decisions. Specifically, they will facilitate greater use of cost effectiveness analysis.

- **More utilisation of cost effectiveness analysis** - Cost Effectiveness Analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of policy actions with their costs. Used well, CEA forces policy-makers and regulators to quantify rigorously the health or environmental benefits of prospective government actions to reduce risks. When properly constructed, CEA provides clear metrics for decision-makers, facilitating comparisons between different ways of managing the same problem, such as reducing risks to human health or public safety. CEA data, derived from a range of risk management actions, can also play a major role in the governance of risk, helping to identify the most efficient ways in which resources can be used to save or improve lives.

  CEA is most often used as part of a structured process for making legislative or regulatory decisions. In many leading countries within the OECD area, it is widely used when policy-makers and regulators examine ways of reducing risks to human health or public safety. It focuses on the ultimate outcomes, such as lives saved or improved, rather than intermediate reductions in emissions or exposures. It helps to inform ex ante impact assessment, facilitating the selection of policy options. It provides policy-makers, moreover, with an important analytical tool when benefits are difficult to monetize or when there are barriers to placing values on health or environmental benefits.

4.2. ROLE OF RISK ASSESSORS

Whilst the ERF is strongly supportive of the proposals set out in the initial report, it believes that the approach taken could be improved if the role of risk assessors in the process of making risk management decisions is set out clearly and explicitly. Specifically, the report should consider recognising formally that:

- Risk assessment and risk management must remain institutionally separate;

- Risk assessors are guardians of good science and of the scientific method;

- Risk acceptance and perception are properly considered as part of the process of impact assessment and risk management;

- Application of precaution forms part of the risk management phase of the decision-making process and should not play a part in the process of assessing risks, including risk characterisation;

5. ADDITIONAL IDEAS

Alongside the excellent recommendations put forward by the working group, the ERF has identified a series of additional ideas that could improve the utility of risk assessment within the risk management process. These include:

- **Focus on quantification of outcomes initially, recognising that monetisation poses particular conceptual, technical, and ethical challenges.** Quantification includes outcomes such as the impact of health risks on quality adjusted life years and other direct measures of mortality and morbidity. If monetisation is used then care should be taken to use appropriate discounting methodologies such that timing effects are properly recognised, and that willingness-to-pay measures, such as the Value of Statistical Lives (VSL), are employed, wherever possible.

- **Base quantified estimates of harms and potential benefits on expected outcomes reflecting real world exposures rather than worst case scenarios and/or theoretical exposures.** This limits over-claiming of benefits, enhancing the credibility of risk management proposals, reduces the likelihood of negative, unintended economic side-effects, and increasing regulatory effectiveness.

- **Introduce detailed guidelines for quantifying estimates of potential harms.** These should be subject to external consultation and reviewed regularly, ensuring that they remain abreast of conceptual and methodological developments.

- **Ensure that estimates of the potential economic and social costs continue to be assessed by risk managers rather than risk assessors.** Identification of the potential costs of regulatory decisions, including measures to manage harms, is a complex that is difficult to undertake. Indeed, it should be undertaken by experts and should be informed fully by extensive consultation processes.

  The most important negative impacts of regulatory decisions are, for example, unlikely to be the burden of paperwork or the initial expense of compliance. Rather, the most significant cost of regulation lies in the distortion of business, individual and societal behaviour triggered by regulatory requirements. This includes changes in investment decisions, innovation activity, technology dissemination, and materials utilisation on the one hand, and stigmatisation of substances or technologies on the other.

  It is also increasingly important to consider the long-term adjustment costs associated with regulatory decisions, especially in regional labour markets.

- **Establish processes to prevent policy-relevant outcomes of risk assessments stigmatising specific materials or technologies, including developing appropriate risk communication techniques.** Whilst new ways of characterising potential harms may improve regulatory decision-making, it could also, unless carefully managed, stigmatise specific materials or technologies.

  Stigmatisation is a form of social amplification of risk. It triggers changes in the materials or technology choices made by private individuals and 'gatekeepers' (such as retailers or 'assemblers' in the manufacturing sector). It occurs when concerns and fears about potential harms are amplified by governments or the media or campaigners.

  Stigmatisation also forms part of new range of risk management tools. It provides governments with a way to influence behaviour of participants in product markets. In the light of the need to separate risk assessment and risk management, and the overall potential of stigmatisation mechanisms to cause economic harms, risk assessors should take considerable care when estimating policy-relevant outcomes and when communicating them to risk managers.

  Use of policy-relevant measures of harm should therefore be based on realistic exposures and expected outcomes. Precaution should not form part of the risk characterisation process, nor should worst case scenarios or equivalent approaches to estimation. Moreover, action should be taken to ensure that internal communication to risk managers places policy-relevant measures within an appropriate context, avoiding creating unnecessary controversy or concern.

- **Establish consolidated 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 risk assessors. 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, where appropriate. By doing this, risk assessors will also act as guardians of good science for the Commission, increasing the credibility, effectiveness, and legitimacy of decision-making.

- **Expand the proposed guidelines for the presentation of scientific advice to risk managers and policy-makers to require written explanations outlining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings.** ECJ case law has identified this as an area where risk assessment needs to be made more transparent, particularly when undertaking assessments as part of the implementation of framework risk management legislation.

- **Require significant risk assessment opinions to be independently and publicly peer-reviewed**. This recognises the role that risk assessments can play in framing public policy and helps increase public confidence in the quality of opinions.

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

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