EUROPEAN RISK FORUM – POLICY NOTE 22

SCIENCE AND DECISION-MAKING – BALANCING EXCELLENCE AND INDEPENDENCE

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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

Used well, science provides effective ways of identifying potential risks, protecting citizens, stimulating innovation, and using resources wisely. It also enables governments to base actions on evidence derived from transparent, rational processes, enhancing accountability, trust, and effectiveness.

Yet policy-makers face the progressive loss of access to some of the best science, and scientific advisers, because of the way in which the EU's policies for providing scientific advice are increasingly implemented. EU policy requires advice to be 'independent', and 'excellent'. But all too often officials, charged with securing scientific advice, deem the requirements of 'independence' and 'excellence' to be satisfied, if evidence and advice are supplied solely by scientists from academia (or equivalent). Whilst this appears to be a practical solution, it can have the effect of preventing decision-makers from gaining appropriate access to the scientific expertise of the private sector. In turn, this makes it difficult for governments to manage harms well.

The best way for regulators to address the trade-off between independence and excellence is through enhanced governance rather than by restricting access to some of the best science and expertise. Access to private sector advice and expertise, especially in areas of applied science, helps risk managers to identify threats; to justify regulatory action; to develop an adequate understanding of scale of potential harms (and of the benefits of action); to gain a complete knowledge of the potential effectiveness and impacts of risk management options; to design effective, high quality technical guidelines; and, because of the potential lack of knowledge and objectivity (due to bias) of some other scientists, to sustain public trust.

The Commission has begun to take steps to strike a new balance between 'independence' and 'excellence', such that decision-makers gain access to the best science without compromising public trust. Building on these initial reforms and using good practices ideas, the ERF has identified a number of additional improvements that, if implemented fully, would improve further the quality, objectivity, and credibility of scientific advice. These include:

- Draw up a formal EU-level policy for risk analysis;
- Establish mandatory standards that define the quality of studies, information and data to be used in scientific assessments;
- Require significant risk assessment opinions to be independently reviewed;
- Develop a new Commission Communication on the use and collection of evidence that emphasises the paramount importance of 'excellence' and defines 'independence' on the basis of objectivity;
- Require all EU risk assessment agencies, and their scientific committees, to adopt the new rules of procedure used by the non-food scientific committees;
- Revise existing agency policies to ensure that tests of 'independence' do not have the effect of limiting access to the best available science;
- Develop guidance notes to identify bias and conflict-of-interest;
- Expand the scope of the EU's regulatory process management standards to encompass scientific and technical guidance; and,
- Amend the Commission's IA guidelines to require measures based on risk assessments to demonstrate that they reflect "real world" experience

1. BACKGROUND

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. It is most readily associated with government actions to protect people at work and to protect citizens and the environment from harms posed by technologies and lifestyle choices.

In managing these risks, scientific evidence has been the key knowledge input for decision-making throughout the "regulatory cycle". Used well, science provides effective ways of identifying potential risks, protecting citizens, stimulating innovation, and using resources wisely. It also enables governments to base actions on evidence derived from transparent, rational processes, enhancing accountability, trust, and effectiveness.

Looking forward, demand from the EU's institutions for excellent, high quality science is likely to increase, as the policy domains for which risk assessments are required grows; as the impact of new technologies becomes more pronounced; and, as the EU implements complex new risk management rules to regulate harms posed by the application of complex technologies

In the face of these requirements, and recognising the importance of high quality science for decision-making, the European Commission has, since the late 1990s, made considerable progress to improve the quality and credibility of scientific advice provided to decision-makers. A network of independent scientific committees has been established, along with new risk assessment agencies in areas including food safety, chemicals, and medicines[1]. A broad policy structure has also been put in place[2]. These improvements have been widely recognised by opinion-formers and stakeholders.

Despite the well-understood benefits of using high quality scientific evidence to manage risks, the appropriate role of science in decision-making is increasingly contested. Some opinion-formers argue for greater use of precaution, supported by social concern or by evidence derived from hypothesis-forming science or weak studies rather than assessing risk using widely accepted high quality studies. Others argue that science should be treated as just one of a number of equally 'valid' opinions, rather than respecting the strengths and qualities of the "scientific method".

Yet the influence of these opinions on stakeholders is not the only challenge facing EU's policy-makers. Of equal concern is **the progressive loss of access to some of the best science, scientists, and scientific advisers, because of the way in which the EU's policies for providing scientific advice are increasingly implemented.** EU policy requires advice to be 'independent', 'excellent' and 'transparent'[3]. It is recognised that getting the balance right, in practice, between 'independent' and 'excellent' is difficult, but a failure to ensure access to the best available science, because of an over-emphasis on the source of evidence or advice rather than on its quality, risks "regulatory failure", and, over time, undermines trust. Action is needed to re-balance the relationship between these two, competing requirements.

[1] See European Commission 'Commission Decision setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health, and the environment' (2008). This repealed the original, founding Decision of 2004.

[2] See, European Commission 'Communication on the Collection and Use of Evidence by the Commission' (2002)

[3] These requirements are set out in the Commission Decisions of 2004 and 2008. They apply to independent scientific committees and risk assessment agencies.

2. INDEPENDENCE VERSUS EXCELLENCE TRADE-OFF

Across the OECD area, policy-makers frequently require scientific advice to be both 'excellent' and 'independent'. Access to good science, the bedrock on which high quality decision-making is based, is assured if advice is excellent, whilst there is greater acceptance of the findings of risk assessments and of risk management decisions if evidence is seen to be independent.

Delivering an effective trade-off between these goals is, however, difficult to achieve in practice. All too often, officials charged with securing scientific advice deem the requirement of 'independence' and 'excellence' to be satisfied, if evidence and advice is supplied solely by scientists from academia, and ideally by those without any significant funding links to the private sector. Whilst this is appears to be a practical solution, it can have the effect of preventing decision-makers from gaining appropriate access to the scientific expertise of the private sector. In turn, this makes it difficult for governments to manage harms well.

Inadequate access to private sector advice and expertise poses five major problems for risk managers:

- **Inability to identify fully threats or to justify credibly regulatory action** - In many policy domains, the private sector possesses important scientific knowledge, often of greater quality than that developed by scientists working elsewhere. Applied science in areas such as food, chemicals, metals, electronics, consumer products, crop protection, and medicines is dominated by industry-funded science[4].

  Without access to industry-funded science, it is difficult for policy-makers to develop a convincing, evidence-based justification for regulatory action or to identify emerging risks or to develop effective risk management options.

- **Inadequate understanding of scale of potential harms and of the benefits of action** - High quality risk management depends, in general, on building an understanding of risk, rather than focusing solely on hazard. Assessments of risk should, ideally, reflect "real world" conditions, providing a credible basis for understanding potential harms and, hence, possible benefits. In contrast, theoretical or worst case analyses of potential exposures, often used by assessors when private sector evidence is unavailable, mislead decision-makers by overstating threats.

  Informed and balanced assessments of risk are difficult to carry out unless scientific advisers have access to private sector expertise including usage experience.

[4] It is an objective of the EU's R&D, innovation and Competitiveness policies that the private sector should invest in applied scientific R&D, preferably in collaboration with other parts of the "innovation system", such as universities and research centres. See for example, European Commission 'Innovation Union" (2010) and "Europe 2020" (2010). Axiomatically, the implementation of these strategies, often through the influence of flows of government grants, will increase scientific knowledge in the private sector in areas of applied knowledge. In 2010, for example, Eurostat data shows that nearly 65% of gross expenditure on R&D in the EU was carried out within the private sector.

- **Incomplete knowledge of the potential effectiveness and impacts of risk management options** – in many instances, risk management options set out to change or restrict the behaviours of users of substances or technologies, ideally without harming incentives to invest in innovation. If risk management is to be 'effective', one of the tests of good regulation set out in the Commission's IA guidance, a comprehensive understanding of production and usage by private sector businesses and of innovation processes within the private sector is required.

  It is difficult for decision-makers to make appropriate choices between risk management options unless they are well developed, recognising "real world" behaviours. This is difficult to achieve without extensive access to private sector knowledge.

- **Difficulty designing effective, high quality technical guidelines** – Many risk management goals are, in the EU and elsewhere, implemented by complex regulatory processes, including the use of technical guidelines. These are non-binding rules that define, for example, the tests that must be carried out to demonstrate safety or efficacy or quality of groups of substances. Such rules are a form of 'soft law' and impose significant costs on society, unless developed appropriately[5].

  If such guidelines are to be of high quality then they must take account of "real world" experience and of the best available science. In many cases, this requires access to private sector expertise and science.

- **Risk of undermining public trust** - A further problem for decision-makers is that excluding private sector input from the risk management process, because it is deemed not to be 'independent' due to its origins, does not guarantee that the remaining sources of advice will be either 'independent' or 'excellent'.

  Scientists not involved with industry may, in many policy areas, lack detailed, current, or relevant knowledge, limiting the quality of their contributions. Some may also be unable to act objectively: They may, for instance, receive funding from campaigning groups, creating an obvious economic conflict-of-interest. Alternatively, they may be biased, holding intellectually motivated views or identifying with the positions or perspectives of a particular group.

  To maintain public trust, it is essential that risk management decisions are of high quality and transparent. This is unlikely to be achieved if advice is of poor quality or is provided by scientists who are perceived to lack objectivity.

The progressive reduction in the involvement of the private sector in EU-level risk management is the result of officials responding to two complex challenges: firstly, developing a workable definition of 'independence'; and secondly, responding to growing political criticisms of industry-funded science.

[5] At worst, poor quality guidelines can handicap innovation by upsetting the balance between market size and the capitalised costs of product development or by triggering the removal of existing substances for economic rather than safety reasons. They may also fail to protect citizens or the environment, if "real world" experience is not taken into account in their development.

In the first place, the EU's institutions have tended to define 'independence', when considering scientific advice, solely in terms of economic conflict-of-interest. They have, moreover, used a wide form of this definition, focusing on the origin of studies and advisers rather than upon issue-specific conflicts facing individual advisors. This definition is, moreover, incomplete. Other, widely respected views consider 'independence' to be the capacity to act objectively when providing scientific advice to governments[6]. This, it is argued, is undermined by two factors: bias and direct economic conflict-of-interest. Any definition of 'independence' should, it is suggested, take both of these issues into account.

A further challenge is the increased opposition amongst some opinion-formers to industry-funded science playing any part in risk management decision-making processes. Many of the arguments are intellectual, reflecting a range of political and conceptual views. Some observers argue that, because it is produced to generate profits, industry science is inherently untrustworthy and biased. Others, using a post-modernist logic, argue that there is no need for industry science because it is simply another opinion. Action can, thus, be taken solely on the basis of political discourse. Finally, other groups, supporting a precautionary, hazard-based approach, to managing risks, claim that traditional risk assessment is used to delay or prevent government action to re-shape economic activity so as to protect people or the environment.

The best way for regulators and decision-makers to respond to these views is through debate and discourse, in other words through enhanced governance, rather than by restricting access to some of the best available science and expertise. Indeed, some of the opinions expressed by interest groups, academics, and campaigners challenge the relevance of science itself in decision-making, as well as criticising the use of industry-funded expertise.

Alongside this debate, the EU institutions need to find new ways to re-balance the trade-off between 'independence' and 'excellence'.

3. PUBLIC TRUST AND HIGH QUALITY SCIENCE - GOOD PRACTICES

Finding ways to provide regulators with access to the best available science, whilst also maintaining public trust, is a problem faced by governments in most OECD countries.

Looking at initiatives undertaken in other countries, it is possible to identify a number of good practices for improving access to the best available science whilst also for strengthening public confidence in the objectivity of risk analysis processes and their findings[7]. Specifically:

- Policies for collection, use, and provision of scientific advice make it clear that the dominant criterion for choosing data, studies and expertise should always be that of 'excellence'. 'Independence' is, in contrast, assured through open processes and institutional checks and balances.

[6] See for example, The US National Academy of Sciences 'Policy on the Committee Composition and Balance and Conflicts of Interest for Committees used in the development of reports' (2003)

[7] These comments also take account of discussions held at meetings of the ERF Risk Forum between 2007 and 2013.

- Within the overall policy framework, 'independence' remains an important goal but is defined on the basis of the objectivity of advice, expertise and advisers. When officials assess scientific advice, two threats to objectivity are considered: bias and conflict-of-interest. Bias is defined as relating to views stated or positions taken that are largely intellectually motivated or that arise from close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group. Tests of conflict-of-interest focus on the financial interests of advisers.

- Transparent processes are in place to identify potential sources of bias and possible financial conflicts-of-interest.

- Advisers are excluded if they have a direct financial interest or if knowledge gained could create competitive advantage or if their biases are likely to prevent them acting objectively. This is deemed to occur if an advisor is totally committed to a particular point of view and unwilling or reasonably perceived to be unwilling to consider other perspectives or relevant evidence to the contrary.

- Rigorous standards for scientific quality are in place. These have a presumption favouring peer reviewed data and results, a definition of scientific quality, and require sufficient transparency to facilitate reproducibility.

- The utility of studies, data, and findings is assessed solely on the basis of transparent quality standards.

- There are transparent standards for risk analysis which include requirements to use the best reasonably obtainable scientific data, and to provide a characterisation of risks that is both qualitative and quantitative.

- It is a formal requirement that all risk assessments must be peer reviewed, ensuring good science, more trust, and less likelihood of undue influence. For 'influential' risk assessments, additional scrutiny is required[8].

- Policies and guidance recognises the importance of basing all advice on the best available science, including that funded by the private sector. Indeed, it is accepted that because of the particular knowledge and experience of the private sector, an industrial perspective may, in many situations, be vital to achieving an informed, comprehensive, and authoritative understanding and analysis.

- Regulatory process standards, including information quality requirements, are applied to scientific and technical guidelines, including those drawn up by agencies.

[8] This involves an independent review of the evidence and findings of important risk assessments. Public notice and comment processes are used to highlight areas of concern but an independent reviewer or panel undertakes the review. The importance of independent peer review, as a mechanism for assuring the scientific quality of risk assessments, has been fully recognized in the USA. Requirements for federal agencies are set out in US OMB 'Final Information Quality Bulletin for Peer Review' (2004). The guidance set out in the bulletin aims to increase the quality and credibility of scientific information generated across the US federal government.

4. EU-LEVEL INITIATIVES

Over the last decade, the need to develop innovative ways to gain access to the best available science, whilst maintaining public trust, has become an increasingly important challenge facing EU-level policy-makers.

Indeed, the extent to which the EU's institutions rely on specialist expertise to anticipate, identify, manage, and communicate risks was identified in the White Paper on Governance published in 2001[9]. Following on from this and building on its recommendations, the Commission drew up in 2002 an initial policy framework for the collection and use of expertise[10]. This remains applicable to the European Commission and forms part of its approach to Better Regulation. It highlights the importance of gaining access to high quality advice. It requires policy-makers to seek input from a range of sources. And, it recognises the need to make trade-offs between independence and excellence.

Reports drawn up by Brussels-based Think Tanks looked at these issues in more detail, as well as highlighting a number of trends in risk management and in the provision of scientific advice[11]. These included new risk governance priorities focusing on uses of technologies rather than their production; shifts in government spending on research in universities; and the ageing of the population of research scientists, reducing the pool of 'independent', expert risk assessors.

External evaluators identified further threats to the future credibility and utility of advice. In 2007, for instance, DG SANCO commissioned RAND, an academic research institute, to evaluate the work of the European Commission's Non-Food Scientific Committees[12]. A major finding of the review was that the quality of advice was likely to be threatened in the future because of the difficulty, in an increasing number of areas, of finding experts who are both 'excellent' and 'independent' of stakeholders. This "excellence gap" was, the evaluators suggested, most pronounced in areas of applied research, where expertise lies predominantly with the private sector.

In response to these observations, the EU institutions have, until recently, focused primarily on improving processes for demonstrating 'independence', emphasising the need to maintain public confidence in the objectivity of advice. The recent policy on scientific independence drawn up by EFSA is a good example of this approach[13]. This focuses on conflict-of-interest tests (for external experts), public consultation, transparency, and institutional independence.

During 2013, however, a new initiative was launched. Using the powers set out in the relevant Commission Decisions of 2004 and 2008, officials have drawn up new, binding

[9] CEC 'European Governance: A White Paper' (2001)
[10] CEC 'Communication from the European Commission: On the Collection and Use of Expertise by the Commission – Principles and Guidance' (2002)
[11] See for example, Bruce Ballantine 'Enhancing the role of science in decision-making of the European Union' (European Policy Centre Working Paper no. 17, 2005), and European Risk Forum 'DG SANCO Consultation – Revision of European Commission Scientific Committees (ERF Communication No. 3, 2008).
[12] RAND Europe 'Evaluation of DG SANCO's Non-Food Scientific Committees: Issues for Scientific Advice, Policy-Making, and Regulatory Decision-Making' (A report for DG SANCO, 2007)
[13] European Food Safety Authority 'Policy on Independence and Scientific Decision-Making Processes' (2012)

rules of procedure for the three independent scientific committees that support the work of the EU's institutions[14]. These introduce a number of new requirements, including:

- Assessment of risks should meet best international standards; be based on the best data, scientific knowledge, and methodology available at the time of the preparation of an opinion; and be quantified if practical;

- Risk assessors should strive to involve or consult the most qualified experts, and to take account of a wide range of views;

- Advice must not be influenced by any consideration other than scientific assessment of risks, and that this principle implies in particular the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations; and,

- Issues of social acceptance of risk should not form part of a risk assessment, and risk management statements should be avoided.

These reforms establish the basis for a formal risk assessment standard; they recognise the importance of taking a "value neutral" approach to obtaining high quality science; they take a new approach to defining 'independence'; and they strengthen accountability by further clarifying the nature of the institutional separation between assessment and management of risk at EU-level.

Whilst further work is needed to build on these changes, they are an excellent start and are to be welcomed.

5. RECOMMENDATIONS

The Commission has begun to take steps to strike a new balance between 'independence' and 'excellence', such that decision-makers gain access to the best science without compromising public trust. Building on these initial reforms and using good practices ideas, the ERF has identified a number of additional improvements that, if implemented fully, would improve further the quality, objectivity, and credibility of scientific advice. These include:

- **Draw up a formal EU-level policy for risk analysis** that includes a requirement to base decisions on the best available science, wherever it is to be found. The policy should apply to all risk assessments undertaken by the European Commission, its agencies, and its scientific committees. Compliance with the policy should, moreover, be a requirement of the impact assessment process;

- **Establish mandatory standards 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

[14] DG SANCO 'Rules of Procedure of the Scientific Committees on Consumer Safety, Health and Environmental Risks, and Emerging and Newly Identified Health Risks' (2013)

assessment agencies, Technical Working Groups, independent scientific committees, and Rapporteur Member States.

These principles should have a presumption favouring peer reviewed data and results and require sufficient transparency to facilitate reproducibility. They should also require studies, information, and data to be based on widely accepted and objective practices (the "scientific method");

- **Require significant risk assessment opinions to be independently reviewed.** Such reviews should be characterised by scientific and process integrity that maximises excellence and transparency, whilst providing substantial opportunities for public comment;

- **Develop a new Commission Communication on the use and collection of evidence that emphasises the paramount importance of 'excellence' and defines 'independence' on the basis of objectivity.** This should define tests of objectivity that encompass both 'bias' and conflict-of-interest'; it should recognise the need to gain access to all sources of expertise, including that funded by the private sector; and it should require studies and data to be assessed solely on the basis of scientific quality.

- **Require all EU risk assessment agencies, and their scientific committees, to adopt the new rules of procedure used by the non-food scientific committees**;

- **Revise existing agency policies to ensure that tests of 'independence' do not have the effect of limiting access to the best available science** or of defining challenges to objectivity too narrowly;

- **Develop guidance notes for all risk assessment committees setting out tests to identify bias and conflict-of-interest**, ensuring that advisers are not included if they are perceived to be unable to act objectively;

- **Expand the scope of the EU's regulatory process management standards to encompass scientific and technical guidance drawn up by the Commission and its agencies**, ensuring that there is appropriate consultation, assessment of the need for action, use of high quality science, and ex post review; and,

- **Amend the Commission's IA guidelines to require measures based on risk assessments to demonstrate that they reflect "real world" experience** rather than solely worst case or theoretical exposures;

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This background note 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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