



EUROPEAN RISK FORUM – COMMUNICATION 02

**EUROPEAN COMMISSION DG SANCO – COMMENTS ON THE
EVOLUTION OF THE ROLE AND STRUCTURE OF THE EU’S
INDEPENDENT SCIENTIFIC COMMITTEES
(ENHANCING THE FUTURE UTILITY AND CREDIBILITY OF SCIENTIFIC
ADVICE)**

February 2008

1. 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 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, costs, 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.

2. EU-LEVEL SCIENTIFIC COMMITTEES – FUTURE CHALLENGES

In managing a wide range of risks to the environment, public safety, and human health in most modern economies, scientific evidence is the key knowledge input for decision-making in all stages of the ‘regulatory cycle’. Used well, science provides effective ways of identifying potential risks, protecting citizens, and using resources wisely. It enables government decisions to be based on evidence derived from transparent, rational processes designed to enhance legitimacy and trust. Moreover, it has, in the past, been highly effective in providing theories with explanatory and predictive power. These theories have enabled policy-makers to anticipate problems and to develop effective solutions.

Most scientific evidence is provided to policy-makers and decision-makers through a process of ‘scientific assessment’. This involves an expert assessment of the state of knowledge, and the implications of ‘known’ scientific evidence. At EU-level, these assessments are increasingly undertaken by scientific committees established on the basis of ‘independence’ and ‘excellence’.

ERF members recognise the considerable progress that the European Commission has made to improve the quality and credibility of scientific advice to policy-makers. Since the late 1990s, and in response to regulatory failures such as BSE and dioxin, the Commission has established a network of independent scientific committees, along with new risk assessment agencies in areas such as food safety and chemicals. In general the work of these new groups is widely respected.

An important challenge for EU-level decision-makers is ensuring that, in the future, advice provided by these committees remains useful to policy-makers and continues to be trusted by citizens and stakeholders.

In order to achieve this goal, decision-makers face a number of significant challenges. ERF members highlighted two areas of concern:

- **Major shifts are taking place in the types of risks that public policy is used to manage, and in the sources of scientific evidence needed to understand such risks.** Alongside traditional large-scale, technologically-based risks to human health, the environment, and public health, governments seek to assess and manage risks created by lifestyle choices, climate change, and the complex uses of specific substances, technologies, and processes.

Effective management of these emerging risks will continue to require access to high quality scientific evidence. Much of this knowledge, however, is likely to be found outside universities and other publicly-funded institutions, especially in areas linked to uses and applications of specific materials and technologies. These are areas of applied science and technology, where scientific resources are concentrated in areas such as the private sector rather than in academia or other independent research institutes.

Policy-makers face the challenge of achieving greater access to this body of knowledge, without undermining credibility and trust, if they are to properly protect citizens and the environment. This poses challenges, because traditional ‘conflict-of-interest’ rules limit the contribution that scientists from outside universities or similar institutions can make to the provision of advice for policy-making. Policy-makers may face the need to make a trade-off between ‘independence’ and ‘excellence’.

- **The ‘pool’ of relevant, independent scientific advisers may, in certain areas be shrinking.** There are, ERF members believe, two possible causes of this. First, as described above, relevant, high quality research may, in some areas of concern to governments, be more likely to be carried out in non-traditional institutions rather than within universities or research institutes. The second problem is more complex and is closely linked to the concept of ‘bias’.

Throughout the OECD area, policy-makers increasingly recognise the value of ensuring that scientific advice used for decision-making is independent. ‘Independent’ advice is valued as a means of strengthening trust and, due to the perceived absence of bias, of increasing utility. In many cases, including the EU, ‘independence’ is often achieved, in practice, through the use of a ‘paymaster’ test to identify conflict-of-interest. Although this is, in part, a proxy measure of the potential for bias, in practice, it favours, for policy-making purposes, academics based in universities or research institutes.

In the past, this process has had the virtues of simplicity and transparency. It is, however, coming under threat because of the increased involvement of academics and other publicly-funded scientists in supporting, through direct involvement in activist campaigns for instance, of specific risk assessment and risk management outcomes that are not necessarily supported by the full weight of existing high quality and widely-accepted scientific evidence. This creates the risk of ‘bias’ amongst supporters of such outcomes, if they participate in the process of providing scientific advice to policy-makers. Traditional conflict-of-interest disclosures are unlikely to identify this new source of potential bias and threat to the ‘independence’ of advice.

3. POSSIBLE CHANGES

In response to these challenges, ERF members have identified a number of possible EU-level reforms. These are designed to strengthen the future credibility and utility of advice provided by independent scientific committees at EU-level. Potential changes include:

- **Focus on excellence** - recognise that the most important factor in selecting scientific advisers is expertise. Selection processes should, therefore, ensure that the advisers selected, including members of independent scientific committees, have the knowledge, experience, and skills to perform relevant reviews.
- **Identify biases** – develop new tests of ‘independence’ designed to identify and highlight potential biases of prospective scientific advisers. These tests should be separate from tests of conflict-of-interest.
- **Limit the impact of biases** - although the presence of biases should not in themselves be a basis for disqualification of a candidate, a person should not provide scientific advice to policy-makers if they are totally committed to a particular point of view and unwilling to consider other perspectives or relevant evidence to the contrary.
- **Independent Committees** – recognise that, because of the possibility of some bias in most scientific advisers, it may be difficult to recruit an adequate number of ‘independent’ scientific advisers. Instead, focus on developing the concept of “independent committees”, balancing known differences in bias whilst emphasising the importance of expertise as the primary criterion for the recruitment of advisers.
- **New conflict-of-interest tests** – limit the scope of conflict-of-interest tests. Prospective advisers should only be excluded from supporting policy decisions if they face direct financial conflicts of interest. Alongside this, the extent of disclosures of financial and other relevant interests should be increased whilst advisers should be required to make formal commitments to act in the public interest when providing advice to policy-makers.
- **Quality standards** – introduce written requirements that define the quality standards that studies and data used by scientific advisers must satisfy. These should, for example,

require evidence used to inform policy-makers to meet the requirements established by the “scientific method” and widely-accepted standards such as GLP or GCP.

- **‘Interpretation’ standards** – set out clearly the methods that should be used by scientific advisers to interpret evidence, defining clearly the boundaries between risk assessment (an expert task) and risk management (a political responsibility). As a general rule, advisers should be required by policy-makers to use the “weight-of-evidence” principle; to avoid the application of the Precautionary Principle; and to ensure that a range of realistic risk scenarios are assessed.
- **Consultation** – develop new consultation processes designed to ensure that scientific advisers are able to gain access to all sources of appropriate high quality evidence.
- **Selection of advisers** – a process of “peer nomination” should be used to identify potential scientific advisers. After taking account of biases and direct financial conflicts-of-interest, advisers should be chosen on the basis of excellence, using a transparent, objective, consistent, and systematic process.
- **Peer review** – findings from reviews by scientific advisers, which are likely to have a substantial impact on public policy or the decisions of private companies or the freedoms of citizens should be subject to peer review.

February 2008

This communication was written by Dirk Hudig, Chairman of the European Risk Forum, and 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 of its members.