



EUROPEAN RISK FORUM – POLICY NOTE 04

RAND EVALUATION OF DG SANCO'S NON-FOOD SCIENTIFIC COMMITTEES: ISSUES FOR SCIENTIFIC ADVICE, POLICY-MAKING AND REGULATORY DECISION-MAKING

2007

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

During 2007, DG SANCO commissioned RAND, an academic research institute, to evaluate the work of the European Commission's Non-Food Scientific Committees. These are SCEP (Committee on Consumer Products), SCHER (Committee on Health and Environmental Risks), and SCENIHR (Committee on Emerging and Newly Identified Health Risks).

In their work, RAND identified a number of important issues facing the non-food scientific committees. These include a lack of clear separation between "risk assessment" and "risk management" recommendations; weaknesses in some of the data on which scientific opinions are based; ambiguity in some of the mandates provided by the European Commission to scientific committees; and, uncertainty about the best and most appropriate way to make use of additional, external experts.

Moreover, the evaluators also highlighted possible threats to the future credibility and utility of advice because of the difficulty, in an increasing number of areas, of finding experts who are both 'excellent' and 'independent' of stakeholders – this is sometimes referred to as the "excellence gap" and is most pronounced in areas of applied research

This is an insightful report and should be welcomed. Its findings and limited recommendations, if acted upon by officials, will help strengthen the trend to towards improvements in the quality of scientific advice used in decision-making at EU-level.

Whilst recognising the limitations imposed on RAND by the Commission's terms of reference, the effectiveness of the evaluation could have been further strengthened by the following additional recommendations:

- Selection of scientific advisers should be based on peer nomination.
- New mechanisms are needed to expand the potential scientific expertise available to the Commission.
- Mandates for scientific committees should be drafted in such a way that scientists are only asked to comment on issues for which they are directly and uniquely qualified.
- Formal risk communication standards, covering a wide range of substantive and contextual issues, should be introduced.
- There is a need to establish, at EU-level, formal and explicit quality standards for the scientific evidence, and its interpretation, that should be used by scientific committees.
- New guidance is needed to ensure that scientific committees do not provide risk management advice.

1. BACKGROUND

During 2007, DG SANCO commissioned RAND, an academic research institute, to evaluate the work of the European Commission's Non-Food Scientific Committees. These are SCEP (Committee on Consumer Products), SCHER (Committee on Health and Environmental Risks), and SCENIHR (Committee on Emerging and Newly Identified Health Risks).

RAND assessed the 'value' of the advice provided by the committees within the context of the EU's decision-making processes. Evaluators gathered evidence through a review of literature; depth interviews with Commission officials and members of the committees; and, five case studies, looking at advice provided by the committees.

2. REPORT: KEY FINDINGS AND RECOMMENDATIONS

2.1. REPORT FINDINGS

The report contains a number of important findings. These include:

- There are possible threats to the future credibility and utility of advice because of the difficulty, in an increasing number of areas, of finding experts who are both 'excellent' and 'independent' of stakeholders – this is sometimes referred to as the "excellence gap" and is most pronounced in areas of applied research where expertise lies predominantly in industry;
- There is a lack of clear separation between "risk assessment" and "risk management" recommendations given by committees on some occasions – in a number of instances, reviewed by the evaluators, scientific advisers exceeded their mandates and gave risk management advice;
- There are weaknesses in some of the data on which scientific opinions are based – there is, the evaluators believe, a lack of resources to review scientific evidence and literature, for example;
- There is ambiguity in some of the mandates provided by the European Commission to scientific committees – whenever this occurs, evaluators argue, the possibility of confusion between risk assessment and risk management is present, leading to a lack of transparency in wider decision-making processes;
- There is uncertainty about the best and most appropriate way to make use of additional, external experts – in some instances, committees use external experts to provide additional perspectives on certain issues, and whilst this may help improve understanding there is a need to clarify the way in which such experts are appointed, so as to ensure that trade-offs between 'independence' and 'excellence' are explicit and understood fully.

2.2. REPORT RECOMMENDATIONS

A number of substantial recommendations are set out in the report, including:

- Mechanisms should be set up to ensure that there is more sharing of information across committees;
- Dissemination of the findings of the committees should be improved, most notably through improvements in the clarity of language used;
- Scientific committees should not focus on risk management. To achieve this, the Commission should draft mandates more carefully and, where appropriate, refuse to accept risk management advice from committees;
- Quality of evidence used by scientific committees should be improved by making additional resources available to review data and carry out searches of relevant scientific literature.

3. ISSUES AND ADDITIONAL RECOMMENDATIONS

This is an insightful report and should be welcomed. Its findings and recommendations, if accepted by the Commission and acted upon by officials, will help strengthen the trend to towards improvements in the quality and relevance of scientific advice used in decision-making at EU-level.

Whilst recognising the limitations imposed on RAND by the Commission's terms of reference, the effectiveness of the evaluation could have been further strengthened by the following additional recommendations:

- **Selection of scientific advisers should be based on peer nomination.** Insufficient emphasis is placed on reviewing the processes used by the Commission to select members of the scientific committees. The limitations and weaknesses of self-nomination (using "expressions of interest"), rather than peer nomination of potential experts, are not examined, for example.
- **New mechanisms are needed to expand the potential scientific expertise available to the Commission.** Some OECD governments have, for example, begun to explore mechanisms for managing conflicts of interest and, hence, opening up the scientific advisory process to new 'pools' of talent, particularly in areas of applied research. The report fails to recognise this adequately.
- **Mandates for scientific committees should be drafted in such a way that scientists are only asked to comment on issues for which they are directly and uniquely qualified.** Members of scientific committees should not be asked or permitted to make value judgements. Within its assessment of the mandates provided to the committees by the Commission, the evaluators did not explore fully the problem of "value judgements". Evidence from other sources, suggests that, in some cases, members of committees supplement risk assessments with personal value judgements. In other cases, mandates fail to limit the scope of work, providing the basis for value judgements to be made by committee members.

- **Formal risk communication standards, covering a wide range of substantive and contextual issues, should be introduced.** Although the evaluators recognise the importance of improving communication of the findings of scientific committees, too much emphasis is placed on improving the clarity of language.
- **There is a need to establish, at EU-level, formal and explicit quality standards for the scientific evidence, and its interpretation, that should be used by scientific committees.** These would, for example, require evidence to meet the standards of the scientific method and, where relevant, be peer reviewed. Equally, the importance of establishing common and transparent standards for assessing scientific evidence is not addressed within the recommendations. Such standards would, for example, require evidence to be assessed using the “weight-of-evidence” approach or modern quantified risk assessment tools (rather than worst case or optimistic scenarios) and would limit the scope for “read across” in the event that there are gaps in knowledge.
- **New guidance is needed to ensure that scientific committees do not provide risk management advice.** The extent to which the Commission’s Non-Food Scientific Committees currently provide risk management advice is not recognised fully by the evaluators. In part, this is a result of the lack of explicit guidelines that define risk management and make clear the different roles of scientists and of officials. In one of the case studies, for example, scientists propose the use of a “positive list” and retrospective application of requirement to old products of requirements established for new ones. Both of these are risk management decisions and each embeds, to some extent, a precautionary approach.

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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 reflect or state those of the European Risk Forum or its members.