EUROPEAN RISK FORUM – COMMUNICATION 06

SCIENCE AND DECISION-MAKING – BETTER REGULATION AND THE ROLE OF THE CHIEF SCIENTIFIC ADVISER

January 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

Effective use of science by decision-makers lies at the heart of the EU's Better Regulation initiative. Used well, science provides effective ways of identifying potential risks, protecting citizens, and using resources wisely. It enables decisions to be based on evidence derived from transparent, rational processes designed to enhance legitimacy and trust. Moreover, it provides theories with explanatory and predictive power, enabling policy-makers to anticipate problems and to develop effective solutions.

There is, however, an emerging debate as to the appropriate role of scientific evidence in determining the outcome of legislative and regulatory decisions. Hence, a challenge facing all governments is to ensure that good science retains its central role in policy-making and decision-making processes, whilst taking appropriate account of its limitations.

Considerable progress has been made by the European Commission to improve the quality and credibility of scientific advice to policy-makers, and this is widely recognised by opinion-formers and stakeholders. There are, however, gaps in these reforms, most notably the lack of formal policies and guidelines in key areas (such as the quality of scientific advice, and risk communication), and weaknesses in the institutional architecture, including a lack of resources.

The recent decision by the President of the Commission to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms carried out by the European Commission, and to create the institutional architecture needed to ensure that reliable, well-founded scientific evidence is used effectively to improve further the quality of EU-level legislative and regulatory decisions. In view of this, it is recommended that:

- The Commission's Chief Scientific Adviser should report directly to the President of the European Commission and should be responsible for ensuring the integrity, quality and effective operation of the scientific advisory system.

- The position of Chief Scientific Adviser should be at a level equivalent to that of a Director-General of the European Commission.

- A central unit to support the Chief Scientific Adviser should be established.

- A steering group, chaired by the Chief Scientific Adviser, should be established to oversee and co-ordinate the use of science by the Commission and its agencies.

- The Chief Scientific Adviser should establish a new policy for the collection and use of scientific advice.

- A policy for managing risks posed by new technologies should be drawn up by the Chief Scientific Adviser.

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- A policy for improving public acceptance of the use of scientific evidence in decision-making should be drawn up and implemented by the Chief Scientific Adviser.

- The Chief Scientific Adviser should develop and publish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments.

- The Chief Scientific Adviser should require significant risk assessment opinions to be independently peer-reviewed.

- Mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication") should be drawn up by Chief Scientific Adviser.

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For more than five years, the ERF, and its founders, have consistently highlighted reforms which could, if implemented, improve the credibility, quality, and effective

use of scientific evidence by the EU's institutions. One way in which these goals could be achieved is by a Chief Scientific Adviser, reporting directly to the President of the European Commission, taking responsibility for ensuring the integrity, and effective operation of the scientific advisory system.

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2. SCIENCE AND BETTER REGULATION

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 provides theories with explanatory and predictive power, enabling 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'.

There is, however, an emerging debate as to the appropriate role of scientific evidence in determining the outcome of legislative and regulatory decisions. This has been caused by rising concerns about the limitations of science and the increased importance of 'non-scientific' factors, including social concern and risk perception.

Hence, a challenge facing all governments is to ensure that good science retains its central role in policy-making and decision-making processes, whilst taking appropriate account of the structural limitations of scientific evidence and the increasing importance of non-scientific factors.

Many governments have managed to undertake reforms to improve the credibility, quality and effective use of scientific evidence. Such reforms are interlinked and are designed to change behaviours and the attitudes that underpin them. Reforms fall into three main categories:

- *Overall Policy and Legislative Context* - this provides the framework that is needed to ensure that good science is used effectively when making strategic decisions;

- *Guidelines for the Operation of the Scientific Advice System* - these describe, in detail, the new processes that must be followed. Guidelines also help to improve coherence of activity and to define expected behaviours;

- *Institutional Architecture* – this defines the organisational roles, responsibilities and resources that will ensure that the strategy and its goals are achieved.

Considerable progress has been made by the European Commission to improve the quality and credibility of scientific advice to policy-makers, and this is widely recognised by opinion-formers and stakeholders. 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.

There are, however, gaps in these reforms, most notably the lack of formal policies and guidelines in key areas (such as the quality of scientific advice, and risk communication), and weaknesses in the institutional architecture, including a lack of resources.

The recent decision by the President of the Commission to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms carried out by the European Commission, and to create the institutional architecture needed to ensure that high quality scientific evidence is used effectively to improve further the quality of EU-level legislative and regulatory decisions.

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3. CHIEF SCIENTIFIC ADVISER – ROLE, RESPONSIBILITIES, AND RESOURCES

The organisational role, responsibilities and resources allocated to the Commission's new Chief Scientific Adviser should recognise the contribution that good scientific advice makes to improving regulatory quality and, in turn, to delivering the EU's Better Regulation goals. In view of this, it is recommended that:

- **The Commission's Chief Scientific Adviser should report directly to the President of the European Commission and should be responsible for ensuring the integrity, quality and effective operation of the scientific advisory system.**

- **The position of Chief Scientific Adviser should be at a level equivalent to that of a Director-General of the European Commission.** This will strengthen the importance and legitimacy of the role.

- **The European Commission should establish a central unit in support of the Chief Scientific Adviser.** The unit should build on the work carried out by DG SANCO, and be responsible for:

    - Developing the overall scientific advice policy and the specific guidelines that underpin the operation of the entire advisory system, including Technical Working Groups, Risk Assessment Agencies, and the Commission's independent scientific committees;
    - Providing additional expert resources, advice and support to Scientific Advisory Committees and officials;
    - Enforcing compliance with common guidelines;
    - Auditing the extent to which science is used effectively in policy-making and decision-making processes;
    - Commissioning periodic external evaluations of the operation of the overall scientific advisory system;
    - Producing an annual review of the effectiveness of the scientific advisory system

- **The central unit supporting the Chief Scientific Adviser should ideally be located within the Secretary-General's department of the European Commission,** ensuring an effective link with the implementation and enforcement of other parts of the Better Regulation initiative (most notably the Impact Assessment and Ex Post Evaluation processes).

- **A steering group, chaired by the Chief Scientific Adviser, should be established to oversee and co-ordinate the use of science by the Commission, its agencies, and its Technical Working Groups.** This group should focus on improving the quality, credibility, and utility of scientific evidence used by Commission Services and EU-level risk assessment agencies and Technical Working Groups to support policy-making, secondary legislation and regulatory decisions (including case-by-case adjudications, guidelines, and rule-making).

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- **The Chief Scientific Adviser should establish a new, coherent policy for the collection and use of scientific advice.** The policy should be applied to all stages of the regulatory cycle and to all sources of scientific advice, including formal Scientific Advisory Committees, Risk Assessment Agencies, Technical Working Groups, Comitology Committees (and equivalent bodies set up to implement legislation using the new mechanisms set out in the Lisbon Treaty), and other bodies such as EEA. The policy statement should:

    - Define a set of guiding principles for the collection, assessment and provision of scientific advice;
    - Require legislative and regulatory decisions to be based on the best available science;
    - Describe clearly the benefits and limitations of using scientific evidence to manage risks to human health and the environment; and
    - Provide a comprehensive set of key concepts and definitions used in the provision of scientific advice, including definitions of 'best available science', the 'scientific method', 'uncertainty', 'hazard' and 'risk'.

- **A formal policy for managing risks posed by new technologies should be drawn up by the Chief Scientific Adviser.** This should highlight the important role that well-designed regulation, based on high quality science, can play in supporting innovation. It should, moreover, require risk management legislation to be technologically-neutral and should recognise the negative consequences for citizens of stigmatising new ideas (or products), and locking-in old technologies;

- **A policy for improving public acceptance of the use of scientific evidence in regulatory and legislative decision-making should be drawn up and implemented by the Chief Scientific Adviser.** This should emphasise the role of high quality science in identifying significant risks and in developing effective risk management outcomes. It should also highlight the link between the EU's Better Regulation goals and the use of high quality science as the key knowledge input for risk management decisions.

- **The Chief Scientific Adviser should develop and publish mandatory written principles that define the quality and relevance 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. Appropriate guidance should also be developed to ensure effective and consistent implementation. Guidance should encompass all forms of scientific evidence including epidemiological studies and animal testing.

- **The Chief Scientific Adviser should require significant risk assessment opinions to be independently peer-reviewed**, strengthening the processes used to collect and review scientific evidence. Use of peer review should be limited to 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.

- **Mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication") should be drawn up by Chief Scientific Adviser.** 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.

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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 its members.