

UNDERSTANDING CONFLICTS OF INTEREST AND MANAGING BIAS FOR SCIENTIFIC EXCELLENCE AND IMPARTIALITY

HIGHLIGHTS NOTE 10

As part of the process of implementing laws, scientific assessments should bring together evidence derived from the best available science and expert risk assessment knowledge from within the scientific community to provide high quality, predictable advice on which risk management decisions are based. To achieve this, the most relevant and eminent experts must carry out scientific assessments.

Increasingly, this is difficult to achieve at EU-level as a result of partial and distorting conflict of interest policies that exclude academic scientists because of their involvement with participants in the market economy. Lack of access to the best experts is contributing to failings in the quality of too many of the EU's scientific assessments. This needs to be rectified.

One of the ways of doing this is to develop new policies for the selection of scientific experts that are based on a comprehensive understanding of bias and of the complex conflicts of interest, including ideals and ideologies, that cause it.

This ERF Highlights Note examines the role that scientific assessments play in the management of risk. It highlights the progressive loss of access by the EU to excellent and relevant scientific expertise. It comments on the existing policies used by most parts of the EU's institutions for the selection of scientific experts and shows why these are out-of-date and no longer relevant or useful. Finally, it sets out the broad principles on which a new Commission-wide policy for the selection of scientific experts should be based.

SCIENTIFIC ASSESSMENTS AND RISK MANAGEMENT

Identification, assessment, and management of risks to humans and the environment posed by technologies and lifestyle is one of the principal roles of government. Citizens expect high standards of protection, whilst continuing to enjoy the benefits of investments in science and technology.

To achieve this demanding trade-off, most governments rely upon evidence derived from scientific assessments undertaken by experts. Through these well-established processes, decisions can be made that recognise risk, that demonstrate the benefits of state intervention, and that deliver successful regulatory outcomes.

Expert scientific assessments, used to guide risk management decisions, must meet two criteria, if they are to support the actions of government. On the one hand they must provide the best available advice: the test of excellence. If this standard is not met, then there is a risk of regulatory failure, whereby state intervention creates additional risks (risk-risk outcomes) or significant unintended costs. At the same time, advice must be impartial. It should be provided in the public interest: private concerns, beliefs, ideologies, ambitions or interests should not influence it. If both tests are met then scientific assessments retain their integrity and underpin the legitimacy of regulatory decisions based on them.

This is an ideal: one that developments over the last decade have made increasingly difficult to achieve at EU-level.

EU SCIENTIFIC ASSESSMENT PROCESS – LOSS OF EXPERTISE

The ERF Monograph 'Scientific Evidence and the Management of Risk' (2016) suggests that whilst there are clear examples of excellent scientific assessments, and of the adoption of best practices by parts of the EU's institutions, there remains a clear lack of consistency, transparency, and predictability. In too many cases, scientific assessments do not meet world-leading standards.

A major cause of these failings is the Commission's increasing lack of access to the most eminent and

relevant experts because of the systematic exclusion of academic scientists who work with or advise investors, risk-takers, or private sector businesses. EU regulators appear to believe that materialistic conflicts of interest are the only significant source of bias, and that by recruiting scientists from research institutes or academia who have no links to commercial society this can be avoided.

Such an approach is, increasingly, no longer feasible or desirable. It is based on a series of out-dated assumptions about who undertakes and funds R&D investment (and hence where relevant expertise is to be found); the types of risk societies seek to manage; and the nature of bias, and the conflicts of interest that cause it. Specifically:

• Knowledge generation has become a more complex process, in part reflecting government policy. R&D is, today, primarily undertaken by the private sector itself or through public-private partnerships with academics. Over 85% of all R&D expenditure involves industry directly or indirectly, and safety research, much of it in response to mandatory requirements, is almost entirely funded by the private sector. - Many of the most eminent and relevant academic scientists have established complex and fruitful links with the private sector. Under current Commission guidelines this leads to their exclusion from participation in the process of public risk management.

• The focus of risk management policy has shifted away from managing large well-understood hazards posed by production technologies and towards controlling, smaller more complex and heterogeneous threats to users of product technologies. Effective risk management now requires a greater understanding of the application of technologies, an area of knowledge dominated by industry and its partners in academia. - Access to this knowledge, essential for understanding risk, is lost, when experts are excluded because of their involvement with the market economy.

• Our understanding of bias, and its nature and causes, has advanced too.

BIAS AND THE CONFLICTS OF INTEREST THAT CAUSE IT

When scientific experts provide advice to policymakers and regulators, bias occurs whenever secondary or private interests excessively and unduly influence judgements. This reflects conflicts of interest that inhibit the capacity of the expert to advise impartially and in the public interest.

Modern research suggests that personal biases, even for those acting in the public interest, reflect an extensive range of complex conflicts of interest. Some are conscious whilst others are not. They Include: • **Conflicts based on personal factors**, such as academic or professional ambitions, national cultures or loyalties, familial relationships, and knowledge (or lack of it). – These conflicts are rarely considered when governments select experts but can pose major challenges for impartiality, particularly in international or intergovernmental risk management institutions, including the European Union;

• **Conflicts based on material factors**, such as the potential for financial or corporate gain. These are the focus of most policies used by the European Commission to select scientific experts. – Such conflicts are easy to identify and manage but all too easily are used to exclude the most eminent and relevant experts. Too often there is also a failure to ensure that funding from campaigning groups or to support future advocacy activity is properly identified within this category of conflict of interest; and,

• **Conflicts based on values**, such as personal beliefs, ideals, ideologies, or political affiliations. – These issues are rarely considered when EU institutions select scientific experts, but behavioural research has identified them as potentially the most pernicious. Evidence from good practices elsewhere in the OECD suggests that ideological or similar conflicts can lead to an expert being 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.

It is more appropriate to consider bias as part of the human condition because it provides a mechanism whereby information can be processed in a complex world. We all have it. Thus, the challenge facing the EU's institutions and bodies is not how to avoid bias, rather how to manage it.

ERF OBSERVATIONS

Over the next decade, the demands placed on the EU's scientific assessment process are likely to increase significantly. The volume of activity will increase, whilst the risks posed by ever more complex applications of specialised technologies will need to be assessed, as existing risk management laws mature. At the same time, the way in which cutting–edge knowledge is generated will continue to change, increasingly involving private sector investments in R&D and in partnerships with academia. To meet these challenges, the Commission will require access to the most eminent and relevant scientific expertise.

Without major changes in the way in which scientific experts are selected and their deliberations are managed, these challenges may not be fully met, leading to regulatory failure and a loss of legitimacy. Arguably, this process may well have begun to occur already in a number of complex risk management domains. In the light of this, new approaches are needed for selecting experts for scientific committees or panels that support policy, legislative or regulatory decision-making by EU institutions.

Reform also offers an opportunity to further develop the Better Regulation strategy, to demonstrate a commitment to base decisions on evidence, and to act as a "thought leader" for the EU's Member States.

A new Commission-wide policy for the selection of scientific experts and the operation of scientific committees should be established, possibly as part of new Decision.

Selection of scientific experts should be based on the following broad principles:

• Scientific assessments should be both excellent and impartial.

• Excellence should be achieved through the selection of the best available experts and by meeting internationally-accepted standards for scientific integrity, including those for the assessment of scientific evidence.

• A series of transparent processes should be established to ensure impartiality, supported by appropriate institutional architecture;

• Selection of experts should be based on a comprehensive understanding of bias and of the complex conflicts of interest that cause it;

• The best available experts meeting accepted, transparent standards of eminence, expertise, and relevance should undertake scientific assessments;

• All relevant scientific experts who meet agreed standards of eminence, expertise, and relevance should be considered for selection;

• Rigorous, fair, and transparent processes should be employed to identify all forms of material conflict of interest that are likely to be relevant to the specific work of the expert group, committee, or panel;

• Academic scientists carrying out paid work for the private sector or for activist groups (or for research institutes the pursue a specific social or political agenda) should not be, on its own, grounds for exclusion from serving on scientific committees or panels;

• As a general rule, committees or panels undertaking scientific assessments should seek to manage conflicts of interest rather than exclude appropriately qualified experts;

• Experts should only be excluded from specific scientific assessments if one of the two following conditions are met: (i) there is substantial evidence of predetermination; or, (ii) there is a credible likelihood of direct, material financial gain;

• Experts selected to carry out scientific assessments must commit formally to act impartially and in the public interest;

• Committees or panels that undertake scientific assessments should be institutionally independent and separate from political influence;

 Committees or panels should be constituted so as to ensure that decision-makers have access to an appropriate range of <u>relevant</u> different types of scientific experts from different scientific disciplines;

• Processes used to assess scientific evidence must be predictable, use the scientific method, meet internationally-accepted standards, and be supported by technical guidelines to ensure the quality of evidence;

• Whilst protecting intellectual debate and commercial confidentiality, there is a presumption of openness throughout the process; and,

• Outcomes of scientific assessments should be subject to independent peer review. All draft assessments should be reviewed procedurally, whilst significant assessments should be subject to an additional substantive review

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Richard Meads, the European Risk Forum's Rapporteur, wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.