ACCESS TO 'EXCELLENT' SCIENCE – RECOGNIZING THE PROBLEMS –

HIGHLIGHTS NOTE 04

LOSS OF ACCESS TO 'EXCELLENT' SCIENCE

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 requirements of 'independence' and 'excellence' to be satisfied, if evidence, and related advice, is supplied solely by scientists from academia, and ideally by those without any significant funding links to the private sector. 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.

Inadequate access to private sector 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.

This is, in part, a reflection of government policy. State support for R&D increasingly requires academic scientists to work collaboratively with scientists in industry, thereby increasing the economic impact of research. It is, for example, 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. Axiomatically, the implementation of these strategies will increase scientific knowledge in the private sector in areas of applied knowledge. The importance of industry-funded scientific knowledge is also a reflection of the economic value of R&D to companies. Indeed, data from Eurostat confirms that nearly 65% of gross expenditure in the EU was carried out within the private sector.

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 the 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.

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- **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 behaviour 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 Impact Assessment 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 in designing effective, high quality technical guidelines** – Many risk management goals in the EU are implemented through 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.

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.

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 and impartiality.

ERF OBSERVATIONS

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

Yet policy-makers face the progressive loss of access to some of the best science, and scientific experts, because of the way in which the EU policies for providing scientific advice are increasingly implemented. This is a result of officials responding to two complex challenges: firstly, developing a workable definition of 'independence'; and secondly, responding to growing political and ideological criticisms of industry-funded science.

In the first place, the EU institutions have tended to define 'independence', when considering scientific advice, solely in terms of economic conflict-of-interest. They have moreover tended to use a wide form of this definition, focusing on the origin of studies and experts rather than upon issue-specific conflicts facing individual experts. This definition is incomplete. *'Independence' ought rather to be considered as the capacity to act objectively and impartially when generating and providing scientific advice. This is undermined by two factors: bias and direct economic conflict-of-interest. Any definition of 'independence' should 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.

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. Getting the balance right between 'independent' and 'excellent' is difficult in practice, 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.

December 2015

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.