EUROPEAN RISK FORUM – POLICY NOTE 32

'SCIENTIFIC INTEGRITY, PUBLIC POLICY, AND BETTER REGULATION' EVENT

INSIGHTS FROM PARTICIPANTS AND THE EUROPEAN RISK FORUM

April 2018

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EXECUTIVE SUMMARY

The European Risk Forum (ERF), in collaboration with the Bulgarian Presidency of the Council of the European Union, held a major high-level event in Brussels on Tuesday 20 February 2018. More than 150 invited guests and fourteen eminent speakers, including distinguished scientists, senior officials from the EU institutions, elected representatives, and experts from think tanks and the business community, focused on the theme of *'Scientific Integrity, Public Policy and Better Regulation'*.

This ERF Policy Note is based on their presentations, reflections, and discussions. It groups together the insights of participants into three themes: scientific evidence and regulatory decision-making; integrity of scientific evidence; and possible improvements in the quality of scientific evidence. It is not a record of the meeting nor does it reflect the contribution made by any single speaker or guest. It is a contribution by the ERF to on-going debates about how to improve the quality of regulatory decision-making at EU-level.

Drawing on the insights of participants and in-house research carried out over more than a decade, the European Risk Forum has identified the following reforms which, if implemented, will trigger substantive improvements in the way in which the EU's institutions **use the best available science to guide decisions** throughout the policy cycle:

- **Collectively the EU institutions should, through a revision of the Inter-Institutional Agreement on Better Law-Making, make a formal commitment to make and implement laws on the basis of high quality evidence, using globally-accepted standards of regulatory management and good administration.**

- **Building on its support for research integrity, the Council of EU Ministers should affirm the requirement to use the best available science as the pre-eminent input to inform and guide risk management decisions to protect health, safety, and the environment, by, for instance, adopting dedicated Conclusions.**

- **In response to this political commitment, the European Commission should take all necessary steps to ensure the integrity and quality of scientific evidence used to inform decisions at all stages of the policy cycle.** These should include the following reforms:

    - **A central oversight function with responsibility for ensuring the effectiveness of the entire scientific advisory system should be set up.**

    - **A new Commission Decision should be adopted setting minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect**;

- **Technical guidance, designed to support the integrity and quality of scientific evidence, should be drawn up by eminent scientists and adopted by the Commission.**

European Risk Forum
April 2018

1. BACKGROUND

More than ever the EU institutions are scrutinised closely and held accountable, not only for the decisions they take but the way in which they take them. Scientific evidence is of pivotal importance in this context, underpinning and communicating the basis of decisions. Used well, it provides effective ways of identifying potential risks, protecting citizens, and stimulating innovation. It enables governments to base actions on evidence derived from transparent, rational processes, enhancing accountability, trust, and effectiveness.

Delivering reforms that ensure regulatory decisions are based on the best available science is a natural complement to the EU's Better Regulation strategy. It is one of the most important ways of ensuring high standards of protection for Europe's people and environment, whilst at the same time helping to stimulate investment in the innovations needed to restore growth and prosperity.

Although the Better Regulation Guidelines commit the Commission to use the best available evidence in a transparent manner, significant steps still need to be taken to enhance the EU's governance framework and procedural requirements for the collection and use of scientific evidence. If regulatory processes are to be fully based on the best available science, then it is essential that quality standards, and supporting institutions, policies, and processes, are developed, adopted, and implemented.

In the light of these issues, the European Risk Forum (ERF), in collaboration with the Bulgarian Presidency of the Council of the European Union, held a major high-level event in Brussels on Tuesday 20 February 2018.

More than 150 invited guests and fourteen eminent speakers, including distinguished scientists, senior officials from the EU institutions, elected representatives, and experts from think tanks and the business community, focused on the theme of *'Scientific Integrity, Public Policy and Better Regulation'*.

Specifically, the event set out to:

- Enhance the effectiveness of the Better Regulation agenda by highlighting the role of evidence, particularly science, in regulatory decision-making;
- Champion the development and implementation of quality standards, and supporting institutions, policies, and processes, for the scientific evidence used to guide the EU's regulatory decisions;
- Consider the importance for well-being and prosperity of ensuring that EU policies, laws, and regulations are guided by scientific evidence that meets the evidentiary standards of the scientific method;
- Identify and review obstacles to achieving this goal;
- Highlight progress made by the EU institutions and recognise where more reform is needed;
- Outline specific ideas for the development of new, horizontal technical guidelines that would, if adopted, improve the quality of scientific evidence used to guide decision-making.

Participants addressed all of these issues. The event programme is attached as Appendix A.

At the event, the ERF Monograph *'Scientific Evidence and the Management of Risk'* was presented and discussed[1].

This ERF Policy Note is based on the presentations, reflections, and discussions that took place at the event. It groups together the insights of participants into three themes:

- **Scientific evidence and regulatory decision-making;**
- **Integrity of scientific evidence; and,**
- **Possible reforms to improve the quality of scientific evidence**

This is not a record of the meeting nor does it reflect the contribution made by any single speaker or guest. It is a contribution by the ERF to on-going debates about how to improve the quality of regulatory decision-making at EU-level.

2. INSIGHTS

2.1. Scientific Evidence and Regulatory Decision-Making

Participants identified a number of issues, including:

- Regulation is a **key driver** of economic growth, and hence improvements in employment and living standards. It also contributes to the achievement of fundamental societal goals, most notably protection of health and the environment, as well as sustainability. Regulation should, therefore, be developed transparently, making appropriate use of well-designed consultation mechanisms, and should be soundly based on evidence, particularly science. Good regulation ensures that benefits justify costs.

- Policies, laws and regulations based on evidence encourage investment in **innovation**, whilst, at the same time, ensuring that citizens and the environment are protected. In mature economies, productivity growth, the main source of higher wages and better jobs, depends primarily on innovation. Our aspirations for a more sustainable future also depend on innovation.

- Many of the improvements in the quality of our lives that have occurred over the last fifty years, and which we tend to take for granted, are the result of **investments by the private sector** in scientific knowledge, leading, over time, to innovation. Moreover, because most investment in innovation involves the private sector, incentives to allocate capital to innovation are strengthened when regulatory frameworks are based on science and implementation is predictable.

- **Risk regulations**, and the way in which they are implemented, influence incentives to innovate. When designed well, risk regulations can help to create consumer confidence in the safety and efficacy of technologies. In contrast, poorly-designed regulations can

[1] The ERF Monograph is freely available on the website of the European Risk Forum at http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf_-_scientific_evidence_and_the_management_of_risk_002.pdf.

undermine productivity growth by, for example, reducing access to ideas, diverting resources away from innovation, eroding process efficiency, and increasing the capitalised cost of product development. Poor quality risk regulations also reduce protection for citizens and the environment because they generate, on too many occasions, risk-risk outcomes whereby net risk is increased rather than reduced.

2.2. Integrity of Scientific Evidence

Participants considered the integrity of scientific evidence used by governments to guide policy, laws, and regulations. They made a number of comments. These include:

- It is a general characteristic of Western societies that citizens seek certainty rather than knowledge. This poses problems for the public management of risk, because scientific knowledge cannot guarantee that any action or technology is completely safe. It is, however, the only credible means of identifying hazards and risks. Scientific assessments recognise this **complexity**.

- A major problem facing governments is that the evidential basis of many scientific assessments is weak. Many scientific studies used to guide decision-making are incorrect because their findings are **not reproducible**. Unless the findings of a study can be reproduced by other scientists, or are capable of being reproduced, then they do not meet the standards of the scientific method. They do not form part of the body of scientific knowledge. They should not be considered scientific evidence and any conclusions based on them are problematic, and probably incorrect. Misallocation of public and private resources is one of the consequences of basing government decisions on bad science.

- Reproducibility problems have been identified throughout the natural and physical sciences but are believed to be endemic in social science. Causes include the growth of open access science, allowing low quality studies to circulate widely, and the proliferation of low quality journals, **lacking rigorous standards of scientific quality and peer review**. Too many new scientific journals are of questionable authority and purpose. A further problem is scientific fraud, which occurs for a number of reasons, most notably conflicts of interest due to idealism, ideology, and career ambitions.

- Some leading scientists are aware of this 'reproducibility crisis' and have begun to take steps to highlight its implications and some of its proximate causes, such as **questionable research practices**. Regulation of the risks posed by phthalates provides a good example of the impact of questionable research practices on public policy. A review of nearly 160 epidemiological studies that claimed to show the potential harms of exposure to phthalates revealed that less than 1% had credible research protocols. Indeed a majority had no research protocol at all.

- Epidemiology has made a major contribution to scientific evidence. It has helped to identify important associations between risk factors and disease at a population-level. Such associations are, however, primarily correlative. Any causal inference requires the potential for systematic error in findings to be eliminated, and this is difficult to achieve. A major problem for risk managers is the prevalence of epidemiological studies that appear to show **weak associations**. Too often this has led to false positives and subsequently to poor quality risk regulation.

- Expert scientific assessments, used to guide risk management decisions, must meet two criteria, if they are to support the actions of governments. On the one hand, they must provide the **best available advice**. If this standard is not met, then there is a risk of regulatory failure whereby state intervention creates additional risks (risk-risk trade-offs) or significant unintended costs. Set against this, advice should also be impartial. It should be provided in the public interest: private concerns, beliefs, ideologies, ambitions, or financial interests should not influence it. If both tests are met, then advice, provided by scientific assessments, will retain its integrity, underpinning the legitimacy of regulatory decisions based on it.

- Traditionally, the twin requirements of best advice and impartiality have been achieved through the recruitment of scientists from research institutes and academia. Experts employed within industry or activist groups have been excluded because of the concern that employment creates materialistic **conflicts of interest** that lead to bias. Such an approach is no longer feasible or desirable. It is based on a series of out-dated assumptions about who undertakes and funds R&D investment; the types of risk society seeks to manage; sources of cutting-edge expertise; and, the nature and causes of bias.

- **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 relationships 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. At the same time, the focus of risk management has shifted from managing large, well-established hazards posed by the production of technologies, to controlling, smaller, more complex threats to users of technologies. Effective risk management now involves a greater understanding of the application of technologies, an area of knowledge dominated by industry.

- Expert understanding of **bias**, and its nature and causes, has advanced too. When scientific experts provide advice to policy-makers and regulators, bias occurs whenever secondary or private interests unduly influence judgements. This reflects conflicts-of-interest that inhibit the capacity of the expert to advise impartially and in the public interest. Arguing that bias may undermine the quality of advice and create a perceived lack of impartiality, governments have sought to avoid it by identifying, through a process of disclosure, evident financial conflicts of interest and, thus, excluding certain experts. Whilst this is the general approach taken throughout the OECD area, and the one used by the European Commission, its agencies and other related institutions, it is no longer appropriate. Existing good practice along with recent findings from behavioural psychology, suggests that this approach, with its primary emphasis on material reward factors, is out-of-date and incomplete.

- Instead, today's 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 financial, academic-professional ambitions, power, status, beliefs and ideologies, political affiliations, national cultures, and knowledge (or lack of it). It is now considered more accurate to consider bias as part of the human condition because it provides a mechanism whereby information can be processed in a complex world. Everyone has it. Thus the problem facing officials is not how to avoid bias, rather **how to manage it**.

- EU-level officials face an increasingly **politicised context** when they seek to make high quality, science-based risk management decisions. Recent controversies include political opposition to the re-licensing of Glyphosate and contested definitions of endocrine disruption, reflecting conflicts of values. Manufactured dissent and organised mistrust, often based on partial or bad or poor quality science, increasingly challenges the outcomes of scientific assessments based on good science and expert judgement. Such conflicts threaten to undermine trust in the EU's institutions and make it difficult for them to meet the goals of the Better Regulation Strategy. They reflect, in part, a growth in risk aversion amongst some influential groups within Europe.

2.3. Reforms to Improve the Quality of Scientific Evidence

Speakers and invited guests identified a number of ways in which the integrity of scientific evidence used to support decision-making could be protected and strengthened. These include:

- **Systematic Review** - as a matter of principle, no single study should ever be used to justify regulatory action: use of the power of government should always require significantly more evidence. All scientific research used to inform the regulatory decision-making process must be carried out following correct processes, including Systematic Review, and must meet the internationally accepted standards of best available science. Any deviation from processes or standards should lead to a study being treated as invalid.

- **Quality Standards** - not all scientific evidence used by regulators is of equal quality. Indeed, much is poor. To assist policy-makers and regulators, it is essential to establish clear standards of evidential quality. Adoption of appropriate principles and guidelines will help to filter out low quality studies, improving the quality of advice provided by scientific assessments, and limiting opportunities for politicisation. Standards will ensure that evidence meets the standards of the scientific method and that assessments use Systematic Review.

- **Characteristics of Best Available Science** - principles and guidelines, based on internationally accepted standards, which set out the characteristics of best available science should be drawn up by eminent scientists who are institutionally independent of the EU's institutions.

- **Implementation of Legislation** - social values and public concern play an important part in shaping policy and legislative decisions. Scientific evidence, whilst a privileged knowledge input, provides important additional insights in these initial stages of the policy cycle. In contrast, scientific evidence should be the primary basis for decision-making when laws are implemented. When this does not occur, implementation decisions become unpredictable, regulatory quality deteriorates, negative unintended consequences become more likely, and incentives to invest in innovation are diminished.

- **Selection of Experts for Scientific Committees** - if they are to protect citizens and the environment effectively and without major negative impacts on net risks and prosperity, policy-makers and regulators need access to the best available science regardless of who produces it. This requires developing a new understanding of bias and the conflicts of interest that cause it, so that eminent, relevant experts are not excluded from providing advice and undertaking scientific assessments.

- **Regulation and Evidential Quality** - leading scientific journals and the US National Institutes of Health have undertaken a detailed review of the reproducibility crisis facing the scientific community. Whilst experts recognised that there was no simple way to resolve problems of fraud or reproducibility, it was accepted that steps could be taken to make it more difficult for low quality or fraudulent studies to be published in the most prestigious journals. In response, a number of leading journals have introduced clear quality standards requiring extensive disclosure of and explanation of experimental methods, results and statistical analyses. Policy-makers and regulators should examine these initiatives and identify ways of learning from them, in order to improve the evidential quality of studies used to guide public policy and risk regulation.

- **Epidemiological Evidence and Regulation** - epidemiology will remain an important source of evidence for the management of risk, particularly when experimental evidence is not feasible. Problems of systematic error and questionable research results are best dealt with by the development and adoption of additional, more rigorous guidelines. For example, the Epidemiology Society of The Netherlands has developed detailed guidelines for epidemiological studies covering issues such as study preparation, study conduct, and reporting. It aims to challenge questionable research practices.

- **Public Consultation** - it is important that all contributions to public consultations should be transparent and should be distinguished clearly from evidence derived from formal scientific assessments. Contributions from organisations funded directly or indirectly by governments should be highlighted: citizens and regulators should be aware of situations where government is, in effect, lobbying itself.

- **Regulation of New Technologies** - regulation of new technology should focus on products and their safety: it should be technologically neutral. Design of regulatory frameworks for new technologies should recognise the potential benefits of new ideas, as well as risks. It should also recognise the importance of risk acceptance.

3. CONCLUSIONS

One of the principal objectives of the EU's Better Regulation Strategy is to strengthen the role that evidence plays in informing decisions, at all stages of the policy cycle.

When making decisions about the best way to manage risks to human health, public safety, and the environment, one of the EU's most important policy domains, scientific evidence provides decision-makers with unique insights.

Unlike opinions or values, scientific evidence enables the EU's institutions to identify the existence of hazards and their causes; to determine which hazards pose the greatest risks; to reduce uncertainties; to characterise risks; and, because it is able to identify the potential benefits of government action, to allocate resources rationally.

Public policy interventions based on poor quality scientific evidence are highly likely to result in regulatory failure, leading to welfare losses, reduced protection for citizens and the environment, weakened incentives to innovate, and an erosion of trust in government.

Despite major improvements over the past two decades, significant weaknesses remain in the way in which the EU institutions collect and use scientific evidence to assess and manage risks.

Outcomes are inconsistent and unpredictable on too many occasions; scientific assessments do not always meet global standards of excellence; and too much of the evidence used by regulators fails to satisfy the standards of the "scientific method".

Action is needed to complete the process of reform, so as to ensure that decisions are based on the best available science, and to protect the integrity and quality of the scientific evidence used to inform decision-making.

Delivering reforms that ensure legislative and regulatory decisions are based on the best available science is a natural complement to the EU's Better Regulation Strategy. It is one of the most important ways of ensuring high standards of protection for Europe's people and environment, whilst at the same time helping to stimulate risk-takers to invest in the innovations needed to restore growth and prosperity.

Legislative and regulatory decisions based on the best available science and expert assessment of risk establish a context within which businesses can invest effectively in the innovative products, processes and services needed to up-grade productivity and to create a sustainable future.

4. RECOMMENDATIONS

Drawing on the insights of participants and in-house research carried out over more than a decade, the European Risk Forum has identified the following reforms which, if implemented, will trigger substantive improvements in the way in which the EU's institutions use the best available science to guide decisions throughout the policy cycle:

- **Collectively the EU institutions should, through a revision of the Inter-Institutional Agreement on Better Law-Making, make a formal commitment to make and implement laws on the basis of high quality evidence, using globally-accepted standards of regulatory management and good administration.**

- **Building on its support for research integrity, the Council of EU Ministers should affirm the requirement to use the best available science as the pre-eminent input to inform and guide risk management decisions to protect health, safety, and the environment, by, for instance, adopting dedicated Conclusions.** As well as recognising the unique characteristics of scientific evidence, the Council should highlight the importance for innovation of using the best available science to guide risk management decisions.

- **In response to this political commitment, the European Commission should take all necessary steps to ensure the integrity and quality of scientific evidence used to inform decisions at all stages of the policy cycle.** These should include the following reforms:

    - **A central oversight function with responsibility for ensuring the effectiveness of the entire scientific advisory system should be set up.** It includes overseeing the quality, objectivity, utility, and integrity of scientific evidence and advice used to guide and inform decision-making in all parts of the EU's executive government, including agencies. It should be adequately staffed with relevant experts and be given strong powers to ensure compliance with common policies and guidelines by all directorates and agencies. It must, moreover, be independent of the JRC, EU agencies, and policy DGs;

- **A new Commission Decision should be developed and adopted setting minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect.** These standards should be based on global best practices;

- **Technical guidance, designed to support the integrity and quality of scientific evidence, should be drawn up by eminent scientists and adopted by the Commission.** To begin with, guidance, and supporting principles, should deal with the following:

  - Characteristics of best available science;

  - Design and use of Systematic Evidence Reviews;

  - Nature and use of epidemiological evidence;

  - Procedures for a balanced way of addressing conflicts of interest, and for managing their resultant biases, when selecting scientific experts.

European Risk Forum
April 2018

Richard Meads, the European Risk Forum's Rapporteur, wrote this Policy 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.

EUROPEAN RISK FORUM CONFERENCE

In collaboration with the BULGARIAN PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION

Scientific Integrity, Public Policy and Better Regulation

Tuesday 20 February 2018 (13h30-17h30, followed by a reception)
Venue: University Foundation
Rue d'Egmont 11, B-1000 BRUSSELS

13h30 **Welcome Coffee and Registration**

14h00 **Welcome by the Chair**

- Iliyana ATANASOVA, Counselor, Competitiveness and Growth, Permanent Representation of the Republic of Bulgaria to the European Union

14h10 **Keynote Speakers**

- Wolfgang BURTSCHER, Deputy Director-General, Directorate-General for Research and Innovation, European Commission
- Sir Colin BERRY, Member of the Leopoldina, the German Academy of Sciences

Panel I – Public Policy and Scientific Integrity

- Pearl DYKSTRA, Deputy Chair, High-Level Group of the Scientific Advice Mechanism
- Paul RÜBIG, MEP, First Vice-Chair of STOA Bureau
- Sierd CLOETINGH, President, Academia Europaea, and Member of the Board, Science Advice for Policy by European Academies of Scientific Academy - SAPEA
- Cristina ALONSO ALIJA, Head of Regulatory Affairs Crop Science, Bayer AG
- Jan BAMBAS, Senior Advisor, BusinessEurope
- Robin NELSON, Science Director, CONCAWE

16h00 **Coffee Break**

Panel II – Technical Guidance and the Evidentiary Standards of the Scientific Method

- Dirk HUDIG, Secretary General, European Risk Forum – *A contribution to the debate*
- Alison ABBOTT, European Editor, 'Nature' – *The importance of Integrity in Scientific Publishing*
- Gerard SWAEN, Senior Epidemiologist, Maastricht University – *Enhancing the role of Systematic Review for decision-making*
- Joe HUGGARD, Managing Director, The Huggard Consulting Group – *Scientific Expertise, Understanding Conflicts of Interest, Managing Biases*
- Paolo BOFFETTA, Bluhdorn Professor of International Community Medicine, Mount Sinai School of Medicine New York – *Epidemiology as a source of evidence for assessing and managing risk*

Concluding remarks

- Vytenis ANDRIUKAITIS, Commissioner for Health and Food Safety, European Commission

18h00 **Reception**

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); and

- 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 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.

For more information visit www.riskforum.eu or contact:

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