European Risk Forum

Risk Management and Scientific Assessments – Understanding Conflicts of Interest and Managing Bias for Scientific Excellence and Impartiality

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Foreword

Today, Europe faces the challenge of overcoming a major pandemic and economic slowdown but also stands on the cusp of a "greener", more prosperous future. The European Green Deal is set to transform the economy and society of one of the world's largest trading areas. As it moves beyond its ambitious goals, the EU's Green Deal must develop complex new laws and implement them through countless implementation decisions.

To deliver such a revolution, the EU's institutions must find a way to manage the challenging trade-offs that are embedded in the Green Deal's valued objectives, without diminishing the innovative spirit of Europeans or increasing the net risks that we face as a society or losing the consent of citizens. Central to achieving this will be ensuring that implementation decisions, and the laws that shape and define them, are based on use of the best evidence available.

Recent work by the European Risk Forum (ERF) has highlighted the role that scientific assessments play in providing the expert evidence that informs the development of laws and their implementation. At their best, these processes bring together our best scientific minds and the highest quality scientific evidence. The evidence provided to regulators is a core foundation on which high quality decisions rest, helping to avoid regulatory failure and sustaining legitimacy and hence consent.

To achieve this, scientific assessments must satisfy two standards simultaneously – they must be 'excellent' and 'impartial'. In an earlier Monograph, the ERF examined extensively the concept of scientific excellence[1]. This new Monograph expands those ideas and investigates the concept of 'impartiality' in detail. It addresses, in particular, the way in which the EU implements policies for selecting scientific advisors and managing scientific assessment processes. The Monograph sets out recommendations to ensure that scientific assessments at EU-level can continue to achieve and strengthen world-leading standards of excellence and impartiality.

With this new study, the ERF once again sets out a forward-looking agenda for the EU Better Regulation Strategy, clarifying the comprehensive understanding of bias and the

1 ERF Monograph 'Scientific Evidence and the Management of Risk' (2016)

conflicts of interest from which bias arises. The impartiality, and excellence of scientific assessments cannot be achieved through the a priori exclusion of experts but only by managing conflicts of interest that may arise from financial factors and from predetermined values, ideals, or ideologies.

We are confident that this Monograph will contribute to improving the quality of scientific evidence that is used to guide EU regulators as they seek to deliver the Green Deal, protect citizens from risks, and ensure that we all continue to enjoy the benefits of innovation.

Howard Chase
Chairman
European Risk Forum

Dirk Hudig
Secretary General
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Executive Summary

1. Management of risk and access to scientific expertise

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 innovation.

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

To gain access to the science needed to inform risk management decisions, EU-level regulators and lawmakers rely primarily upon scientific assessments[2]. These expert processes 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. Indeed, scientific assessments are a core foundation on which an evidence-based strategy for decision-making rests.

Over the next decade, the demands placed on the EU's scientific assessment processes are likely to increase significantly, not least because of the urgency of meeting the objectives set out in the EU Green Deal. The volume of activity is also expected to grow as existing risk management laws mature and new ones are developed and implemented. 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 public-private partnerships with academia. To meet these challenges, the Commission will require access to the most eminent and relevant scientific expertise.

2 Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget.)

If they are to be effective scientific assessment processes must meet two tests: they must be excellent, and they must be perceived to be impartial.

Expert scientific assessments used to guide risk management decisions must meet, therefore, two seemingly contradictory criteria. 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 or fails to achieve a high standard of protection. 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 reached then scientific assessments retain their integrity and underpin the legitimacy of regulatory decisions based on them.

Yet, too many scientific assessments undertaken at EU-level are unable to meet these standards of excellence and impartiality because of the way in which policies for selecting scientific experts and the functioning of committees are implemented. These policies continue to focus on material factors, most prominently links of academics to the market economy, as the greatest challenge to the impartiality of scientific assessment processes. This is an out-dated approach that risks excluding the most eminent and relevant experts but without eliminating bias. If fails to recognise the way in which knowledge is generated; the nature of the risks being managed by the EU's Administrative State; and, a comprehensive understanding of bias and the complex conflicts of interest that cause it.

2. Bias and conflicts of interest

When scientific experts provide advice to policy-makers 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.

The latest research suggests that we all have biases, even when acting in the public interest, resulting from an extensive range of complex conflicts of interest. Some are conscious conflicts 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 to perceptions of the impartiality of the outcomes of scientific assessments;

- **Conflicts based on material factors**, such as the potential for financial or corporate gain. These conflicts are largely covered by most policies used by OECD governments and the European Commission to select scientific experts. Such conflicts are easy to identify and manage but they often focus primarily on private sector funding while neglecting other possible sources of material gain. Many often overstate the relevance of historic or indirect relationships.

- **Conflicts based on values**, such as personal beliefs, ideals, ideologies, or political affiliations. These issues are rarely considered across the OECD area. Behavioural research, supported by good practices from leading scientific bodies, 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 predetermination.

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. It is part of the human condition and cannot be totally eliminated.

Accordingly, the challenge facing governments is not how to avoid bias, rather how to manage it. Indeed, when selecting scientific experts, regulators need to address bias in a holistic manner, informed by modern research, with processes and procedures that recognise the potential for resultant bias from all types of conflict of interest and seek to minimise it.

To reflect this, new approaches are being developed throughout the OECD area by national governments, advisory bodies, and scientific institutions. These seek to deliver the twin goals of scientific assessments by combining revised selection procedures for individual experts, thereby delivering excellence, with new processes and procedures for the functioning of scientific committees and management of conflicts of interest, thus ensuring impartiality. Indeed, a body of good practices can increasingly be identified.

3. Scientific evidence and access to expertise at eu-level

3.1. Political, Legal and Policy Framework for the Use of Scientific Evidence

Policies, and associated guidelines, for the selection of scientific experts and functioning of committees form part of the overall political, legal, policy, and institutional framework used by policy-makers to ensure that the best available science is used to guide risk management decisions. In recent years, the European Commission has implemented a number of reforms that recognise the importance of high quality scientific evidence for policy-making. Specific examples include the White Paper on Governance; the Commission's Communication on the Collection and Use of Expertise; the Commission's Better Regulation Policy; and the Commission Decision establishing the Scientific Advice Mechanism.

Despite these improvements, there are a series of important weaknesses in the EU's overall framework for ensuring that the best available science guides risk management decisions. Specifically:

- Public support from politicians at the highest level is an essential pre-condition for the use of the best available science as the pre-eminent knowledge input for the management of risk. At EU-level, these commitments have been unsystematic, ambiguous, fragmented, and limited thus far.

- A characteristic of the most effective scientific advisory systems is the presence of a strong central oversight body equipped with the authority and institutional power to establish and enforce common standards for the quality, collection, and use of scientific evidence, including the functioning of scientific committees. There should also be formal mechanisms for sharing good practice. No such powerful, horizontal institutions exist at EU-level.

- One of the most important characteristics of the best scientific advisory systems is the presence, within the legal framework, of laws of administrative procedure that require the executive function to adhere to standards of good administration when implementing laws, including those designed to manage risk. No such law has currently been adopted at EU-level, despite the presence, in the Treaty, of legal bases enabling its establishment.

- Powerful, mandatory horizontal policies and guidelines are a common feature of the most effective scientific advisory systems. They are designed to ensure that advice and evidence are of the highest quality; that processes of scientific assessment are consistent; and, that standards of good administration are met. There are weaknesses and major gaps in the EU's policy framework that make it difficult to achieve this standard. There are, for example, no common requirements for scientific evidence or for the selection of scientific experts. There are also no common rules of procedure for the functioning of scientific committees or common standards for risk analysis.

3.2. Scientific Assessments, Access to Expertise, and Impartiality

At EU-level, there is clear evidence of a number of good practices that could, along with additional improvements, form the basis of an effective framework of policies and guidance to ensure that scientific assessments meet the twin tests of excellence and impartiality. Examples of good practices can be found in the 2013 Common Rules of Procedure for the Independent Scientific Committees; the requirement for peer review of scientific assessments adopted by EMA; and, the requirements for excellence and independence set out in the Commission's Better Regulation Guidelines and in the Decisions setting up the Independent Scientific Committees and the Scientific Advisory Mechanism;

However effective these practices are in their specific areas of application, they do not constitute a cohesive, 'horizontal' framework of policies and guidelines. Indeed, no consolidated horizontal Commission-wide policy has yet been adopted for the selection of scientific experts and the functioning of scientific committees that reflects a comprehensive understanding of the nature of bias and the complex conflicts of interest that cause it, the way in which knowledge is generated in modern economies, and, the nature of the risks managed at EU-level. Indeed some agency-level and Commission-wide policies may act to limit access to expertise but without eliminating bias. EMA, ECHA, and EFSA, for example, continue to focus unduly on financial links and relationships of academics with the market economy as the primary challenges to the impartiality of experts.

In too many cases, EU regulators charged with securing scientific advice continue to deem the requirements of impartiality and excellence to be satisfied, if evidence and advice is solely provided by scientists from academia without material links to the market economy. It is assumed that the trade-off between independence and excellence can be achieved

primarily through the systematic exclusion of academic scientists who work with 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. By doing this, regulators believe that they can ensure that experts act impartially, hence maintaining trust in the advice provided by scientific assessments.

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. Its continued application increases the risk of regulatory failure because of the resulting lack of access to expertise this approach causes.

A further problem for decision-makers is that excluding academics with links to the market economy from the scientific assessment process, because they are deemed not to be 'independent' due to the impact of materialism on their capacity to act impartially, does not at the same time guarantee that the remaining sources of advice will be either 'independent' or 'excellent'.

Scientists untainted by links to commercial society or the market economy may, in many policy areas, lack detailed, current, or relevant knowledge, limiting the quality of their contributions. Some may also be unable to act impartially. They may, for instance, receive funding from campaigning groups, creating an obvious economic conflict-of-interest. Alternatively, they may be predetermined in their approach to a problem, 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 because of their idealistic or ideological conflicts of interest. Moreover, the legitimacy of risk management decisions may be undermined if advice is tainted due to the influence of advisers whose views are predetermined by non-materialistic conflicts.

4. Recommendations

This ERF Monograph sets out a programme of reform that, if implemented, will help ensure that scientific assessments, the foundation on which high quality risk management measures rest, are excellent and impartial. To achieve this, the reforms focus on the underlying and proximate causes of the failings of the current EU-level approach, and build on existing good practices in the Commission and elsewhere.

The following actions should be taken over the next 1-3 years:

- 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 human health, public safety, and the environment by, for instance, adopting dedicated Conclusions.

- The **EU Legislature** should, building on the work of the European Parliament, develop and adopt a comprehensive Law of Administrative Procedures;

- The **European Commission** should revise the mandate of the Scientific Advice Mechanism to establish explicit and formal oversight mechanisms to ensure the effective functioning of the entire scientific advisory system;

- The **European Commission** should expand the mandate of the Regulatory Scrutiny Board (RSB) to ensure that all scientific assessments used to justify individual risk management measures have been subject to a relevant and appropriate peer review;

- The **European Commission** should establish, for instance in a new Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect;

- The **European Commission** should set out, for instance in a new Decision, the key principles for the selection of scientific experts and the operation of scientific committees that reflect a comprehensive understanding of bias and the complex conflicts of interest that cause it, and the way in which knowledge is generated in modern economies;

- The **European Commission** should develop guidelines for the selection of experts and functioning of committees. They should be based on a comprehensive understanding of bias and of the complex conflicts of interest that cause it. They should set out ways in which conflicts of interest can be managed such that regulators gain access to the most eminent and relevant expertise.

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Introduction

1. Background

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. It is most readily associated with government actions to protect people at work and to protect citizens and the environment from harms posed by technologies and lifestyle choices.

In managing these risks, scientific evidence has been the key knowledge input for decision-making throughout the "regulatory cycle". Used well, science provides effective ways of identifying potential risks, protecting citizens, stimulating innovation, and using resources wisely. It also enables governments to base actions on evidence derived from transparent, rational processes, enhancing accountability, trust, and effectiveness.

Looking forward, demand from the EU's institutions for excellent, high quality science is likely to increase, as the policy domains for which risk assessments are required expands; 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. 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 as well as public-private partnerships with academia. To meet these challenges, the European Commission will require access to the most eminent and relevant scientific expertise.

In the face of these requirements, and recognising the importance of high quality science for decision-making, the European Commission has, since the late 1990s, made considerable progress to improve the quality and credibility of scientific advice provided to decision-makers. A network of independent scientific committees has been established, along with new risk assessment agencies in areas including food safety, chemicals, and medicines[3]. A broad policy structure has also been put in place. In addition, the Scientific Advisory Mechanism has been established to provide independent scientific advice to the European

3 See for example, European Commission 'Commission Decision on establishing Scientific Committees in the field of Public Health, Consumer Safety, and the Environment' (2015, C(2015) 5383) – this updates the original 2008 Commission Decision.

Commission[4]. These improvements have been widely recognised by opinion-formers and stakeholders.

Despite the well-understood benefits of using high quality scientific evidence to manage risks, the appropriate role of science in decision-making is nonetheless increasingly contested. Some opinion-formers argue for greater use of precaution, supported by social concern or by evidence derived from hypothesis-forming science, discredited science, or low quality studies rather than assessing risk using widely accepted high quality studies. Others argue that science should be treated as just one of a number of equally 'valid' opinions, rather than respecting the strengths and qualities of the "scientific method".

Yet the influence of these opinions on stakeholders is not the only challenge facing EU policy-makers. Of equal concern is **the progressive loss of access to some of the best science, scientists, and scientific advisers, because of the way in which the EU's policies for providing scientific advice are increasingly implemented.**

EU policies require scientific advice to be 'independent', 'excellent' and 'transparent'. It is recognised that getting the balance right, in practice, between 'independence' and 'excellence' is difficult, 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.

Without major changes in the way in which scientific experts are selected and their deliberations are organised, the EU may be unable to fully meet its future risk management challenges, leading to regulatory failure and a loss of legitimacy. Arguably, this process may well have begun to occur in a number of complex risk management domains.

In the light of this, new approaches are needed for selecting, and organising, experts for scientific committees or panels that support policy, legislative or regulatory decision-making by EU institutions. A new approach is needed that focuses on ensuring that the overall process of undertaking scientific assessments delivers outcomes that are excellent and impartial. To achieve this, any such policy should take account of the risks that the EU seeks to

4 European Commission 'Commission Decision establishing the High Level Group of Scientific Advisers' (2016)

manage; the way in which scientific knowledge is generated; and the most up-to-date understanding of bias and of the conflicts of interest that cause it.

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[5].

2. Objective

This Monograph examines the selection, and organisation, of experts for EU bodies and committees that undertake scientific assessments for the EU's institutions, specifically when they develop or implement risk management laws. It highlights the importance of the quality and impartiality of advice provided by scientific assessments for the effectiveness and legitimacy of risk management decisions, including those made by the EU's Administrative State when implementing legislation. It assesses the problems associated with the traditional approach to selecting experts to participate in the scientific assessment process. It examines the policies and practices that determine how the EU institutions select experts for the scientific assessment process. It highlights good practices, along with weaknesses and failings.

Its principal aim is to set out a new policy framework for the selection of scientific experts and functioning of committees. If implemented fully, these recommendations will ensure that scientific assessments supporting EU risk management decisions meet world-leading standards of excellence and impartiality, and thereby assist the EU institutions in realising the objectives set out in the Better Regulation Policy.

Finally, the Monograph builds on and complements work carried out by the European Risk Forum (ERF) team over the last decade, including the findings and conclusions of the 2016 ERF Monograph *'Scientific Evidence and the Management of Risk'*, and the recently published 2019 ERF Monograph *'Risk Management and the EU's Administrative State – Implementing Law through Science, Regulation, and Guidance'*.

5 European Commission 'Better Regulation for Better Results – An EU Agenda' (2015, European Commission, COM (2015)) – this was up-dated in 2017.

3. Scope

Reflecting the wider goals of the European Risk Forum, this Monograph focuses on the selection of experts and the organisation of the deliberations of scientific assessments within the process of managing risks posed by the production and use of technologies, and by lifestyle choices, to human health, public safety, and the environment.

It focuses primarily on assessments of evidence derived from natural and physical sciences and engineering because of their importance for understanding and managing risks posed by the production and use of technologies.

The selection of experts to undertake scientific assessments is considered at all stages of the policy cycle, including policy formulation, legislation, and implementation, by the EU's Administrative State, through regulations and substantive guidance.

4. Methodology and Report Structure

The findings, conclusions, and recommendations set out in this Monograph are the result of a long-term programme of research carried out by the ERF team over a four-year period beginning in 2016.

The programme of research encompassed three strands of work: confidential in-depth interviews with a wide range of experts; meetings with experts to debate insights and ideas; and an extensive desk research exercise.

More than 40 confidential in-depth interviews were undertaken with eminent scientists, academic experts, legal scholars, scientific advisers and government officials in Member States, science journalists, members of the secretariat of EU institutions, MEPs, senior officials from several policy directorates of the European Commission and from EU risk assessment agencies, and experts from companies and business organisations.

In order to further examine ideas and insights developed by the ERF team, the findings were presented to a wide range of experts at meetings hosted by business organisations, OECD, the European Parliament, and a number of European Commissioners. Further

expert discussions took place at meetings of the ERF Risk Forum and the ERF Scientific Evidence and Management of Risk Task Force held in 2018 and 2019.

An extensive desk research exercise was also carried out. It reviewed academic literature; OECD publications; policies and guidelines used by scientific publications, academic bodies, scientific institutions, and governments throughout the OECD area and EU Member States; and, EU policies and guidance.

The Monograph is structured in a number of Chapters:

- In the first part (Chapter 2), the role that scientific evidence plays in managing risk is considered. It identifies why decisions have, traditionally, been based on the best available science. It highlights the importance of scientific assessments in developing the evidence that informs risk management decisions, and comments on the challenges faced by these critical processes. It finishes by examining the use of scientific assessments at EU-level and identifies strengths and weaknesses.

- Chapter 3 examines bias and the conflicts of interest that cause it. Utilising findings from the latest research, supported by practices employed by leading scientific institutions, this chapter highlights a comprehensive approach to understanding the interaction between bias and its causes. It recognises that personal biases, even for those acting in the public interest, reflect an extensive range of conflicts of interest. Bias is a problem to be managed: it cannot be avoided, simply by excluding experts on the basis of economic factors. This diminishes excellence without enhancing impartiality. Indeed, it may, in certain instances, erode legitimacy because conflicts of interest that are the result of values or political beliefs are not identified or managed. A new framework for selecting experts and for managing the process of scientific assessments is provided.

- Chapter 4 sets out a good practice framework. Based on a detailed review of policies and guidelines developed by other OECD governments, EU bodies, academic groups, and scientific institutions, it sets out a framework of ideas that, taken together, ensure that scientific assessments are able to meet world-leading standards of excellence and impartiality. It provides a set of benchmarks against which to compare the EU's approach to the selection of experts for the conduct of scientific assessments.

- Chapter 5 maps and reviews the EU's policies and guidance for the selection of experts for the processes of scientific assessment. It includes an assessment of current practices that makes extensive use of the good practices framework and the findings from the programme of interviews. It highlights good practices and strengths. Weaknesses and issues are also identified.

- In the final parts of the Monograph conclusions are set out (Chapter 6), along with recommendations for reform (Chapter 7).

Scientific evidence and risk management

1. Science and the Management of Risk

When making decisions about the best way to manage risks to human health, public safety, and the environment, scientific evidence provides decision-makers with unique insights.

'Science' is a way of looking at the world through the testing of hypothetical explanations of the behaviour of natural or man-made systems. It is based on rationality. Through inductive and deductive reasoning science seeks to establish cause-and-effect relationships based on evidence rather than dogma, beliefs, values, opinions, common sense, feelings, or superstition.

It is a process of enquiry: the "scientific method". It is designed to be objective and to limit the impact of bias. It is governed by a rigorous methodology and principles of verifiability, reproducibility and scientific integrity. Findings from one set of experiments must be documented, reproduced by other independent and similarly qualified scientists and subject to independent peer review, before they become accepted as part of the existing body of knowledge. They must also meet tests of methodological soundness, and of falsifiability. Scientific findings, moreover, remain provisional and subject to challenge.

Though science is not an encyclopaedia of facts, well-established scientific methods and theories have proven to be highly effective in identifying risks posed by technologies and in developing ways to mitigate them without damaging economic activity, or possibly enhancing it.

Uniquely, scientific evidence enables governments to:

- Identify the existence of hazards, and their causes;
- Determine which hazards pose the greatest risks to human health or the environment;
- Reduce uncertainties in decision-making;
- Characterise risks;
- Identify the existence of new, unintended risks that might be created through government action;
- Develop technologically effective strategies to manage risks;
- Identify future and emerging hazards;
- Identify the benefits of government action;
- Avoid targeting inconsequential problems whilst ignoring greater risks; and
- Allocate resources efficiently

Moreover, experience of governments throughout the OECD area, built up over more than 150 years, suggests that basing risk management decisions on the best available science and expert assessments of risk, leads to a series of wider beneficial outcomes. These include greater regulatory quality; enhanced legitimacy; better protection of human health, public safety, and the natural world; more efficient use of social resources; less trade friction; and stronger incentives to innovate. If these benefits are to be achieved, then scientific assessments must be undertaken by leading experts and utilise the best available science.

2. Scientific Assessments and Evidence

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 innovation and technological progress[6].

To achieve this demanding trade-off, most governments rely upon evidence derived from scientific assessments undertaken by experts[7]. The latter are well-established processes that allow decision-makers to recognise risk, demonstrate the benefits of State intervention, and deliver successful regulatory outcomes.

Scientific assessments, including risk assessments, are one of a large number of expert processes used by the executive function of government to implement laws and as such form part of the so-called "administrative state". They are the most important source of evidence for the management of risk. They bring together evidence derived from the best available science and expert risk assessment knowledge from within the scientific community to provide high quality advice on which risk management decisions are based. This includes regulation, as well as the complex substantive guidance needed to interpret legislative requirements.

Today, thousands of expert scientific assessments are carried out each year. Most are undertaken to implement the requirements of complex risk management laws that often encompass the production or use of technologies. They include actions by companies to ensure compliance with product standards; mandatory reviews of regulated technologies by government advisers; and, advice on emerging issues provided to regulators by panels of eminent scientists.

Over the next decade, the demands placed on the EU's scientific assessment process are likely to increase significantly, not least because of the urgency of meeting the objectives set out in the EU Green Deal. The volume of activity is expected to increase as existing risk management laws mature and new ones are developed and implemented. At the same time, the way in which cutting–edge knowledge is generated will continue to change,

6 See, for example, Moss D.A. 'When All Else Fails – Governments as the Ultimate Risk Manager' (2002)

7 Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget.)

increasingly involving private sector investments in R&D and in public-private partnerships with academia. To meet these challenges, the Commission will require access to the most eminent and relevant scientific expertise.

At their best, scientific assessments are impartial and excellent. A number of conditions help achieve these two standards:

- Eminent, relevant experts undertake assessments;
- Findings are based solely on credible, relevant, and high quality scientific knowledge;
- Assessment of evidence uses accepted theories that respect accumulated wisdom, the scientific method, and reflects the weight of evidence;
- Use of the Precautionary Principle is avoided at this stage;
- Important assessments are subject to independent peer review; and,
- Scientific integrity is respected by adherence to agreed principles and guidelines.

Expert scientific assessments used to guide risk management decisions must meet, therefore, two apparently contradictory criteria. On the one hand they must provide the best available advice: the test of excellence. If this standard is not met, a risk of regulatory failure ensues, 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.

3. Scientific Assessments at EU-Level – Insights from the ERF

The ERF Monographs *'Scientific Evidence and the Management of Risk' (2016) and 'Risk Management and the EU's Administrative State – Implementing Law through Science, Regulation, and Guidance'* (2019) suggest that whilst there are clear examples of excellent scientific assessments, and of the adoption of best practices by parts of the EU institutions, there remains a clear lack of consistency, transparency, and predictability.

In too many cases, EU-level scientific assessments do not meet world-leading standards, and regulators have not acknowledged sufficiently that not all science is of an equal standard of quality. In addition, EU-level conflict of interest policies increasingly exclude eminent and relevant academic scientists because of their involvement with the market economy, thereby limiting access to the best experts but without eliminating bias.

Specific problems include:

- **Undue influence of old or low quality or unscientific evidence in scientific assessments** – most EU risk management legislation requires companies to demonstrate the safety (and sometimes efficacy and quality too) of new and existing technologies using internationally-recognised standards. In some instances they also require scientific assessments to consider all known studies.

  Good practice suggests that this provision should not, however, require poor quality studies or other inappropriate forms of evidence to influence the final outcome of an assessment, rather that there should be a rational and scientific process for considering and, where appropriate, excluding such studies and forms of evidence.

  Final scientific assessments by the EU's scientific advisory processes, however, are not always based solely on scientific studies or evidence that meets accepted standards of quality. In a number of cases, the outcomes of scientific assessments appear to have been shaped by studies that no longer reflect scientific knowledge or are inappropriately interpreted or do not meet the standards of the scientific method. As a result of this, there have been, on too many occasions, inconsistencies in evidential standards, leading to poor quality scientific assessments (Exhibit 1).

EXHIBIT 1

LOW QUALITY SCIENTIFIC STUDIES – SOME CHARACTERISTICS

- Out-of-date studies that fail to reflect modern scientific understanding, have been discredited or even retracted;
- Experimental, investigative studies that do not form part of the body of scientific knowledge;
- Untested theories of harm;
- Novel hypotheses;
- Inappropriate or irrelevant exposure methodologies;
- Environmental impact models without publicly available data or assumptions;
- Weak epidemiological studies that fail to meet well-established standards of quality and utility;
- Failure to identify questionable research practices (such as citation bias);
- Inaccurate statistical analysis;
- Failures to differentiate adequately between correlation and causation; and,
- Hypothesis-forming assumptions without robust scientific justification.

Source: ERF Monograph *'Risk Management and the EU's Administrative State: Implementing Law, through, Science, Regulation, and Guidance'* (2019)

- **Inappropriate application of the Precautionary Principle within scientific assessments** – EU institutions recognise formally that the Precautionary Principle should only be applied during the risk management phase of the overall process of risk analysis. It should not be used within the process of assessing risk[8].

  Scientific assessments undertaken at EU-level do not always demonstrate that this requirement is respected fully. Instead, there is evidence of inappropriate application of the concept of systematic precaution, unjustified by long-established approaches of toxicology, within the process of scientific assessment (Exhibit 2).

- **Inadequate expertise of some Technical Working Groups and Scientific Committees** – as a means of taking advantage of the scientific expertise within the Member States, and of increasing political support for difficult technical decisions, the EU institutions use Technical Working Groups (TWGs) and Scientific Committees to undertake scientific assessments in some areas. TWGs and Scientific Committees comprise representatives, with relevant expertise, from each Member State government. In some cases, these groups function well, providing predictable, high quality scientific assessments. In other cases, however, assessments do not meet world-leading standards or are inconsistent or are based on poor quality science.

  These problems are due to a diverse range of factors including inequalities of scientific knowledge between Member States; failure to appoint eminent experts; pursuit of national political goals rather than assessment of scientific evidence; lack of relevant up-to-date scientific knowledge; and over-ambitious mandates that stretch expertise too thinly, leading to major gaps in scientific and technical knowledge.

- **Lack of expertise of some independent scientific assessment committees** – in some policy areas, committees of independent scientists provide scientific assessments, thereby enabling the EU institutions to make use of the expertise that lies within the EU's wider scientific community. At its best, this approach has helped to improve the quality of scientific assessments used to guide risk management decisions.

8 European Commission 'Communication from the Commission on the Precautionary Principle' (2000, COM (2000)1)

EXHIBIT 2

INAPPROPRIATE APPLICATION OF THE PRECAUTIONARY PRINCIPLE WITHIN SCIENTIFIC ASSESSMENTS – EXAMPLES

- "Cherry picking" data or studies that support precautionary action;
- Unscientific reliance on poor quality studies;
- Failure to ensure that scientific assessments are based on the weight-of-evidence derived from modern Systematic Evidence Review;
- Failure to rank studies, using internationally accepted standards, on the basis of quality and relevance;
- Failure to exclude low quality studies;
- Unjustified use of worst case and hypothetical exposures;
- Exclusion of high quality "nil effect" studies;
- Drawing conclusions based on single studies or 'outliers';
- Hidden precautionary defaults or assumptions, such as no threshold exposure or read across assumptions employed without credible scientific justification;
- Reliance on models and academic studies unrelated to real world experience; and,
- Application of excessively conservative defaults and other bridging assumptions not justified by scientific evidence.

Source: ERF Monograph *'Risk Management and the EU's Administrative State: Implementing Law, through, Science, Regulation, and Guidance'* (2019)

Increasingly, however, important weaknesses have become apparent. These include a lack of understanding of risk assessment practices in industry or of real world uses of substances and technologies; lack of cutting edge scientific knowledge in new areas such as mathematical modelling; and a lack of scientific eminence.

These weaknesses are the result of a range of factors: low rewards for participation; appointment on the basis of criteria other than excellence; and 'ad hominem' criticisms of scientists. It is also a direct result of the way in which conflict-of-interest rules are applied by the Commission and its agencies, leading to the exclusion of many leading experts because of their work with the market economy.

- **Exclusion of academic and other experts with links to industry** – in most of the areas regulated by EU risk management laws, scientific advances, and accompanying safety research, take place primarily within industry. Today, over 85% of all of R&D carried in the EU involves industry funding or, reflecting the goals of wider innovation promotion policies, partnerships between the private sector and research institutes or universities. Access to this knowledge is essential if scientific assessments are to be of the highest quality, thereby protecting citizens and avoiding regulatory failure[9].

  Too often, this knowledge is not available to decision-makers because scientists are excluded from advising EU institutions because they currently work with industry or have worked with business in the past or are perceived to have financial or other links with the private sector. This is an emerging, but clear, trend and its impact will worsen over time, as leading scientists are forced to choose between working alongside the private sector at the cutting edge of science or advising EU institutions.

  At the same time, the exclusion of scientists with links to the market economy makes it more difficult for policy-makers to understand how knowledge is developed in modern economies. This also makes it more difficult for regulators to understand and take into account, dynamic impacts on innovation and investments in research when designing and implementing regulatory interventions.

9 It is to be noted that industry-funded research and knowledge is playing a critical role in the search for vaccines to combat COVID-19, and for advanced, rapid diagnostic technologies to detect its presence. Exclusion of such expertise and knowledge, because of links to commercial society and the profit motive, is unlikely to be viewed by citizens as being in the public interest.

- **Failure to ensure impartiality of all scientific experts** – good practice requires all forms of conflicts of interest, including material and non-material factors, to be considered before appointing scientists to expert groups. The purpose is to highlight all potential factors that might undermine the capacity of an individual to act impartially and in the public interest. This acts to increase public trust in the utility of scientific assessments and to increase confidence in the competence of public risk management institutions.

  At present, tests of commitments to ideologies or ideals appear not be applied systematically and rigorously to prospective scientific experts by the EU institutions. Unless this is done, ideological or emotional narratives rather than the quality of scientific evidence may unduly influence the outcomes of scientific assessments. This reduces the effectiveness of risk management rules and, if such failings are revealed publicly, erodes trust.

One of the most important causes of these problems is the failure to ensure that the most eminent relevant experts undertake scientific assessments.

Global good practices require that scientific assessments, including those used to implement risk management laws by the EU Administrative State, should be undertaken by the most eminent and relevant experts and that all conflicts of interest, including personal, values and financial, be considered prior to the appointment of experts.

Bias and the extensive conflicts of interest that cause it

When scientific experts provide advice to policy-makers 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.

The latest research suggests that we all have biases, even when acting in the public interest, resulting from an extensive range of complex conflicts of interest. Some are conscious conflicts 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 to perceptions of the impartiality of the outcomes of scientific assessments, 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. Potential financial rewards include employment relationships, consulting relationships, investments in financial instruments, intellectual property, research funding, and other forms of research. Competitive advantage may be created because of the opportunity to gain access to confidential information during the course of a scientific assessment.

  These conflicts are largely covered by most policies used by OECD governments and the European Commission to select scientific experts. Such conflicts are easy to identify and manage but they often focus primarily on private sector funding while neglecting other possible sources of material gain. Many often overstate the relevance of historic or indirect relationships.

- **Conflicts based on values**, such as personal beliefs, ideals, ideologies, or political affiliations.

  These issues are rarely considered across the OECD area. Behavioural research, supported by good practices from leading scientific bodies, 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 predetermination.

  Ordinarily, predetermination occurs because of the close identification or association of a potential expert with a particular point of view or the positions of a particular group to such an extent that he or she is unwilling or reasonably perceived to be unwilling to consider other perspectives or relevant evidence to the contrary. Predetermination is largely intellectually or emotionally motivated and is reflected in personal beliefs, commitments, ideological perspectives, or intensely advocated policy positions.

Different types of evidence provide indications of predetermination, including public positions and statements, research focus, activism, memberships and affiliations, and employment or advisory roles. Relevant evidence will frequently encompass patterns of activity over a number of years.

Scientific assessments unduly influenced by predetermination amongst experts may fail to provide regulators with the best possible advice whilst at the same time undermining perceptions of impartiality.

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. It is part of the human condition and cannot be totally eliminated.

Accordingly, the challenge facing governments is not how to avoid bias, rather how to manage it. Indeed, when selecting scientific experts, regulators need to address bias in a holistic manner, informed by modern research, with processes and procedures that recognise the potential for resultant bias from all types of conflict of interest and seek to minimise it.

To reflect this, new approaches are being developed throughout the OECD area by national governments, advisory bodies, and scientific institutions. These seek to deliver the twin goals of scientific assessments by combining revised selection procedures for individual experts, thereby delivering excellence, with new processes and procedures for the functioning of scientific committees and management of conflicts of interest, thus ensuring impartiality. Indeed, a body of good practices can increasingly be identified.

Good practices from OECD countries

This chapter consolidates and summarises good practices that focus on designing an overall approach to managing conflicts of interest. This includes collection and use of scientific evidence, the selection of experts, and the operation of scientific committees[10].

1. Overall Approach

Policies, and associated guidelines, for the selection of scientific experts and functioning of committees form part of the overall political, legal, institutional, and policy framework used by policy-makers to ensure that the best available science guides risk management decisions designed to protect man and nature from technological risks. Indeed, they are unlikely to be effective in shaping the collective behaviour of policy-makers and regulators unless they form part of, and are supported by, this wider governance framework. In the light of this, any set of good practices must include the key dimensions of this overall framework.

Awareness amongst scientists and policy-makers of the difficulties of ensuring that scientific assessments are both excellent and impartial is not new. Guidance developed by the US National Academy of Sciences in 2003, for example, highlighted the risks to perceptions of impartiality, if the ideological or similar commitments of potential experts are not identified. Indeed, the guidance concluded that the threat posed by such intellectual or emotional conflicts of interest to both excellence and impartiality was, because of the possibility of predetermination, at least as pernicious as the challenges posed by material conflicts[11].

Over the past two decades things have begun to change. A number of leading scientific institutions, advisory bodies, and national governments have developed new ways of

10 This framework is derived from a review of initiatives undertaken by governments, scientific bodies, and academic institutions in Australia, Canada, France, Germany, Hungary, Italy, Latvia, Netherlands, New Zealand, Poland, Portugal, Spain, Switzerland, UK and USA. It is also informed by work undertaken by the European Commission's Scientific Advisory Mechanism, and more than a decade of research by the ERF team, and expert contributions by the ERF's advisors, and participants in Risk Forum meetings.

11 US National Academy of Sciences 'Policy on the Committee Composition and Balance of Conflicts of Interest for Committees used in the development of reports' (2003)

identifying and managing conflicts of interest, selecting scientific experts, and structuring more formally the functioning of scientific committees.

New ideas have been put forward at EU-level as well. A recent formal opinion of the European Commission's Scientific Advisory Mechanism highlighted the need to make use of the comprehensive understanding of bias, and the wide range of conflicts of interest that cause it, when selecting scientific advisors. It also recommended establishing a new institutional architecture for developing and implementing horizontal standards of scientific integrity[12].

Analysis of these international and EU activities, complemented by insights from behavioural research, insights from experts, and detailed long-term work by the ERF, highlights a framework of good practices that ensure that scientific assessments are excellent and impartial.

Rather than providing a rigid and prescriptive approach, the framework provides a benchmarking model against which to assess the current activities at EU-level and to highlight areas of possible reform.

2. Good Practices – Scientific Evidence and the Management of Risk

These practices include:

- Politicians at the highest level of government make **formal, public commitments** to use the best available science as the pre-eminent knowledge input to inform and guide risk management decisions, recognising its unique insights;

- There is a **central oversight body**, reporting directly to the head of government. It is responsible for the effective governance of the process of collecting, and using scientific evidence;

- Legislative requirements include a **law of administrative procedures** that establishes due process standards for the implementation of laws by the executive

12 European Commission 'Scientific Advice to European Policy in a Complex World' (Scientific Opinion No. 7 by the Group of Chief Scientific Advisors, 2019)

function that can be subject to judicial review and which embed the major principles of good administration;

- A clear, government-wide policy requires government decision-making to be guided by the **best available science**. It sets out the objectives and principles that determine the quality of scientific evidence, as well as its use and collection. It recognises the unique characteristics of scientific evidence and states explicitly that 'excellence' and relevance, regardless of the source of funding, are the sole criteria for determining whether or not scientific evidence is included within a scientific assessment.

3. Good Practices – Scientific Assessments, Access to Expertise, and Impartiality

There is a **clear, government-wide ('horizontal') policy** for the selection of experts and for the operation of scientific committees. It is based on the following principles:

- Scientific assessments are expected to be both excellent and impartial.

- Excellence is 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. All relevant scientific experts who meet agreed standards of eminence, expertise, and relevance are considered for selection;

- Selection of experts is based on a comprehensive understanding of bias and of the complex conflicts of interest that cause it. Rigorous, fair, and transparent processes are 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;

- Committees or panels undertaking scientific assessments seek to manage conflicts of interest rather than exclude appropriately qualified experts. Experts are only be excluded from specific scientific assessments if one of the two following conditions are met: there is substantial evidence of predetermination; or, there is a credible likelihood of direct, material financial gain;

- Experts selected to carry out scientific assessments commit formally to act impartially and in the public interest;
- Committees or panels that undertake scientific assessments are institutionally independent and separate from political influence;
- Whilst protecting intellectual debate and commercial confidentiality, there is a presumption of openness throughout the process; and,
- Outcomes of scientific assessments are subject to independent peer review. All draft assessments are reviewed procedurally, whilst significant assessments are subject to an additional substantive review.

Scientific evidence and access to expertise at EU-level

1. Scientific Evidence and the Management of Risk

1.1. Political Commitment

Public support from politicians at the highest level is an essential pre-condition for the use of the best available science as the pre-eminent knowledge input for the management of risk. **At EU-level, these commitments have been unsystematic, ambiguous, fragmented, and limited thus far.**

There is, for example, no formal commitment from the Council recognising the role of the best available science in regulatory decision-making, nor is this included in the 2016 Inter-Institutional Agreement on Better Law-Making[13].

A further problem is the inconsistent emphasis placed, in formal public political statements by EU leaders, on the importance of scientific excellence when making risk management decisions. President Juncker, for instance, appeared to express a preference for his Commission to base controversial risk management decisions also on political

13 The Council has issued Conclusions on research integrity (December 2015) but not on the need for best available science to guide risk management decisions.

considerations rather than solely on the best available scientific evidence[14]. This ambiguity towards the importance of science for the management of risk is further demonstrated by a series of high profile decisions to overturn or revise the findings of high quality scientific assessments carried out by the EU's risk assessment agencies[15].

Similar ambiguities appear to be present in the most recent political commitments by the European Commission. Despite the pivotal role that scientific evidence is likely to play in shaping the EU Green Deal, the Political Guidelines launched by President von der Leyen do not include any reference to science and its role in policy-making[16]. Although, the need to base these new policies on innovation and "cutting-edge research" is acknowledged, the importance of ensuring the quality of scientific evidence for the formulation and implementation of policy is not highlighted.

In contrast, the European Commission has recognised elsewhere, the importance of robust high quality scientific evidence for policy-making. Specific examples include the White Paper on Governance[17], the Commission's Better Regulation Policy[18] and the Commission Decision establishing the new Scientific Advice Mechanism[19]. These comments and commitments, whilst important, need to be consolidated and supported by all of the EU's institutions.

1.2. Central Scientific Oversight

A characteristic of the most effective scientific advisory systems is the presence of a strong central oversight body equipped with the authority and institutional power to establish

14 See statements included in President Juncker's 'Political Guidelines for the 2014-2019 Commission' (2014)

15 Important examples include restrictions on the use of bisphenol-A (BPA), and the failure to renew fully the license to use Glyphosate, a crop protection substance. Both cases involved implementation decisions, working within frameworks defined by legislation. And, in both instances, the findings of high quality scientific assessments, carried out by EFSA, were not accepted: final decisions were not based on best available science.

16 See statements included in President von der Leyen's 'Political Guidelines for the 2019-2024 Commission' (2019)

17 European Commission 'European Governance – A White Paper' (2001) – this recognized the importance of expert advice, particularly scientific, as a means of improving the quality of legislation. Scientific advice, the paper argued, enabled lawmakers to anticipate and identify the nature of problems; inform decisions; and explain risks.

18 European Commission 'Better Regulation for Better Results – An EU Agenda' (2015, European Commission, COM (2015)) – this was up-dated in 2017.

19 European Commission 'Commission Decision establishing the High Level Group of Scientific Advisers' (2015). This decision identifies the importance of robust evidence for policy-making and highlights the importance of high quality scientific evidence for improving the quality of EU legislation.

and enforce common standards for the quality, collection, and use of scientific evidence, including the functioning of scientific committees. There should also be formal mechanisms for sharing good practice. **No such powerful, horizontal institutions exist at EU-level.**

There is, however, some evidence of progress. Under the Barroso Presidency, a Chief Scientific Advisor was appointed, creating the possibility of developing an institutional structure and raising the profile of the need for the best available science, regardless of its origin, to guide risk management decisions[20]. Although political momentum and operational continuity were lost by the decision to not renew the post, a new framework was launched in 2015 – the **Scientific Advice Mechanism (SAM)**.

With the aim of providing scientific advice independent of institutional or political interests to the College of Commissioners, the SAM has two main features. First, there is a High-Level Group of Scientific Advisers appointed to improve the interaction with the scientific community, and to ensure independence, transparency, and scientific integrity of the advice provided to the Commission through the SAM process. According to its formal mandate, advice should be based on the best possible scientific evidence. The second feature is a close working relationship with Europe's science academies. An initial step towards achieving this was the Memorandum of Understanding, signed in 2015, between the five main associations (Academia Europea, ALLEA, EASAC, Euro-CASE, and FEAM) of more than 100 regional and national academies and learned societies.

The creation of the SAM marks a major step forward in the development of a central, horizontal institutional framework, designed to ensure the quality and consistency of scientific evidence used throughout the European Commission and its agencies. Despite this, more needs to be done to expand significantly the institutional authority and powers of the SAM. It is not responsible, for example, for developing, overseeing, and steering 'horizontal' policies for scientific evidence and scientific committees.

Finally, an underlying strength of the Commission's scientific advisory process is its in-house scientific directorate, the **Joint Research Centre (JRC)**. This powerful body, with

20 President Barroso, in his speech to the European Parliament in 2009, highlighted the importance of this role for delivering scientific advice throughout all stages of policy development and delivery. The post of Chief Scientific Adviser was created in 2012.

its deep technical and scientific resources, provides the Commission with an institutional mechanism for rapidly strengthening the role of best available science in risk management decisions. Its 2016 strategy review demonstrated a commitment to achieving new goals, including a strategic focus as a knowledge manager for the Commission[21]. Action is needed, however, to embed the JRC in a wider set of reforms, so as to take full advantage of its institutional, scientific, and technical strengths.

1.3. Law of Administrative Procedures

One of the most important characteristics of the best scientific advisory systems is the presence, within the legal framework, of laws of administrative procedure that require the executive function to adhere to standards of good administration when implementing laws, including those designed to manage risk. No such law has currently been adopted at EU-level, despite the presence, in the Treaty, of legal bases enabling its establishment[22].

At present, **the EU legal framework lacks clarity and consistency**. Although various provisions of the Treaty, most notably those dealing with approximation of laws and with environmental protection, require scientific evidence to be taken into account, the requirements are incomplete. Quality thresholds are not set out by the EU Treaties and there is no attempt to establish a hierarchy of importance of different sources of evidence to be used in decision-making. Instead, these issues are dealt with, albeit unsystematically, in secondary legislation, guidance documents, and in CJEU case law.

The **European Courts** have engaged repeatedly with the role that scientific assessments should play in regulatory decisions. When considering actions by Member States that would limit trade within the Single Market, the Courts have tended to require restrictions to be based on assessments of risk, supported by the best available science. In contrast,

21 European Commission 'Joint Research Centre: The European Commission's Science and Knowledge Service – JRC Strategy 2030' (2016)

22 Since 2016, the European Parliament has been active in advocating for comprehensive rules on good administration. It adopted, in 2016, a dedicated resolution calling for a new EU Regulation constituting a general Law of Administrative Procedures (LAP). It underpinned this initiative with an EP European Added Value Assessment, an impact assessment and a public consultation, as well as legal opinions and studies by leading European legal scholars. Evidence from this range of sources concluded that an EU-level LAP would increase legal certainty significantly; better protect the public; enhance trust between citizens and the EU administration; reduce litigation; and increase legitimacy through better transparency and accessibility.

over the last twenty years, the Courts have shown greater deference to actions of the EU executive, in part because the Treaties do not provide an indication of the standard of review that should be applied to scientific evidence. They have refrained from establishing strong procedural or substantial constraints on the use by the EU's institutions of scientific evidence to guide risk management decisions.

Secondary EU legislation, designed to manage specific risks, establishes, in some instances, clearer quality thresholds and procedural requirements for scientific evidence. The EU General Food Law of 2002, for instance, requires the European Food Safety Agency (EFSA) to provide the best possible scientific opinions[23]. Evaluation of the quality, safety, and efficacy of medicinal products for human or veterinary use by European Medicines Agency (EMA) should, according to the 2004 statute, be based on the best available science[24]. And, the REACH Regulation requires the European Chemicals Agency (ECHA), the agency responsible for assessing risks posed by chemicals and their use, to focus on providing the best possible scientific and technical advice[25]. Whilst these are all clear requirements, they are relevant only for each specific area of legislation[26]. They are not 'horizontal' standards. Moreover, they need further definition, including, for example, guidance that sets out the characteristics of the best available science. Horizontal guidance dealing with this and similar critical technical issues does not exist at EU-level.

More recently, the **proposal for a framework "European Climate Law"** of March 2020, which will place into law the goals set out in the EU Green Deal, requires the Commission to make use of the "best available technology" and the "best available and most recent scientific evidence" when developing implementing actions to deliver the 'trajectory' needed to achieve climate neutrality. Requiring the executive function of the EU to adhere to these and other core Better Regulation principles is a welcome step in framing the delegation of power. Reliance on the best available scientific evidence in this policy domain has also been mandated by the European Parliament Decision of January

23 EC Regulation 178/2002

24 EC Regulation 726/2004

25 EC Regulation 1907/2006

26 A further concern is that there remains room for improvement in many of these 'vertical' risk management laws. Although REACH, for example, sets out requirements for the quality of scientific evidence, important aspects are not addressed in a clear and transparent way.

2020 that called on the European Commission to ensure that the Climate Law recognises the importance of scientific excellence.

These references to scientific excellence as an important input into decision-making are critical for the potential effectiveness of the EU Green Deal because they will have cross-sectoral implications. It will be of critical importance for the EU's good governance that such requirements are not only confirmed during the legislative process but are also applied to implementing measures.

1.4. Policy Framework

Powerful, mandatory horizontal policies and guidelines are a common feature of the most effective scientific advisory systems. They are designed to ensure that advice and evidence are of the highest quality; that processes of scientific assessment are consistent; and, that standards of good administration are met. **There are weaknesses and major gaps in the EU's policy framework that make it difficult to achieve this standard. There are, for example, no common requirements for scientific evidence** (covering issues, for instance, such as the characteristics of best available science, Systematic Evidence Reviews or interpretation of complex forms of evidence including modelling and epidemiology), **selection of scientific experts, rules of procedure for the functioning of scientific committees, and risk analysis**.

A 'horizontal' risk analysis policy is yet to be adopted at EU-level. The nearest equivalent is included in the 2002 General Food Law. This sets out the general principles of risk analysis, but its focus is on food safety only and it is not a mandatory requirement for the management of other risks.

The fragmented and incomplete policy framework for the quality, collection, and use of scientific evidence poses a further challenge. A Commission Communication in 2002 covers the collection and use of expertise, and includes some general principles such as independence, excellence and transparency[27]. It is not, however, focused specifically on scientific evidence and its requirements are not binding. They take the form primarily of practical tips and general advice.

27 European Commission 'Communication on the Collection and Use of Expertise' (2002, COM (2002) 713)

The **Commission's Better Regulation Guidelines in 2017** constitute a marked improvement in this respect[28]. Whilst they do not focus on scientific evidence specifically, they do commit the Commission to using the best available evidence in a transparent manner to support decision-making. These requirements are clarified further in the supporting technical guidance that advises regulators to base measures on the best evidence, including scientific advice. Criteria for quality standards are not, however, provided and measures to manage risks to human health, public safety and the environment do not require explicitly the support of a scientific assessment.

The intention to use the best available science to support scientific assessments is further reinforced in the 2015 Commission Decision to restructure DG SANTE's independent scientific committees[29].

From this range of different policy statements, requirements for the quality, collection, and use of scientific evidence can be pieced together. The next step is to build on this and establish a single, horizontal policy, supported by technical guidance. At present, however, no such policy, or supporting guidance, is in place.

2. Scientific Assessments, Access to Expertise, and Impartiality

2.1. Policy Framework

No consolidated horizontal, Commission-wide binding policy has yet been adopted that sets out common requirements for the selection of scientific experts and the functioning of scientific committees. At present, requirements are fragmented and, in most instances, fail to reflect a comprehensive understanding of the nature of bias and of the complex conflicts of interest that cause it.

A number of Commission-wide policies examine different aspects of the process of selecting scientific experts and the functioning of scientific committees.

28 European Commission 'Better Regulation Guidelines' (2017)

29 European Commission 'Commission Decision on establishing Scientific Committees in the field of Public Health, Consumer Safety, and the Environment' (2015, C(2015) 5383)

The **2002 Commission Communication 'Use and Collection of Evidence'** recognises that the public must be convinced of the legitimacy of decisions made by regulators. This will be achieved, the Communication explains, through robust transparent processes, as well as the quality of experts. It argues that experts must act in an independent manner but recognises that individuals can never entirely set aside their personal background. In the light of this, the Communication recommends the adoption of policies that minimise the risk of vested interests distorting advice. Its most specific suggestion is that the 'dependencies' of experts should be made explicit by requiring declarations of direct or indirect interests.

The Communication provides a number of important insights. It appears to recognise the complexities inherent in trying to find experts who are free of all potential conflicts of interest, and highlights the importance of processes as one way of strengthening perceptions of the impartiality of advice. The Communication is, however, not formally binding and does not apply to formal legislative procedures of comitology. Moreover, it lacks detailed guidance about how to ensure that advice, provided by scientific assessments, meets the twin standards of excellence and impartiality.

The **Commission Better Regulation Guidelines**, first issued in 2015 and up-dated in 2017, and the Commission Decision of 2015 setting up the Scientific Advisory Mechanism, re-state the general requirements for expertise to be both excellent and independent that are set out in the 2002 Communication. They also reinforce the importance of experts acting independently and in the public interest.

For EU decentralised agencies, their overall approach to ensuring that advice is excellent, independent, and transparent is anchored in the Common Approach adopted in 2012 and specifically the **Guidelines on the Prevention and Management of Conflicts of Interest in EU Decentralised Agencies adopted in 2013**. These outline a framework for the management of conflicts of interest by agencies with similar mandates, acknowledging that a "one-size-fits-all" approach is neither desirable nor possible at the present. Despite this, the Common Approach explicitly underlines the importance of agencies being independent of commercial interests, while neglecting other possible causes of bias.

Alongside this, the Commission has set out general rules for expert groups. In 2016, in response to an own-initiative enquiry by the European Ombudsman into the composition of Commission expert groups, the European Commission up-dated its rules for creating and operating expert groups[30]. A new **Commission Decision ('Horizontal Rules on Creation and Operation of Commission Expert Group' 2016)** was issued, replacing a Communication from 2013 and up-dating a framework originally set out in 2010[31].

The Decision is an important horizontal statement of Commission policy. It sets out general criteria for how experts should be selected. It defines conflicts of interest and provides guidance as to how they should be identified and which represent the most important challenges to the impartiality of experts. It includes revised requirements for the selection of experts and the management of potential conflicts of interest. Using public calls for participation, experts should be selected on the basis of a series of criteria: high level of expertise; geographic representation; a balanced representation of relevant knowledge; and, gender balance. Most notably, the Decision defines a conflict of interest widely: as any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest.

Whilst the Decision provides an important framework, it has significant weaknesses. It lacks a comprehensive awareness of the nature of bias and the complex range of conflicts of interest that cause it. This is reflected in the working definition provided in the accompanying guidance. In contrast with the Decision itself, the guidance places emphasis primarily upon the extensive disclosure of historic and current materialistic conflicts relating to employment or other widely-defined links to the market economy of the applicant and his or her family. By doing this, it fails to consider the importance of identifying ideological and other similar non-materialistic conflicts that can contribute to predetermination, hence undermining the legitimacy of advice and increasing the risk of regulatory failure.

30 European Ombudsman 'Recommendation in the strategic inquiry concerning the composition of Commission expert groups' (2016)

31 European Commission 'European Commission Decision establishing horizontal rules on the creation and operation of Commission expert groups' (2016, C(2016) 3301)

Overall, the primary emphasis on materialistic factors established by the Commission Decision on Expert Groups, most notably links to the market economy, poses major problems for the quality of scientific assessments. This anachronistic approach may exacerbate existing trends to exclude scientists with links to the market economy but without eliminating bias. It does not appear to take adequate account of the way in which knowledge is created or the nature of the risks that the EU seeks to manage, and thus the importance of gaining access to the scientific knowledge developed by academics with close links to the market economy.

2.2. *Scientific Committees and Risk Assessment Agencies*

Commission-wide requirements for the selection of experts and functioning of advisory committees have been interpreted and implemented in different ways by EU-level risk assessment bodies. The policies developed by the long-standing Independent Scientific Committees provide an important framework of good practices, reflecting the modern approach to ensuring excellence and impartiality when delivering scientific assessments. EMA, ECHA and EFSA, however, continue to focus unduly on financial links and relationships of academics with the market economy as the primary challenges to the impartiality of experts.

In 2015, the European Commission up-dated its 2008 Decision setting up independent scientific committees in the field of public health, consumer safety, and the environment[32]. Expertise, independence, and transparency were confirmed as the key principles that should underpin the functioning of the committees and the advice they provide. Work should be undertaken, the Decision stated, in conformity with best practices and the principles of risk assessment. The assessment of risk should, moreover, be independent from risk management, and experts should be appointed on the basis of proven scientific expertise, independence, and the absence of conflict of interest. Experts, the Decision pointed out, should act in a personal capacity, independently, and in the public interest. Conflicts of interest were not defined in detail, instead experts were required to

32 European Commission 'Commission Decision on establishing Scientific Committees in the field of Public Health, Consumer Safety, and the Environment' (2015, C(2015) 5383)

disclose any interest that my compromise or reasonably be perceived to compromise their independence.

Included within this policy framework are many important good practices, most notably institutional independence of risk assessment from risk management processes and the importance of ensuring both excellence and impartiality (described as 'independence' in the Decision). There are, however, important gaps. The Decision seeks a complete absence of conflicts of interest when selecting experts, whereas modern research, reflected in global good practices, suggests that this is not possible. Insufficient emphasis is also placed on the wide range of conflicts of interest that can lead to bias, and thus the need to identify them rigorously and, wherever possible, manage them so as to ensure access to the most eminent and relevant experts. Finally, the Decision does not require all scientific assessments to be peer reviewed: a critical mechanism for enhancing the perception of impartiality and avoiding regulatory failure.

There are, however, other good practice examples at EU-level that could serve as part of a framework for the development of a future horizontal policy for the selection of scientific experts and functioning of committees. The Independent Scientific Committees established by the Commission's 2004 and 2008 Decisions adopted, in 2013, **Common Rules of Procedure** that emphasise the relevance, excellence, and balance in the selection of scientific experts, and recognise that values, along with political and ideological stances, threaten independence[33]. These conflicts are not, however, explored in detail in the guidance notes for declarations of interest.

The use of peer review by the **EMA** to assure the quality of scientific assessments of new medicines provides a further example of a good practice within the EU institutions. Its current policy for managing competing interests of scientific members and experts, issued in 2016, differentiates between various levels of involvement that experts may have in EMA's activities depending on the nature and relevance of their conflicts of interest. This approach seeks to manage conflicts of interest and ensure access to the best available expertise by avoiding exclusion if possible. However, the guidance focuses primarily on materialistic factors as the most important challenge to independence.

33 European Commission 'Rules of Procedure of the Scientific Committees on Consumer Safety, Health, and Environmental Risks, and Emerging and Newly Identified Health Risks' (2013)

ECHA has adopted a similar tiered approach to managing conflicts of interest. **In 2019, the agency published detailed guidance for detecting, recording, and accessing competing interests and for imposing mitigating measures**[34]**.** The guidance focuses on interests or facts that might prejudice ECHA's independence. Specifically, it requires all interests that may interfere with the work of the agency and its duty to take impartial and objective decisions to be declared.

ECHA's approach to managing potential conflicts of interest makes use of a series of declarations of conflicts and structured exclusions, based on defined criteria and specific circumstances. It focuses on a wide range of financial interests and other links between experts and companies (including research support and membership of advisory bodies), as well as selected non-financial interests. It is a rules-based approach.

The procedure acknowledges the need for ECHA to gain access to high-quality relevant expertise, whilst at the same time avoiding conflicts of interest influencing or being seen to influence the decision-making process. There is, however, no clear statement setting out how this balance is to be achieved.

ECHA's procedure recognises explicitly that non-financial interests might prejudice independence, and requires active involvement by potential experts within interest groups to be disclosed, leading to restrictions in certain clearly defined circumstances. Such groups are defined on the basis of their intention or purpose: namely to influence the formulation or implementation of policy or decision-making processes of the agency. This is a wider approach to defining conflicts.

Nonetheless, ECHA's approach to managing conflicts of interest does not fully reflect the most modern understanding of the links between bias and the conflicts of interest that cause it. This leads to an incomplete analysis of the full range of potential non-financial conflicts, limiting the value of the disclosure process. Moreover, the overall approach, based on rules rather than principles, fails to adequately examine the possibility of 'predetermination' because of ideologies, ideals or beliefs. Finally, the procedure prevents scientists from participating in the work of the agency if they have been involved with any

34 ECHA 'Prevention and Management of Potential Conflicts of Interest' (2019)

scientific advisory body that has an interest in any area of ECHA's work. This may limit access to expertise.

In 2018, the EFSA published a Decision by the Executive Director on Competing Interest Management[35]**.** It aims to ensure that there is trust in the advice provided by EFSA and its scientific committees, and to align requirements for the management of conflicts of interest facing scientific experts with EFSA's wider policies on independence. The decision applies to membership of scientific assessment groups and to the criteria for awarding grants for the development of regulatory science.

Like other recent, similar guidance issued by other EU bodies, EFSA's guidance focuses almost entirely on so-called 'objective' measures of conflicts of interest. These are defined as links, financial and non-financial, between scientists and the market economy. This approach is not based on the most up-to-date understanding of bias and the wide range of conflicts of interest that cause it.

EFSA's formal decision creates significant barriers to the involvement in scientific assessments or in the provision of regulatory science of academic experts who work with industry, including receiving extensive research funding, providing consultancy advice, or participating in scientific advisory groups. In view of the nature of the risks assessed by EFSA, the extensive links between industry and academia in these areas, and modern patterns of funding of R&D, this decision may limit the access of regulators to many eminent and relevant experts.

3. Managing Conflicts of Interest and Bias at EU-Level – An Appraisal

At EU-level, there is clear evidence of a number of good practices that could, along with additional improvements, form the basis of an effective framework of policies and guidance to ensure that scientific assessments meet the tests of excellence and impartiality.

Such a framework does not, however, currently exist, and some agency-level policies may act to limit access to expertise but without eliminating bias.

35 EFSA 'Decision of the Executive Director of EFSA on Competing Interest Management' (2018)

3.1. Failure to Balance 'Excellence' and 'Impartiality'

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 impartial. Delivering an effective trade-off between these goals is, however, difficult to achieve in practice.

A major cause of these problems is the way in which Commission bodies and officials seek to achieve the twin requirements of best available science and impartiality that must be met when advice is used to support policy, legal, and regulatory actions.

All too often, regulators charged with securing scientific advice deem the requirement of 'impartiality' and 'excellence' to be satisfied, if scientists from academia, without material links to the market economy, solely provide evidence and advice. It is assumed that the trade-off between impartiality and excellence can be achieved primarily through 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 this can be avoided by recruiting scientists from research institutes or academia who have no links to the market economy.

By doing this, regulators believe that they can ensure that experts act impartially, hence maintaining trust in the advice provided by scientific assessments.

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. Its continued application increases the risk of regulatory failure, because of the lack of access to expertise. The legitimacy of risk management decisions may also be challenged if advice is tainted due to the influence of advisers whose views are predetermined by non-materialistic conflicts.

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 regulatory 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 market economy. 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.** 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 approach taken by some governments in the OECD area, and the one use by the European Commission, it is no longer appropriate. Existing good practice along with recent findings from behavioural psychology, suggest that this approach, with its primary emphasis on material reward factors, is out-of-date and incomplete (see section 3.0.). And, moreover, its application increases the likelihood of regulatory failure and potentially undermines the legitimacy of risk management decisions.

Whilst this form of exclusion appears to be a practical solution, it can have the effect of preventing decision-makers from gaining appropriate access to the

most advanced applied scientific knowledge, including safety research. It limits understanding of new technologies and applications. Knowledge of real world experience and usage, and thus an understanding of risk, is curtailed as well. Taken together, these gaps in the knowledge available to risk managers make it difficult for governments to manage harms effectively. The following section (section 5.3.2.) provides additional insights into the potential negative consequences.

3.2. Loss of Access to Expertise - Problems

The growing loss of access to expertise contributes to undermining the quality of scientific assessments at EU-level. It results from the failure to ensure that the most eminent and relevant experts undertake scientific assessments.

This is, moreover, not a new problem. It was first identified more than fifteen years ago. Reports drawn up by Brussels-based Think Tanks looked at these issues in more detail, as well as highlighting a number of trends in risk management and in the provision of scientific advice[36]. These included new risk governance priorities focusing on uses of technologies rather than their production; shifts in government spending on research in universities; and the ageing of the population of research scientists, reducing the pool of 'independent', expert risk assessors.

External evaluators identified further threats to the future credibility and utility of advice. In 2007, for instance, DG SANCO commissioned RAND, an academic research institute, to evaluate the work of the European Commission's Non-Food Scientific Committees[37]. A major finding of the review was that the quality of advice was likely to be threatened in the future because of the difficulty, in an increasing number of areas, of finding experts who are both 'excellent' and 'independent' of stakeholders. This "excellence gap" was, the evaluators suggested, most pronounced in areas of applied research, where expertise lies predominantly within the private sector.

36 See for example, Bruce Ballantine 'Enhancing the role of science in decision-making of the European Union' (European Policy Centre Working Paper no. 17, 2005), and European Risk Forum 'DG SANCO Consultation – Revision of European Commission Scientific Committees (ERF Communication No. 3, 2008).

37 RAND Europe 'Evaluation of DG SANCO's Non-Food Scientific Committees: Issues for Scientific Advice, Policy-Making, and Regulatory Decision-Making' (A report for DG SANCO, 2007)

Inadequate access to the scientific knowledge developed by academics working with the market economy poses five major problems for risk managers:

- **Inability to fully identify 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. Leading academics increasingly work with the private sector to develop this knowledge. Applied science in areas such as food, chemicals, metals, electronics, consumer products, crop protection, and medicines is dominated by science developed with the support of the private sector.

  Without access to science developed within the market economy, it is difficult for policy-makers to establish a convincing, evidence-based justification for regulatory action or to identify emerging risks or develop effective risk management options.

- **Inadequate understanding of 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 without access to real world evidence, mislead decision-makers by overstating threats.

  Informed and balanced assessments of risk are difficult to carry out unless scientific advisers have access to expertise developed by academics within the market economy, including usage experience.

- **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 behaviours 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 Better Regulation guidance, a comprehensive understanding of the production and use by businesses and of innovation processes within the market economy 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 knowledge developed with the private sector.

- **Difficulty designing effective, high quality substantive guidance**–implementation of risk management laws is increasingly undertaken by the EU's Administrative State using complex regulatory processes, including the use of substantive guidance. 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 and proportionately.

  If such guidance is to be of high quality then it must take account of "real world" experience and of the best available science. In many cases, this requires access to expertise and science developed within the market economy.

A further problem for decision-makers is that excluding academics with links to the market economy from the scientific assessment process, because they are deemed not to be 'independent' due to the impact of materialism on their capacity to act impartially, does not guarantee that the remaining sources of advice will be either 'independent' or 'excellent'.

Scientists untainted by links to commercial society or the market economy may, in many policy areas, lack detailed, current, or relevant knowledge, limiting the quality of their contributions. Some may also be unable to act impartially. They may, for instance, receive funding from campaigning groups, creating an obvious economic conflict-of-interest. Alternatively, they may be predetermined in their approach to a problem, 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 because of their idealistic or ideological conflicts of interest.

Conclusions

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

To gain access to the science needed to inform risk management decisions, regulators and lawmakers rely primarily upon scientific assessments. These expert processes 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. Indeed, scientific assessments are a core foundation on which an evidence-based strategy for decision-making rests.

If they are to be effective, scientific assessment processes must meet two tests: they must be excellent, so that regulatory failure is avoided, and they must be perceived to be impartial. When assessments are seen to be impartial, the legitimacy of legal and regulatory decisions is strengthened.

Yet, too many scientific assessments undertaken at EU-level are unable to meet these standards because of the way in which policies for selecting scientific experts and the functioning of committees are implemented. These continue to focus on material factors, most prominently links of academics to the market economy, as the greatest challenge to the impartiality of scientific assessment processes. This is an out-dated approach that risks excluding the most eminent and relevant experts without eliminating bias. It fails to recognise the way in which knowledge is generated; the nature of the risks being managed by the EU's Administrative State; and the modern understanding of bias and the complex conflicts of interest that cause it.

In contrast, good practices, derived from policies implemented by scientific bodies, for example, seek to deliver the twin goals of scientific assessments by combining revised selection procedures for individual experts, thereby delivering excellence, with new processes and procedures for the functioning of scientific committees and management of conflicts of interest, thus ensuring impartiality.

Two groups of factors contribute to the weaknesses of the EU's approach. The most important proximate cause is the lack of a framework of institutional mechanisms, policies, and guidance for the selection of experts and functioning of committees that reflects the new model of global good practice, thereby recognising bias, its nature, and its complex causes, as well as the changes that have taken place over the past two decades in the nature of knowledge generation and in the EU's risk management strategy.

Lying behind this, however, are a series of underlying causes, most notably the weaknesses in the EU's political, legal, institutional, and policy framework to ensure that the best available science guides risk management decisions. Resolving the problems facing the effectiveness of scientific assessments at EU-level requires these wider concerns to be taken fully into account and reforms implemented.

Whilst there have been major improvements in the EU's approach to delivering evidence-based decision-making, more needs to be done to protect the excellence and impartiality of scientific assessments. Reforms are needed that build on the existing good practices already present within the Commission, whilst making use of additional good practice ideas.

Recommendations

This ERF Monograph sets out a programme of reform that, if implemented, will help ensure that scientific assessments, the foundation on which high quality risk management measures rest, are excellent and impartial. To achieve this, the reforms focus on the underlying and proximate causes of the failings of the current EU-level approach, and build on existing good practices in the Commission and elsewhere.

The reforms are designed to change behaviours within a complex institutional framework. As such, they focus on two complementary areas of activity. First, they target change in the political commitments, legislative requirements, institutional architecture, and policy framework designed to ensure that the best available science informs risk management decisions. Second, they focus on the framework of policies and guidance for the selection of experts and functioning of scientific committees.

1. EU Institutions and Best Available Science

1.1. Political Commitments

Inter-Institutional Agreement on Law-Making (Recommendation 1): Collectively, the EU institutions should, through a revision of the 2016 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;
- Design and implement risk management measures that protect human health, public safety and the environment whilst at the same time promoting economic growth, innovation, and job creation;
- Use the best available science as the pre-eminent knowledge input to inform and guide risk management decisions to protect human health, public safety, and the environment, recognising its unique characteristics as a source of insights and evidence;
- Require scientific assessments, including risk assessments, to reflect fully real world experience and normal conditions of usage and exposure; and,
- Communicate fully, objectively, and in a timely manner the potential risks posed by substances, technologies, and processes whilst recognising explicitly that a zero risk society is neither possible nor desirable.

Council Conclusion (Recommendation 2): Building on its support for research integrity, the Council of EU Ministers should affirm the requirement to use of the best available science as the pre-eminent input to inform and guide risk management decisions to protect human health, public 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.

1.2. Legislation

Law of Administrative Procedures (Recommendation 3): The EU legal framework should be reformed to include a Law of Administrative Procedures (LAP), that recognises the central role that risk assessment, and other forms of expert scientific assessment, plays in the implementation of laws. These activities should fall within the scope of an EU LAP. It should establish standards of due process for the implementation of laws by the executive function that can be subject to judicial review and which embed the major principles of good administration. These are transparency and consistency; public participation; public record; and accountability. Finally, there should be a specific requirement for the public record to include all of the scientific evidence relied upon by risk managers.

1.3. European Commission – Institutional Architecture

Central Scientific Oversight Body (Recommendation 4): An oversight body with responsibility for ensuring the effective functioning of the entire scientific advisory system should be set up within the European Commission – preferably at the centre or directly reporting to the centre of the Commission. The oversight function includes reviewing 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 EU agencies and scientific bodies, and policy DGs.

This could be achieved, for instance, by expanding the scope of responsibilities of the SAM Group of Chief Scientific Advisors. This should be a permanent 'horizontal' function of the SAM. Accordingly, the mandate of the Group, supported by the Scientific Advice Mechanism and possibly the Joint Research Centre, should be expanded so as to include responsibility for:

- Providing an institutional mechanism to ensure that 'science' has a voice in decisions at all stages of the policy cycle;

- Championing the role of the best available science as the pre-eminent knowledge input, including for the understanding and management of risk;

- Promoting balance and rationality in controversial debates about the opportunities and risks posed by new and existing technologies;

- Developing 'horizontal' scientific advice policies (covering issues such as the quality, collection and use of scientific evidence; scientific committees and experts; and risk analysis);

- Developing the 'horizontal' methodological guidelines that underpin the operation of the advisory system. Panels of eminent scientists, with relevant experience and independent of the EU institutions, should carry out this work;

- Overseeing, enforcing, and steering the implementation of 'horizontal' policies and guidelines throughout the policy cycle;

- Producing an annual review of the effectiveness, utility, and quality of the scientific advisory process;

- Acting as a public interest advocate when scientific evidence must be kept confidential;

- Commissioning periodic evaluations of the operation of the overall scientific advisory system;

- Promoting a constructive, balanced, and informed public debate about the role of scientific evidence in managing risk and, by promoting innovation, in creating the conditions for prosperity

Regulatory Scrutiny Board and Peer Review of Scientific Assessments (Recommendation 5): The European Commission should expand the mandate of the Regulatory Scrutiny Board (RSB) to include the explicit review of the implementation of risk management decisions taken on the basis of substantive guidance or through the implementing and delegated acts procedures ('comitology'). This should ensure that the RSB oversees the interventions made through the EU Administrative State, including risk management decisions. As a part of this, the RSB's mandate should encompass oversight of the quality of scientific evidence and scientific assessments used to justify individual risk management measures. To this end, the RSB should ensure that all scientific assessments

have been subject to a relevant and appropriate peer review. This should be an explicit test of the quality of a proposed intervention.

Organisational and procedural arrangements should be designed to ensure the closest coordination possible between the RSB and the Scientific Advice Mechanism. In addition, transparent mechanisms based on objective criteria should be put in place to tailor the review activity of the RSB so as to ensure proportionate yet effective scrutiny.

1.4. European Commission - Policies

Quality, Collection, and Use of Scientific Evidence Policy (Recommendation 6): The European Commission should establish, for instance in a Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect. The Decision should:

- Require all forms of regulatory decision-making to be guided by the best available science gathered using widely accepted, consistent, open and transparent processes;

- Set out robust quality controls for ensuring that scientific evidence meets this standard, including a catalogue of characteristics of the best available science; requirement to use the established methodology of Systematic Evidence Review to collect and assess evidence; use of weight-of-evidence; use of peer review; and, provision of an independent right of appeal, prior to dissemination of the findings of significant scientific assessment; and,

- Establish 'excellence' and relevance as the sole criteria for determining whether or not scientific evidence is to be included within a scientific assessment.

1.5. European Commission - Guidance

Scientific Integrity Guidelines (Recommendation 7): Working under direction of the central oversight body (as referred to in Recommendation 4 above), independent committees of eminent scientists should draw up all significant technical guidelines required to support the Commission-wide policies for the quality of scientific evidence and risk analysis, and to ensure that scientific integrity is respected This process should

ensure that guidelines are independent of political considerations, that they are based on leading-edge science; that they reflect lessons learned from retrospective evaluation of scientific evidence; and that they embed the expertise of the scientific community.

They should focus on four areas: study quality; assessment of evidence; communication of findings to risk managers; and selection of experts.

Precautionary Principle Supplementary Guidelines (Recommendation 8): The European Commission should develop supplementary guidelines that clarify the role of the Precautionary Principle in decision-making. These should be in addition to and should not replace the existing Commission Communication of 2000. They should re-state the requirements of the Communication, emphasising that the Precautionary Principle should only be used as a justification for risk management measures, and that it should not be used to influence scientific assessments that form part of the processes of understanding risks. Precautionary measures, if considered, should be proportionate and subject to review.

The guidelines should remind all agencies and directorates of these requirements and highlight questionable practices that appear to use forms of the Principle in scientific assessments. These include basing opinions on 'unknowns' or low quality studies or studies that are 'outliers' instead of the weight-of-evidence provided by extensive data packages; changing defaults and assumptions without scientific justification; and using hypothetical or unrealistic exposures.

2. Access to Expertise, Impartiality, and Functioning of Committees

2.1. European Commission - Policies

Access to Expertise, Impartiality and Functioning of Scientific Committees Policy (Recommendation 9): The European Commission should set out, for instance, in a new Decision, the key principles for the selection of scientific experts and for the operation of scientific committees. It should seek to deliver the twin goals of scientific assessments by combining revised selection procedures for individual experts, thereby delivering excellence, with new processes and procedures for the functioning of scientific committees and management of conflicts of interest, thus ensuring impartiality.

These should be minimum standards and should apply to all agencies and directorates, and all forms of scientific committee including Technical Working Groups. Within its provisions, the Decision should:

- Require scientific assessments to be carried out by scientific experts who meet agreed standards of eminence, excellence, and relevance;

- Allow all relevant scientists who meet agreed criteria of eminence, excellence, and relevance to be eligible for selection.

- Establish transparent selection processes to identify all forms of material conflicts of interest that may create bias and are likely to be relevant to the specific work of the group. This should include, but should not be limited to: beliefs, ideals, ideologies, political affiliations, support from or links to interest groups; financial interests; and, personal factors.

- Develop procedures to manage conflicts of interest, such that the most appropriately qualified experts are only excluded in very limited circumstances, such as a credible risk of direct current financial benefits or substantial evidence of personal beliefs or commitments or ideological perspectives that suggest predetermination;

- Require membership of scientific committees to be constituted so as to ensure that decision-makers have access to a range of relevant different types of scientific experts from different scientific disciplines; and,

- Require all outcomes of scientific assessments to be subject to independent peer review. All draft assessments should be reviewed procedurally whilst significant assessment should be subject to an additional substantive review.

2.2. European Commission - Guidance

Selection of Experts and Functioning of Committees Guidelines (Recommendation 10): The European Commission should develop guidelines for the selection of experts and functioning of committees. Their scope should be Commission-wide and encompass all Commission services and EU agencies and scientific bodies. The

Guidelines should be designed to ensure that scientific assessments meet the twin tests of excellence and impartiality. They should be based on a comprehensive understanding of bias and the conflicts of interest that cause it. They should encompass detailed guidance for ensuring the disclosure of all forms of conflict of interest, including non-material factors. They should set out ways in which conflicts of interest can be managed such that regulators gain access to the most eminent and relevant expertise.

Ideas for inclusion in a draft guidance note are set out in Appendix A.

Richard Meads and Lorenzo Allio, the Rapporteur and a Senior Policy Analyst at the European Risk Forum, wrote this Monograph. However, the views and opinions expressed in this Monograph do not necessarily reflect or state those of the European Risk Forum or its members.

European Risk Forum
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Appendix A

1. Selection of Experts - Guidance

1.1. General Principles

Selection of experts for scientific panels or committees should be based on the following principles:

- The primary objective of any selection process is to ensure that the best available experts, who meet accepted, transparent standards of eminence, expertise, and relevance, undertake scientific assessments.

- Citizens must have confidence in the impartiality of the process of providing scientific assessments. This is best assured when the following conditions are met:

  - Committees or panels are institutionally independent, and separate from political influence;

  - Experts are selected who are able to act impartially, and in the public interest;

  - Assessment processes are predictable, based on the scientific method, and 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;

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

- Bias, or the failure to act impartially and in the public interest, is the result of conflicts of interest. These are multiple and encompass materialistic factors (such as financial gain), beliefs and ideologies, political affiliations, and personal factors, including ambition, power and status. They are part of the human condition. We all have them, and the

biases they trigger. Appropriately qualified experts should not be excluded from joining scientific committees or panels simply because they have one of more demonstrable conflict of interest.

- 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.

- Genuine scientific disagreement, if based on well-founded evidence, is not in itself a form of conflict of interest. It is evidence of intellectual debate and difference, provided scientific perspectives have been developed in a transparent, open-minded manner and are revised in the light of compelling evidence to the contrary.

- Undertaking paid work for industry or for activist groups (or research institutes that pursue a specific social or political agenda) is not, on its own, grounds for exclusion from serving on advisory groups, panels, or committees. Whilst such activity may be evidence of relevant conflicts of interest, exclusion solely on this basis may prevent advisory groups from gaining access to the best advice. Taking this into account, appropriately qualified experts should only be excluded if one or more of the following conditions are met:

    - There is a credible risk of direct, material financial benefit for the adviser or his or her immediate family or employer from current or expected activities or investments;

    - There is substantial evidence of personal beliefs or commitments or ideological perspectives or intensely advocated policy positions that suggest predetermination, where an adviser is 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.

1.2. Guidance

SCOPE

This guidance applies to the selection of scientific experts to serve on groups, panels, and committees that undertake scientific assessments to guide policy, legislative, and regulatory decision-making by governments. It also applies to the selection of invited scientific experts who provide advice to such groups on specific issues.

KEY DEFINITIONS

Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions, and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science report; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments.

Bias occurs whenever secondary or private interests unduly influence judgements. This reflects a conflict of interest that inhibits the capacity of the expert to advise impartially and in the public interest. Traditional approaches to understanding bias emphasise material reward factors as creating conflicts of interest. Findings from behavioural psychology suggest that this approach is out-of-date and incomplete. Conflicts of interest are complex and extensive. Bias is part of the human condition because it provides a means of processing information in a complex world. We all have it. Thus the problem facing regulators is not how to avoid it but rather how to manage it.

Conflicts of interest trigger bias. They are extensive and take many forms. Some are conscious whilst others are not. They include financial, academic-professional ambitions, power, status, beliefs and ideologies, personal commitments and experiences, political affiliations, national cultures, and knowledge (or the lack of thereof).

Direct financial gain refers to two groups of conflicts: financial rewards and corporate competitive advantage. Potential financial rewards include employment relationships,

consulting relationships, investments in financial instruments, intellectual property, research funding, and other forms of research support. Such conflicts are current, not historic, and encompass the potential expert and his or her immediate family. Commercial competitive advantage may be created because of the opportunity to gain access to confidential information during the course of a scientific assessment. It may occur because of existing, current employment or consulting relationships. Direct financial gains should be material.

Predetermination ordinarily occurs because of the close identification or association of a potential expert with a particular point of view or the positions of a particular group to such an extent that he or she he or she is unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary. It is largely intellectually motivated and is reflected in personal beliefs or commitments or ideological perspectives or intensely advocated policy positions. Different types of evidence provide indications of 'predetermination', including public positions and statements, research focus, activism, memberships and affiliations, advocacy, and employment. Relevant evidence will frequently encompass patterns of activity over a number of years.

ASSEMBLING PANELS OR COMMITTEES

Expert groups, in whatever form, should be assembled using the following three-stage process:

- **Stage One** – in this first stage, a pool of appropriately qualified experts should be identified. Based on the tasks to be undertaken by the group, experts should be selected that meet transparent and widely accepted tests of eminence, expertise, and relevance. No other factors should be taken into account at this stage. The process of identifying experts should be transparent and should involve peer nomination, as well as open calls of interest. A panel of experts, independent of political influence, should oversee the process of identifying appropriately qualified experts, reviewing conflicts of interest, and balancing membership of the expert group.

- **Stage Two** – after a pool of experts has been identified a transparent process of identifying potential sources of bias should be undertaken. This should focus on the disclosure of conflicts of interest, using a structured questionnaire and confidential interviews. (The process is described more fully in section 2.4.) At the end of this stage,

the panel overseeing the process will identify those experts who will not be considered for membership of the group as a result of likely powerful biases that can only be managed through exclusion.

- **Stage Three** – in the final stage of the process, the expert panel will assemble a panel that recognises the different scientific disciplines needed to undertake the defined scientific assessments of the group. In certain instances, it may also take into account different scientific perspectives where this is relevant to the work of the group, based on well-founded evidence, and supported by experts who are willing to act in an open-minded manner. No other factors should be considered. Scientific assessments will in general solely require expert knowledge of natural science or engineering. Social scientists and lay people do not, in general, possess such knowledge. If insights are sought from these groups then they should form part of the management phase of the risk analysis process.

IDENTIFYING RELEVANT SOURCES OF BIAS

A panel of experts, independent of political influence, should oversee the process of identifying relevant sources of bias (see section 2.3.). This is best undertaken using the following structured process:

- **Disclosure Form** – all appropriately qualified experts should complete a confidential disclosure form. Information should be disclosed for activities undertaken over the previous five years, including:

  - Organisational affiliations – business relationships or personal positions or memberships within groups that might benefit in a direct way from the findings of the scientific assessment, including professional societies, charities, advocacy or campaigning organisations, civil society groups, academic institutions with social or political goals, and trade associations;

  - Financial interests – financial interests, whether through employment, consultancies, or investments in companies or other entities whose value or business would be directly affected by the findings of the scientific assessment. This includes financial interests of the direct family of the expert;

- Research support – financial or other support from organisations that might have an interest in the outcome of the scientific assessment;

- Government service – receipt of research support from government agencies or other similar institutions that might have an interest in the assessment; and,

- Public positions and advocacy – publication of articles, intensely argued advocacy positions, framing of research, legal or public testimony, or links to organisations that might be viewed as stating a commitment to a particular view on the issues to be considered in the scientific assessment

- **Screening interview** – the independent panel should undertake this. It should consider each of the areas of conflict of interest, and should seek to identify potential biases that may arise as a result of them. Other sources of bias, such as personal or professional ambitions, should also be identified. The interview should be confidential.

- **Classification of impact on the work of the panel or committee of sources of bias** – after completing the process of interviewing prospective, appropriately qualified experts and examining information included in the completed disclosure forms, the panel must classify sources of bias for each candidate. Classification should highlight those sources of bias that warrant exclusion of potential experts. For other sources of potential bias, the process should consider the materiality, relevance, and impact of the conflicts of interest identified. This information will then be used as part of the process of managing bias during the process of undertaking scientific assessments. Finally, the panel will need to consider the issue of perceived bias. Some conflicts of interest may be identified that could create the perception of bias in certain circumstances. This should not as a general rule require a potential expert to be excluded. Instead, such an action should only be considered if a person with equivalent expert knowledge, and with access to the same knowledge, could reasonably challenge the impartiality of the potential expert. Historic relationships with industry or activist groups are not a basis for such a challenge.

MANAGING BIAS

At the end of the processes of identifying appropriately qualified experts, identifying sources of bias, assessing the impact of conflicts of interest on the work of the scientific committee, and balancing scientific disciplines, the independent panel will appoint a scientific committee or group. Experts with egregious forms of bias, direct potential for financial gain or predetermination, will have been excluded.

The biases of the members of the scientific committee will then be managed through a series of mechanisms. These will include:

- Public disclosure – information provided by committee members, in the form disclosing conflicts of interest, will be made public, thereby ensuring transparency and strengthening the integrity of the process;

- Public declaration – each committee member will make a written public declaration, recognising the need to act impartially and in the public interest, and agreeing to report any new potential sources of bias that may emerge;

- Training – all committee members will be required to attend a training programme designed to help them recognise and manage sources of bias within themselves and other members of the committee;

- Peer discussions – confidential discussions, orchestrated by the chair of the group of scientific experts, will be held to enable experts to share their knowledge of sources of personal bias;

- Recusals – in some instances, the chair of the group of scientific experts, may ask a specific expert to recuse his or herself from consideration of a particular issue. This will be a matter of judgement based on the information provided by the disclosure form and screening interviews.

References

ALLEA 'The European Code of Conduct for Research Integrity' (2017)

Andresson F. 'Improving Scientific Advice to Government' (Issues in Science and Technology 19, No. 3, 2003)

Australian Research Council 'Conflict of Interest and Confidentiality Policy' (2017)

Babor T.F. and Miller P.G. 'McCartyism, conflict of interest and Addiction's new transparency declaration procedures ' (Addiction, 139, 2014)

Ballantine A.B. 'Enhancing the Role of Science in the Decision-Making of the European Union' (2005)

DeAngelis C.D. and Fontanarosa P.B. 'Impugning the integrity of medical science – the adverse effects of industry influence' (The Journal of the American Medical Association, 299, 2008)

EASAC 'Guidelines on advising policy makers and society' (2013)

European Chemicals Agency 'Prevention and Management of Potential Conflicts of Interest' (2019)

European Commission 'Communication on the Precautionary Principle' (2000)

European Commission 'European Governance: A White Paper' (2001)

European Commission 'Communication on the Collection and Use of Evidence by the Commission' (2002)

European Commission 'Commission Decision setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health, and the environment' (2008)

European Commission 'Communication on the Framework for Expert Groups' (2010)

European Commission 'Rules of Procedure of the Scientific Committees on Consumer Safety, Health, and Environmental Risks, and Emerging and Newly Identified Health Risks' (2013)

European Commission 'Communication on Better Regulation for Better Results – An EU Agenda' (2015)

European Commission 'Commission Decision establishing the High Level Group of Scientific Advisers' (2015)

European Commission 'Commission Decision establishing horizontal rules on the creation and operation of Commission expert groups' (2016)

European Commission 'Scientific Advice Mechanism: Rules of Procedure of the High-Level Group of Scientific Advisors' (2016)

European Commission 'Scientific Advice to European Policy in a Complex World' (Scientific Opinion No. 7 by the Group of Chief Scientific Advisors, 2019)

European Food Safety Authority 'Policy on Independence and Scientific Decision-making Processes' (2012)

European Food Safety Authority 'Decision of the Executive Director of EFSA on Competing Interest Management' (2018)

European Ombudsman 'Recommendation in the strategic inquiry concerning the composition of Commission expert groups' (2016)

Gmel G. 'The Good, the Bad, and the Ugly' (Addiction, 105, 2010)

Government of Canada 'A framework for Science and Technology Advice' (2000)

Moore D.A. and Lowenstein G. 'Self-interest, automaticity, and the psychology of conflict of interest' (Social Justice Research, 17, 2004)

Moore D.A., Tanlu L., and Bazerman M.H., 'Conflict of interest and the intrusion of bias' (Judgement and Decision Making, 5, 2010)

Moss D.A. 'When All Else Fails: Government as the Ultimate Risk Manager' (2002)

Netherlands Scientific Council for Government Policy 'The profile and working methods of the Netherlands Scientific Council for Government Policy' (2017)

OECD 'Recommendation of the Council of the OECD on Improving the Quality of Regulation' (1995)

OECD 'Guiding Principles for Regulatory Policy' (2005)

OECD 'Conflict of Interest Policies and Practices in Nine EU Member States: A Comparative Review' (Sigma Papers No. 36, 2007)

OECD 'Recommendation of the Council of the OECD on Regulatory Policy and Governance' (2012)

OECD 'Guidelines for Managing Conflict of Interest in Public Service' (2014)

OECD 'Scientific Advice for Policy-Making: the role and responsibility of expert bodies and individual scientists' (OECD Science, Technology, and Industry Papers no. 21, 2015)

RAND Europe 'Evaluation of DG SANCO's Non-Food Scientific Committees: Issues for Scientific Advice, Policy-Making and Regulatory Decision-Making' (2007)

Royal Dutch Academy of Arts and Sciences 'Code for the prevention of improper influence due to conflicts of interest' (2012)

Royal Society of Canada 'Expert Panels: Manual of Procedural Guidelines' (2005)

Royal Society of Canada 'Strengthening Government by Strengthening Scientific Advice' (2015)

SAPEA 'Guidelines on Advising Policymakers and Society & Procedures for Quality Assurance of Scientific Advice' (2017)

SAPEA 'Making sense of science under conditions of complexity and uncertainty (2019)

Sarewitz D. 'Beware the creeping cracks of bias' (Nature, 485, 2012)

Shalvi S., Gino F., Barkan R., and Ayal S. 'Self-serving justifications- doing wrong and feeling moral' (Current Directions in Psychological Science, 2015)

Standards New Zealand 'General guidance on conflicts of interest in New Zealand standards development committees' (2016)

Swiss Academies of Arts and Sciences 'Scientific Policy Advice: Recommendations for Researchers' (2011)

Thagard P. 'The moral psychology of conflict of interest – insights from affective neuroscience' (Journal of Applied Philosophy, 24, 2007)

The Brussels Declaration 'Ethics & Principles for Science & Society Policy-making' (2017)

UK Government Office for Science 'Code of Practice for Scientific Advisory Committees' (2011)

US Bipartisan Policy Center 'Improving the Use of Science in Regulatory Policy' (2010)

US Government Accounting Office 'Report on ensuring balance and independence on federal advisory committees' (2004)

US National Academy of Sciences 'Policy on the Committee Composition and Balance of Conflicts of Interest for Committees used in the development of reports' (2003)

US Office of Management and Budget 'Final Information Quality Bulletin for Peer Review' (2004)

Vershuere B. and Shalvi S. 'The truth comes naturally! Does it?' (Journal of Language and Social Psychology, 33, 2014)

Weisel O. and Shalvi S. 'The collaborative root of corruption' (Proceedings of the National Academy of Sciences', 112, 2015)

Young S.N. 'Bias in the research literature and conflict of interest – an issue for publishers, editors, reviewers, and authors, and it is not just about the money' (Journal of Psychiatry & Neuroscience, 34, 2009)

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.

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