European Risk Forum – Monograph

Scientific Evidence and the Management Of Risk

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Foreword

Ten years ago, the Risk Forum published a ground-breaking study, *'Enhancing the Role of Science in the Decision-Making of the European Union'*. It has structured and informed the policy agenda in this critical area ever since.

This new study, produced by the European Risk Forum (ERF), revisits and up-dates those original findings. Its timing is opportune. It is a contribution to the emerging debate about how to improve the quality of the EU's governance, in the wake of Brexit and in the face of other powerful challenges to the Union. It recognises that progress has been made, and that there are good examples, at EU-level, of the use of scientific evidence to make high quality regulatory decisions. It notes, however, that important failings identified in the earlier work have not been resolved and that new problems have emerged that challenge the role of scientific evidence in decision-making.

On too many occasions, Europe's leaders have hesitated to affirm their historic commitments to use the best available scientific evidence when making risk management decisions. Instead, there has emerged a degree of deference to relativism, accompanied by a lack of trust in science and scientific experts.

Within the EU's institutions, common requirements for the collection and use of scientific evidence are lacking. This has contributed to an undue emphasis on who produces science, rather than on the excellence of the quality of the evidence itself. It has resulted in a failure to define and enforce standards of evidence for the use in decision-making based on the characteristics of the best available science.

Similar problems are present when recruiting scientific experts to support regulatory decision-making. Selection procedures, based on out-of-date assumptions about the funding of research and the causes of bias, place the greatest emphasis on identifying potential financial conflicts of interest. This increasingly prevents the best experts being chosen, limiting the quality of scientific assessments. And, it ignores powerful forms of bias that result from other complex conflicts-of-interest, including status, ambition, experience, values and ideologies, undermining perceptions of impartiality.

In this monograph, the ERF explains why science remains the pre-eminent knowledge input when the EU makes risk management decisions. It highlights the importance for the EU institutions, in an era of economic and political crisis, of reinforcing commitments to basing decisions on the best available science. It shows how, by doing this, proportionality, accountability, predictability, effectiveness, and legitimacy can be enhanced.

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

Finally, the ERF would like to warmly thank the members of the project Steering Group for their insights, advice, and help.

Veronique Steukers (Nickel Institute) chaired the Steering Group. Its members were Esther Agyeman-Budu (CEFIC); Professor Sir Colin Berry (Royal London Medical School); Rachel Bonfante (Chevron); Jean-Pierre Busnardo (DuPont); Rick Clayton (IFAH-Europe); Bernd Halling (Bayer); Rudi Hielscher (acatech, National Academy of Science and Engineering, Germany); Paul Leonard (BASF); Alicia Martin (Plastics Europe); Katharina Mayer (VCI); Professor Piet van der Meer (Ghent University) and, Dr Michael Rogers (visiting professor Tokyo University);

The ERF is also grateful to the experts who agreed to be interviewed - academics from the EU and the USA, legal scholars, eminent scientists, scientific advisers and government officials in Member States, senior officials from several policy directorates of the European Commission and from EU risk assessment agencies, members of the secretariat of the European Parliament, and senior managers from companies and business organisations in the EU and the USA.

Our thanks go as well to those experts who critically reviewed earlier drafts of the manuscript.

We believe that this monograph will prove to be as influential as its predecessor was in 2005, and that it will contribute constructively to a debate about the role of the best available science in decision-making. Implementation of its recommendations will, we believe, help strengthen the governance of the EU, resolving immediate problems and providing a basis for new opportunities.

Howard Chase
Chairman
European Risk Forum

Dirk Hudig
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Executive Summary

Background

When making decisions about the best way to manage risks to citizens and the environment, scientific evidence provides unique insights. Unlike opinions or values, it enables governments to identify the existence of hazards and their causes; to determine which hazards pose the greatest risks; to reduce uncertainties; to characterise risks; and because it is often able to identify the potential benefits of action, to allocate resources rationally.

At EU-level, there is an increasing requirement for scientific evidence. Rising demands from citizens for protection against risks and the emergence of new and more complex potential threats to health and the environment pose challenges to regulators. At the same time, living standards depend increasingly on investment in and exploitation of scientific knowledge.

Yet this is not easy to achieve. Significant numbers of citizens have little trust in science, experts, or politicians. There are also intellectually-based concerns that challenge the view that the best available science should be the pre-eminent form of evidence relied on by governments when they make risk management decisions.

Overcoming these challenges, and meeting the needs of citizens for both protection and prosperity, is particularly difficult at EU-level, where scientific advisory processes have developed in a piecemeal fashion since the 1950s.

Objective

This ERF monograph sets out a comprehensive and internally consistent framework of political commitments, institutional and legal 'architecture', and policies that, taken together, ensure that the best available science is the key input to the legislative, regulatory, and administrative decisions made by the EU institutions when they assess and manage risks to citizens and the environment.

The study examines the way in which the EU's institutions use scientific evidence to make decisions about the best way to manage risks to humans and the environment. It assesses the problems associated with the increased use of poor quality and non-scientific evidence. It examines the practices, policies, processes, and structures of the EU's scientific advisory system. And, it highlights good practices, along with weaknesses and failings.

The nature of 'science' and of the scientific method is explained in the study, along with an explanation of the role that scientific evidence plays in the different parts of the policy cycle. Policy formulation and legislation tend to use science as a privileged input but base final decisions on a range of factors, including politics. In contrast, implementation decisions tend to be based on science. Whilst recognising the limitations of scientific evidence, the study highlights the benefits of managing risks on the basis of the best available science.

The study focuses on natural and physical sciences and engineering because of their importance for understanding the potential risks posed by the production and use of modern technologies. It also distinguishes between "science advisers" and "science experts". Science advisers mediate between politicians and regulators and the processes designed to generate scientific evidence. They are part of the process of regulatory management. In contrast, scientific experts solely provide evidence.

Weaknesses of the EU's Structural Framework

Over the last two decades, significant improvements have been made in the way in which the EU's institutions collect and use scientific evidence to assess and manage the risks to humans and the environment posed by technologies and lifestyle choices. In some policy areas, this has stimulated the development of policies and processes that deliver widely-respected high quality scientific assessments on a regular basis. However, the process of reform remains incomplete. It lacks powerful horizontal institutions, policies, and guidance designed to ensure that scientific evidence and advice is of the highest quality; that processes of scientific assessment are consistent; and, that standards of good administration are met. Major 'horizontal' weaknesses include:

- Political commitments to base risk management decisions on the best available scientific evidence are limited, ambiguous, and inconsistent;

- No central oversight mechanism exists, with the institutional power to establish, and enforce common standards for the quality, collection, and use of scientific evidence;
- No common policies and standards for the collection and use of scientific evidence, selection of scientific experts, functioning of scientific committees, and risk analysis have been developed and adopted; and
- Critical 'horizontal' guidelines, dealing with issues such as the characteristics of best available science or the best practices for Systematic Evidence Review, are missing.

Weaknesses of the Operation of the EU's Scientific Assessment Process

Many of the scientific assessments carried out by the EU institutions are of high quality, and a number of good practices have been developed to improve consistency and utility, as well as to share ideas across different parts of the Commission. However, there remains a clear, general lack of consistency, transparency, and predictability. In too many cases, scientific assessments do not meet world-leading standards. Specific problems include:

- Inadequate expertise of some Technical Working Groups and scientific committees;
- Exclusion of experts with links to industry and a failure to ensure impartiality of all scientific experts;
- Undue influence of low quality or unscientific studies, including a failure to exclude old studies that have been discredited or retracted;
- Unpredictability and inconsistency of test requirements;
- Inappropriate application of the Precautionary Principle in scientific assessments;
- Politicisation of mandates for scientific committees and undue influence of public opinion on selection and interpretation of scientific evidence;
- Lack of a "public record" requirement;

- Poor risk communication, contributing to insufficient transparency and weak accountability; and,

- Failure of regulators to defend science and scientists

Recommendations

The monograph identifies more than twenty reforms. They build on the many good practices already present within the EU's institutions. Taken together, they target the underlying causes of the failings of the current EU-level system, along with the weaknesses in practices, structures, policies, and processes identified by the ERF's research. The reforms have been designed as a comprehensive, internally consistent programme, targeting political commitment, institutional architecture, policies, and guidance, and should be implemented as a whole.

In the short-term (1-3 years), the following actions should be taken:

- 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;

- Political responsibility within the **European Commission** for the quality and effectiveness of the overall process of collecting and using scientific evidence to make risk management decisions should rest with the First Vice-President in charge of Better Regulation;

- The **European Commission** should set up a central oversight body with responsibility for the quality, utility, and integrity of scientific evidence and advice used to guide and inform risk management decisions. This could be based, for example, on the Scientific Advisory Mechanism;

- A **European Commission** should develop and adopt minimum standards for the quality, collection, validation and use of scientific evidence that all directorates and agencies must respect. These could be set out, for instance, in a new Decision;

- The **European Commission** should set out, possibly in a new Commission Decision, the key principles for the selection of scientific experts and for the operation of scientific committees. These should be minimum standards and should apply to all forms of scientific committee, including Technical Working Groups;

- The **European Commission** should issue supplementary guidance that clarifies the role of the Precautionary Principle in regulatory decision-making. It should, based on the requirements of the existing Communication, make it clear that the Precautionary Principle should not be used to influence, directly or indirectly, scientific assessments that form part of the process of understanding hazards or risks;

- The **European Parliament** should expand the focus of the STOA Panel to promote debate amongst MEPs about the benefits of using the best available science; enhance the standards of scientific evidence provided to legislators by the EPRS; and, provide additional resources to support the work of the EP Group on Risk;

- The **Scientific Community** should develop specific proposals to define methodological guidelines for improved scientific assessment. This should include a catalogue of characteristics of best available science; Systematic Evidence Review; use and interpretation of epidemiological evidence; and statistical analysis and interpretation;

- **Businesses** should participate financially in transparent programmes, jointly, with EU institutions, to improve regulatory science in areas of importance including methodologies for scientific assessments, new technologies, and complex hazards.

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1. Introduction

1.1. Background

At EU-level, there is an ever increasing requirement from policy-makers for scientific evidence. Rising demands from citizens for protection against risks and the emergence of new and more complex potential threats to human health and the environment pose challenges to governments that scientific evidence can help define and resolve effectively.

At the same time, living standards depend increasingly on investment in and exploitation of scientific knowledge. Fostering the expansion of this knowledge-based economy is a major objective of public policy in the EU, as well as in other OECD economies.

Yet despite (or perhaps because of) the rising importance of science for achieving economic and social objectives, there has emerged a debate about the appropriate role of scientific evidence in guiding the outcome of policy, legislative and regulatory decisions. On the one hand, significant numbers of citizens have little trust in science or in politicians. There are also intellectually-based concerns that challenge the view that the best available science should be the pre-eminent form of evidence relied on by governments when they make decisions about the best way to manage technological risks to human health, public safety, and the environment (Exhibit 1).

Exhibit 1

CURRENT PUBLIC DEBATE ABOUT THE ROLE OF SCIENCE IN DECISION-MAKING

The current debate, and the accompanying scepticism about the value of relying on scientific evidence, is the result of a number of factors. These include:

- Progressive changes in policy-making models used in EU Member States away from traditional, technocratic, consensual models dominated by experts and towards more open and, in some cases, more adversarial models;

Historic regulatory failures, most notably risks to human health linked to BSE, dioxin, and contaminated blood, that undermined public trust in regulators and regulatory science in the EU in the 1980s and 1990s;

- Ideological conflicts about the most effective and appropriate way to manage risks from new technologies and to protect the environment;
- Criticisms of scientific evidence, as a key knowledge input for policy-makers, because of its inability to provide certainty. Some commentators also claim that the traditional scientific method is conceptually inadequate when faced with the complexity of multi-factorial health and ecological problems created by mankind and economic activity;
- Public disagreements amongst scientists, especially in areas linked to threats to human health and the environment from new technologies, such as biotechnology, nanotechnology, and synthetic biology;
- Perceptions amongst some citizens and stakeholders that, in the past, EU policy-makers and decision-takers have abused scientific evidence and used it to justify decisions that were made, in reality, on the basis of non-scientific factors. This has undermined public confidence in the decision-making methods used by the European Union.

One consequence of this debate has been the increased reliance by governments in some OECD economies, including the European Union, on low quality studies and non-scientific evidence when making decisions about the best way in which to manage technological risks to public safety, human health and the environment. Where this has happened, it has significantly increased the risk of regulatory failure, whereby poor legislative and regulatory decisions are taken, additional risks to citizens and the environment are created, and incentives to invest in innovation are blunted.

Urgent and systematic reform is needed to overcome these failings. Britain's decision to seek its own path ('Brexit') and the failure of Europe's economy to generate growth exacerbates the impact of these governance weaknesses, posing further challenges to the EU. In response, the EU's institutions need to demonstrate that they can stimulate innovatory activity, whilst at the same time protecting citizens and meeting world-class standards of governance. One way to do this is to ensure that the best available science is the key input to the legislative, regulatory, and administrative decisions used to manage risk.

1.2. Objective

This monograph examines the way in which the EU's institutions use scientific evidence to make decisions about the best way to manage risks to humans and the environment. It assesses the problems associated with the increased use of poor quality and non-scientific evidence. It examines the practices, policies, processes, and structures of the EU's scientific advisory system. It highlights good practices, along with weaknesses and failings.

Its principal aim is to set out a comprehensive and consistent framework of political commitments, institutional and legal 'architecture', and policies that, taken together, ensure that the best available science is the key input to the legislative, regulatory, and administrative decisions made by the EU institutions when they assess and manage risks to citizens and the environment posed by technologies. The monograph also highlights the importance for innovation of basing risk management decisions on the best available science.

If implemented fully the recommendations will assist the EU institutions in realising the objectives set out in the Better Regulation Policy[1].

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 2005 study *'Enhancing the role of science in the decision-making of the European Union'*[2].

1.3. Scope

Reflecting the wider goals of the European Risk Forum, this monograph focuses on the use of scientific evidence 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.

1 European Commission 'Better Regulation for Better Results – An EU Agenda' (2015, Commission Communication, COM (2015))

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

It focuses primarily on 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[3].

Finally, it considers the use of the best available science and scientific assessments[4] at all stages of the policy cycle: policy formulation; legislation; and implementation through regulations, and substantive guidance[5].

1.4. Methodology and Report Structure

The findings, conclusions, and recommendations set out in this monograph are the result of an extensive programme of research carried out by the ERF project team in the first half of 2016.

The programme of research includes more than 60 confidential, in-depth interviews with academic experts from the EU and the USA, legal scholars, eminent scientists, scientific advisers and government officials in Member States, senior officials from several policy directorates of the European Commission and from EU risk assessment agencies, members of the secretariat of the European Parliament, and experts from companies and business organisations in the EU and the USA. An extensive desk research exercise was also carried out. It reviewed academic literature; OECD publications; government policies and guidelines throughout the OECD area and EU Member States; and EU policies and guidance.

3 A similar emphasis on excellence, supported by standards of evidential quality, oversight mechanisms, and advisory standards, should apply to evidence generated by social science to support government decision-making.

4 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)

5 Derived through administrative processes, substantive guidance decisions are a form of 'soft' law. These non-binding decisions are made by the Executive function when implementing complex legislation. They define technical, scientific, or regulatory requirements needed to meet statutory obligations. Substantive guidance also includes detailed interpretations of statutory rules by officials. They tend to have general applicability and to apply in the future. For most businesses affected by substantive guidance, they provide, in practice, a detailed definition of the legal requirement. Failure to adhere to substantive guidance is, all too often, seen to be 'prima facie' evidence of non-compliance with the law. Most OECD governments and the European Commission make extensive use of them, particularly when implementing risk management laws.

The work of the project team benefitted from the expert input from members of a dedicated Steering Group and from the work carried out by the European Risk Forum team over more than two decades.

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 and considers how scientific evidence is used at different stages of the policy cycle. It finishes by examining some of the challenges facing decision-makers when they seek to use scientific evidence to guide risk management decisions.

- Chapter 3 sets out a good practice framework. Based on a detailed review of initiatives taken by other OECD governments, and by the EU institutions, it sets out a framework of political commitments, institutional and legal architecture, and policies that, taken together, ensure that the best available science plays a pre-eminent role in the effective management of risk. It provides a set of benchmarks against which to compare the EU's scientific advisory system.

- Chapter 4 assesses the EU's scientific advisory process and the structural framework of politics, law, institutions, and policies that underpins and guides it. The assessment makes extensive use of the good practice framework; a detailed review of current policies, guidelines, and institutional structures; and, the findings from the programme of interviews. It provides a brief description of the EU's system for providing scientific advice for risk management throughout the policy cycle. It highlights good practices and strengths. It assesses, and comments on, the structural dimensions (political commitments, institutions, policies, and guidance) of the EU's system, as well as appraising its operation. Weaknesses and issues are identified.

- In the final parts of the monograph conclusions are set out (Chapter 5), along with recommendations for reform (Chapter 6).

2. Governments, Risk Management and Excellent Science

2.1. Governments and the Management of Risk

For more than 150 years, beginning with factory legislation in the first half of the 19th Century, public management of risks to human health, public safety, and the environment posed by technologies has been one of the core functions of government. Over time, moreover, governments have recognised that this is best achieved when measures recognise the importance of economic vibrancy for longevity, improved health, and greater freedoms. This requires governments to develop and implement risk management strategies that deliver a high standard of protection whilst at the same time sustaining incentives to innovate.

To achieve these twin goals, most OECD governments seek to base risk management measures on the findings of expert, systematic assessments of risk, that use evidence derived from the best available science, and that are informed by credible knowledge of real world exposures.

Today, thousands of expert scientific assessments are carried out each year. Most are undertaken, as part of the executive function of government, to implement the requirements of complex risk management laws that often encompass production or usage 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 officials by panels of eminent scientists.

Scientific assessments, including risk assessments, are one of a large number of expert processes used by the executive function to implement laws and as such form part of the so-called "administrative state". Conceptually, they are similar in nature to the expert processes used to make decisions about welfare and education provision or market competition, for example.

At their best and as part of the process of implementing laws, scientific assessments bring together evidence derived from the best available science and expert risk assessment knowledge from within the scientific community

to provide high quality, predictable advice on which risk management decisions are based. This includes regulation, as well as the complex substantive guidance needed to interpret legislative requirements.

Indeed, over the last 30-40 years, governments have made increasing use of scientific evidence when managing technological risks to human health and the environment. Growth in the use of scientific evidence for decision-making has occurred for a number of reasons. These include:

- A progressive expansion in the risk management responsibilities of governments;
- The emergence of new, complex threats to human health and the environment, identified through scientific research;
- The increased importance of the knowledge-based economy based on investments in science and technology as one of the principal drivers of growth in jobs and improvements in living standards and quality of life. As a result, modern economies are dominated by products and processes derived from scientific research. Science provides the principal mechanism for understanding the potential impacts of these products and processes on human health, public safety, and the environment; and,
- Finally, scientific evidence and the scientific method have been highly effective in providing theories with explanatory and predictive power. These reveal links between human health or the environment and technological hazards, and enable decision-takers to anticipate problems and develop effective solutions. Basing risk management decisions on the best available science helps governments meet the needs of citizens for high standards of protection, without blunting incentives to innovate.

2.2. Science: The Pre-Eminent Knowledge Input

2.2.1. Scientific Evidence

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, or superstition.

It is a process of enquiry: the "scientific method". It is designed to be objective and to limit 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. Uniquely, it 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

2.2.2. Managing Risks – The Benefits of Using Best Available Science

Experience of governments throughout the OECD, built up over more than 150 years, suggests that basing risk management decisions on the best available science and expert assessment of risk leads to a series of beneficial outcomes (Exhibit 2).

Exhibit 2

BENEFITS OF USING THE BEST AVAILABLE SCIENCE FOR THE PUBLIC MANAGEMENT OF RISK

- **Regulatory quality** – the best available science provides decision-takers with the opportunity to base decisions on credible evidence derived from widely-accepted rational processes. This leads, over time, to increased regulatory quality. It is also consistent with commitments made by all members of the OECD, beginning in 1995, to base regulatory measures on evidence[6].
- **Legitimacy** - risk management decisions based on science improve public confidence in the capacity of governments to protect citizens from technological risks. It provides a transparent "intervention logic", based on evidence, to justify the use of state power. Public confidence, and, to a lesser extent, trust, is enhanced because decisions based on science, unlike those based on emotion or values, are also more likely to be effective, more rational, and more transparent.
- **Protection** – using the findings of expert risk assessment, derived from the best available science, enables risk managers to design highly effective measures that limit risks to citizens and the environment without creating unintended additional risks or damaging economic activity. Over time, this approach has contributed to increased longevity, health, environmental quality, and wealth. It also enables measures to evolve in response to scientific and technical progress, facilitating even higher levels of protection.

6 The most important commitments are set out in: OECD 'Recommendation of the Council on Improving the Quality of Government Regulation' (1995); OECD 'Guiding Principles for Regulatory Quality' (2005); and, OECD 'Recommendation of the Council of the OECD on Regulatory Policy and Governance' (2012)

- **Efficiency** – scientific evidence, with its rigorous focus on identifying causation, helps risk assessors to develop estimates of potential benefits of risk management measures. By combining this with estimates of the costs of proposed actions, governments are able to ensure that benefits justify costs and that societal resources are efficiently allocated.
- **Risk-taking** – when governments base risk management measures on the best available science and expert assessment of risk, it sends strong positive signals to entrepreneurs and risk-takers. It demonstrates that government decisions will be rational, guided by evidence and will deliver predictable regulatory outcomes. It recognises that a risk-free world is neither possible nor desirable. It supports a culture of risk acceptance. By achieving these things, incentives to develop and use new technologies are strengthened.
- **Trade** – global trade is based on rules that are, in turn, anchored in the best available science and expert risk assessment. WTO membership requires adherence to these rules. Trade frictions occur when countries design risk management measures that fail to reflect these requirements. Openness to trade expands markets, strengthens competitive intensity and facilitates the spread of world-leading ideas, as well as improving internal productivity through specialisation and comparative advantage..

If these benefits are to be achieved, then scientific assessments must be undertaken by leading experts and utilise the best available science. Yet this does not always occur. On too many occasions regulators fail to accept that not all science is of an equal standard of quality. Many studies are erroneous or fail to meet the demanding requirements of the scientific method or are based on out-of-date scientific knowledge. And, sometimes the findings from public consultations are treated as being a form of scientific knowledge.

Interventions based on poor quality evidence are more likely to result in regulatory failure, creating welfare losses, reducing protection, and undermining trust in the effectiveness of government and, ultimately, in its legitimacy.

2.3. Science, Risk Management, and Innovation

In mature economies, higher living standards primarily depend on improvements in productivity fuelled by investments in innovation. Most are

made by the private sector, and many involve large-scale expenditures on cutting-edge science to develop understanding, to exploit ideas, and to demonstrate safety, quality, and efficacy. Similar investments are made to ensure that existing substances and technologies meet modern safety standards.

When making investments in excellent science, companies assume that governments will assess risks using evidence of a similar standard and follow world leading risk assessment processes, leading to predictable outcomes.

Regulatory decisions based on the best available scientific evidence and expert risk assessments establish a context within which businesses can innovate effectively and invest in new processes needed to up-grade productivity. By basing decisions on the best available science, regulators provide investors and managers with regulatory predictability: one of the most important ways of reducing uncertainty and expanding the potential value of investment opportunities. Lack of regulatory predictability undermines the value of potential investments and erodes incentives to innovate.

Utilisation of the best available scientific knowledge, as a means to assess and demonstrate safety and to design risk management rules, also plays a critical role in creating incentives to invest in developing and adopting new technologies. Good practice acknowledges the need for governments to invest heavily, alongside experts in industry, in safety research and regulatory science[7], and to design risk management laws based on specific applications rather than technologies, if investment in new technologies is to be promoted.

"Upstream engagement", whereby governments promote early public debates about technologies and risks can help too, so long as its weaknesses are recognised. It is a process of discourse. It is not a substitute for representative government and has no political legitimacy. And, when such discourse takes place it is all too easily dominated by vested interests or it becomes subject to "ideological capture", leading, in turn, to distorted outcomes.

7 Regulatory science is the science of developing new tools, standards, and approaches to assess the safety (and sometimes the quality and efficacy as well) of regulated products. (Source: derived from the definition used by the US FDA)

2.4. Scientific Evidence and The Policy Cycle

Governments use scientific assessments at different stages of the policy cycle, when developing measures to protect human health, public safety, and the environment. In some stages scientific evidence acts to inform decision-makers, whilst in other parts of the cycle, most notably during the implementation of laws, decisions tend to be based on science. Specifically:

- During the **preparation of policy**, scientific evidence helps, alongside other insights, to inform and shape options, helping policy-makers to understand threats and design risk management strategies that are likely to be effective. Whilst, scientific evidence, because of its unique characteristics, enjoys a privileged position as a source of knowledge, its role, alongside other factors, is to inform policy-makers.

  Scientific advice is provided through a range of mechanisms including panels of eminent scientists, foresight programmes, consultancy studies, and government scientists.

- In the **legislative phase**, risk assessments, based on the best available scientific evidence, are a critical input and provide the basis of a robust "intervention logic", justifying the use of the powers of the state. They provide the only credible means of identifying problems and their causes, and hence the potential benefits of action. Final risk management decisions are, however, formed through political processes that take into account a range of factors: scientific evidence informs but does not always decide.

  Whilst it is the role of politicians to mediate between different values within society, risk management decisions based on robust rationales derived from evidence deliver better outcomes and greater accountability.

  In this stage, sources of scientific evidence include risk assessment agencies, government scientists, consultancy studies, and research programmes.

- Most national governments base **implementation decisions** on the outcomes of science-based risk assessments, recognising the importance of predictable, high quality decisions for achieving protection and sustaining incentives to innovate. Decisions are science-based in this stage of the cycle. They include regulatory decisions such as pre-

market approvals for new pharmaceuticals and limit values for emissions, as well as substantive guidance required to interpret and define the technical requirements of risk management legislation.

Scientific evidence normally forms part of formal risk assessment processes undertaken by government agencies or permanent committees of independent scientists. In this stage, evidence generated by scientists with close links to industry is likely to be one of the most important sources of knowledge.

- Finally, scientific evidence forms an essential input into the review phase of the regulatory cycle: **ex post evaluation**. Findings from new scientific research provide important insights into the need for and effectiveness of legislative decisions.

2.5. Limitations on the Use of Scientific Evidence

As an input into the regulatory cycle, science, along with all other forms of evidence used by policy-makers and decision-takers, has its limitations (Exhibit 3).

Exhibit 3

MOST IMPORTANT LIMITATIONS ON THE USE OF SCIENTIFIC EVIDENCE[8]

- **Structural limitations of scientific evidence** – it cannot resolve "values-based questions"; it cannot demonstrate absolute safety; uncertainties are often present; and, findings are frequently provisional. These are characteristics of the scientific method, as well as some of its strengths. Increasingly, however, they are used, to manufacture controversies, providing a mechanism to obfuscate debates about values.

8 Some of the critiques of scientific evidence argue that because of these and other limitations it should be viewed as simply another opinion, and hence should have no more weight than any other opinion in the legislative and regulatory process. This argument fails to recognize the process through which scientific evidence is generated – the "scientific method". It is this powerful and well-established process, and the nature and quality of the evidence generated by it, that makes the best available science a privileged input in risk management decisions in most OECD countries.

- **Lack of capability of policy-makers and decision-takers to make use of scientific evidence**– some policy-makers and officials lack "scientific literacy", leading to a failure to understand the strengths and limitations of scientific evidence. There is a lack of understanding of methodological principles and of the concepts that underpin scientific evidence and its assessment. Such gaps in knowledge contribute to a lack of understanding of the differences between 'correlation' and 'causation' or between 'hazard' and 'risk', as well as a growing failure to recognise that not all studies are of good quality.
- **Lack of public confidence in the utility of scientific evidence** – there has been a noticeable decline in public trust in government institutions over the last three decades, reflecting a general decline in social deference. This wider shift in public attitudes, along with a series of regulatory failures in the 1980s and 1990s, has helped undermine the confidence of citizens in the ability of governments to use scientific evidence to protect human health, public safety, and the environment.
- **Technological threats and scientific uncertainty** – the type of risks that governments focus on is changing. There is increased emphasis on trying to understand complex diseases and disorders (such as behavioural difficulties or fertility problems); lifestyle impacts; multi-factorial hazards; multiple exposures; and very low-level exposures. Many of these pose challenges for traditional scientific boundaries; some are very small risks, detectable only through advances in measurement technologies; and others reflect social concerns rather than scientific knowledge. Indeed, some of these policy issues, such as those surrounding lifestyle choices, may prove to be debates about values that cannot be resolved by scientific evidence.
- **Ideologically based concerns about the appropriateness of using scientific evidence to resolve "values-based" issues** – this is a characteristic of affluent societies. It draws together a wide range of different critiques of modernism, industrialisation, and capitalism.

2.6. Challenges to Using High Quality Scientific Evidence

Not all of the scientific evidence used by regulators is of an equal standard of quality. Much fails to meet the demanding requirements of the scientific method, for example. **Basing risk management decisions solely on scientific evidence that**

meets the highest standards of quality is, however, difficult. Governments must overcome a number of problems. These include:

- **Challenges intrinsic to scientific progress** - scientific knowledge has advanced dramatically in the past two decades, in areas such as genetic influences on cancer, PBTs, and allergens, making old studies redundant and questioning some of the traditional methodologies used to understand hazards and risks.

- **The negative impact of low quality studies** - a succession of alleged hazards, exaggerated uncertainties and apparent scientific controversies have emerged based on low quality studies or misinterpretations of evidence or poor quality hypothesis-forming science.

- **Gaps in reproducibility and verifiability** - recent research across all branches of natural, physical, and social science suggests that there are problems of reproducibility and verifiability; a central feature of the scientific method. The problem is most acute in social science, an area of knowledge increasingly important for understanding usage behaviour as part of the risk assessment process. Unless the findings of scientific studies can be replicated then their value for scientific assessments, and hence for protecting citizens, is questionable.

  New initiatives, most notably the movement towards "open science" publishing, have been established to try and speed up the availability of findings from scientific research. At its best, this may make more high quality studies available more quickly; at its worst, because it by-passes traditional peer review processes, it could trigger a wave of alleged hazards based on low quality or misleading studies that have not been reviewed independently or replicated.

- **Complex, multi-causal risks** - understanding complex, multi-causal risks poses challenges to regulators. One way of achieving this is to widen the range of disciplines involved in risk assessment. When complementary scientific disciplines are brought together, as has occurred in recent work to exploit mathematical modelling knowledge to improve understanding of allergens, then this approach is effective. In contrast, when it involves integrating lay knowledge or social science with natural and physical sciences, then the utility of scientific evidence risks being undermined.

- **Inconsistent standards of assessment** - scientific assessments are increasingly provided to risk managers by a variety of national and international institutions. In some cases, the extent to which such reviews meet good practices for scientific assessments or are properly informed by "real world' knowledge or by modern scientific understanding is increasingly contested by expert risk assessment agencies and eminent scientists. Concerns have also been raised about the impartiality of some conclusions because of apparent failures to identify and highlight fully conflicts of interest and ideological biases of contributors.

- **Restricted access to knowledge** - access to the best available science and excellent scientific experts is, in some cases, restricted, because scientists who work with industry are prevented from providing advice to governments. This poses a serious risk to the future utility of scientific assessments used by governments. Indeed, in the areas regulated by modern risk management laws, almost all major scientific advances take place primarily within industry. This includes most safety research, reflecting legal requirements. If scientists are excluded from advising governments because they work with industry, then scientific assessment is weakened, citizens are not protected, and there is regulatory failure. 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 government institutions.

- **Expert criticism** - retrospective analysis, by expert scientists, of scientific assessments has identified a number of problems with some of the evidence used and its interpretation. Problems include citation bias; publication bias; "outcome shifting"; over-influence of old studies based on out-of-date scientific knowledge or subsequently falsified or never reproduced; poor statistical analysis; low quality epidemiological studies given inappropriate prominence; and confusion between correlation and causation[9].

In the light of these concerns, it is increasingly important for governments to establish robust quality standards to ensure that scientific assessments are based solely on the best available scientific evidence.

9 The Cochrane Collaboration has documented many of these failings. Further insights can be found in: Berry C. 'Relativism, regulation, and the dangers of indifferent science – The Sir Roy Cameron lecture to the Royal College of Pathologists' (Toxicology, Vol. 267, 2009); Berry C. 'Reproducibility in experimentation – the implications for regulatory toxicology' (Royal Society of Chemistry, Toxicology Research, 2014); and Nuzzo R. 'Statistical Errors: P values, the gold standard of statistical validity, are not as reliable as many scientists assume' (Nature, Vol. 506, 2014)

Evidence from a detailed review of reforms undertaken, suggests that many governments in the OECD area have begun to take steps to ensure this. Indeed, these reforms, when taken together, provide the basis for the development of a framework of good practices that link political commitments, institutions, policies and guidance. Used appropriately, such a framework provides a benchmark, alongside other sources of evidence, against which the current scientific advisory system of the EU's institutions can be assessed, providing a means to identify potential gaps and recommendations.

3. A Good Practice Framework

3.1. Overall Structure

It is the collective behaviour of policy-makers and officials that determines whether the best available science guides risk management decisions designed to protect human health, public safety, and the environment from technological risks. Behaviour is the result, in part, of shared attitudes and values, as well as custom, practice, and organisational incentives.

Shaping behaviours in complex organisations is not easy and there is no single, or simple, right way of ensuring that the best available science plays a pre-eminent role in the effective management of risk.

However, over more than two decades, governments have undertaken reforms, in the face of common problems and in pursuit of similar goals. Analysis of these international activities, complemented by insights from experts and detailed long-term work by the ERF, highlights a framework of good practices that underpin the effective use of the best available science for regulatory decision-making[10].

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

The practices are interlinked and are designed to change behaviours and the attitudes that underpin them. They are grouped into four main categories, so as to highlight their strategic, comprehensive, and internally consistent nature. Specifically:

- Political commitments in democratic societies shape the expected behaviours of government officials and make elected representatives accountable for results;

10 The framework is derived from a review of initiatives undertaken in Australia, Canada, the European Union, Finland, France, Germany, Italy, Japan, New Zealand, Switzerland, South Korea, United Kingdom, and the United States of America. It is also informed by more than two decades of research by the ERF team, and expert contributions by the ERF's academic advisers, and participants in Risk Forum meetings.

- Legal changes, where appropriate, reinforce this, by ensuring clarity and consistency;

- Institutional structures allocate authority and power, establishing accountability, allocating resources, creating oversight, and ensuring compliance;

- Policies provide a detailed framework, defining objectives, principles, and standards in key areas, particularly the quality, collection, and use of evidence; scientific experts and committees; and risk analysis. Together with legal requirements, they are essential for ensuring long-run adherence to political commitments; and,

- Finally, operational guidelines describe, in detail, the new processes that must be followed, including interpreting and complementing legislation. They allow processes to respond flexibly to advances in scientific and technical knowledge. And, they reassure citizens that action is being taken.

The framework also distinguishes between "science advisers" and "science experts". Science advisers mediate between the processes designed to generate scientific evidence and politicians and regulators. They form part of the wider structure responsible for regulatory process management. In contrast, scientific experts solely provide evidence.

3.2. Good Practices - Highlights

The 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

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

- There is a well-resourced, long-term programme of investment in the **development of regulatory science**;

- 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 describe 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;

- Clear, 'horizontal' policies are also drawn up for the **selection of scientific experts** and for the **operation of scientific committees**. Selection processes for participation focus primarily on 'excellence' and 'relevance', and take account of different challenges to impartiality, most notably current financial conflicts-of-interest and ideological bias.

A more extensive description of the framework of good practices is included as **Appendix A**.

4. Scientific Evidence and EU Management of Risk

To understand and describe the EU's scientific assessment system, and to identify its strengths and weaknesses, it is necessary to utilise a range of different forms of evidence. Interviews with officials, academics and experts from companies and business organisations provide important insights. Comparisons with the framework of good practices highlight gaps and opportunities for reform. And, a detailed review of existing activities, processes, policies, and structures provides additional ideas.

This Chapter sets out the findings of this review:

- Section 4.1 describes the main characteristics of the EU's scientific assessment system, focusing on its 'horizontal dimensions;
- In Section 4.2, the structural framework is assessed, covering political commitments, institutional architecture, legal requirements, and policy framework; and,
- In Section 4.3, the operation of the EU scientific assessment process is examined.

4.1. EU Scientific Assessment System

At EU-level, the system of scientific advice used to support decision-making has developed progressively since the Union's inception. Since the 1980s, there has been a proliferation of scientific advisory processes reflecting a shift in policy priorities away from facilitating trade and towards acting as a public risk manager.

To support **policy-making**, including measures to manage risk, officials draw on a wide range of 'institutional' sources of scientific evidence. These include opinions and reports from EU agencies; opinions from formal scientific committees and expert groups managed by policy directorates; expert studies and advice from the Joint Research Centre (JRC); bespoke consultancy reports commissioned by directorates or agencies; reports from scientific advisory bodies in the EU Member States; in-house analyses by officials; and reports for the European Parliament provided by the Science and Technology Assessment Panel (STOA) and the European Parliament Research Service (EPRS).

In contrast, a more limited range of sources of scientific evidence is used to support the **implementation of risk management laws.** Broadly, these can be grouped into three categories:

- Independent scientific committees controlled by DG SANTE (SCCS and SCHEER committees), EFSA and DG EMPL (SCOEL committee). These bodies are made up of experts appointed in their personal capacities, following self-application to public calls of interest;

- Scientific assessments by Member States (so-called 'reference' or 'rapporteur' Member State), then overseen or endorsed by a Technical Working Group or Scientific Committee of other experts drawn from Member States. EMA and ECHA use this approach, for example; and,

- "Comitology committees" set up by the legislator (Council and Parliament or Council alone) to assist the Commission in policy areas where it is empowered to implement legislation.

In most cases, legislation prescribes the process by which risk management laws are implemented, including, where appropriate, the need for and sources of scientific advice. This further strengthens tendencies towards fragmentation and a lack of consistency.

Alongside these agencies and committees, the Joint Research Centre (JRC), the European Commission's in-house scientific service, provides additional scientific and technical expertise to the Commission DGs, whilst the High Level Group of Scientific Advisers of the new Scientific Advice Mechanism (SAM) provides scientific advice to the College of Commissioners on specific policy issues where such advice is critical to the development of Union policies or legislation.

In overall terms, the structure and nature of the scientific advisory system supporting the EU's institutions primarily reflects the specific decisions of a series of different risk management laws and their disparate political considerations, combined with the bureaucratic practices of different parts of the European Commission.

4.2. Structural Framework

4.2.1. 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 are unsystematic, ambiguous, fragmented, and limited.**

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[11].

A further problem is that recent public statements by the European Commission appear to express a preference for basing controversial risk management decisions on politics rather than the best available scientific evidence[12]. This ambiguity towards the importance of science for the management of risk is further demonstrated by the cessation of the mandate of the Chief Scientific Adviser appointed by President Barroso[13], and 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[14].

In contrast, the European Commission has recognised elsewhere, the importance of robust high quality scientific evidence for policy-making. Specific examples include the Commission's Better Regulation Policy and the Commission Decision establishing the new Scientific Advice Mechanism[15]. Statements by Carlos Moedas, the

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

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

13 The creation of this position represented a major step forward in the creation of institutional structures that could, with additional reforms, oversee the quality of scientific evidence used to inform decision-making. However, the post created was weak structurally: it lacked human and financial resources; it was not integrated into the Commission's procedures; it had no legal basis; there was no institutional link to the JRC or to DG RTD; and, ultimately, it did not enjoy sufficient political support. A further problem was the restriction on transparency.

14 Important recent 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.

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

Commissioner for Research, Science, and Innovation, have reinforced these commitments[16]. These comments and commitments, whilst important, need to be consolidated and supported by all of the EU's institutions.

4.2.2. Institutional Architecture

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**.

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[17]. This initiative, and attendant political momentum, was lost, however, when the current presidency did not renew the post. In its place, a Commission Decision established, 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. Advice should, for example, 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.

16 See for example his speech in May 2015

17 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.

Creation of the SAM marks a major step forward in the development of central, horizontal institutions, 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.

A further institutional reform took place in 2013 with the creation of the **EU Agencies Network for Scientific Advice (EU-ANSA)**. Established under the direction of the Heads of EU Agencies, this informal and part-time group promotes co-operation between agencies on issues of common interest related to the provision of scientific and technical advice. Its work is becoming progressively more influential. In 2016, for example, it considered the role that peer review of scientific assessments, an established good practice in other parts of the OECD area, could play in improving the quality of evidence used to guide regulatory decisions. More needs to be done, however, if this nascent institution is to thrive. Additional resources, a wider mandate, and institutional permanence are all needed.

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 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 recent strategy review demonstrates a commitment to achieving new goals, including a strategic focus as a knowledge manager for the Commission[18] .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.

4.2.3. Legal Requirements

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.

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

Instead, **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, 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[19]. 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[20]. 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[21]. Whilst these are all clear requirements, they are relevant only for each specific area of legislation[22]. They are not 'horizontal' standards. Moreover, they need further definition, including, for example,

19 EC Regulation 178/2002

20 EC Regulation 726/2004

21 EC Regulation 1907/2006

22 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.

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.

4.2.4. 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**.

The steady proliferation of scientific advisory processes at EU-level has exacerbated the inadequacies of the Commission's weak horizontal institutions, policies and guidance for ensuring the quality and consistency of scientific advice. In turn, this has led to criticisms by the EU Ombudsman of the failure of some parts of the scientific advisory system to meet expected standards of good administration.

There are a number of specific problems. To begin with, there is no 'horizontal' risk analysis policy. 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.

A further problem is the fragmented and incomplete policy framework for the quality, collection, and use of scientific evidence. A Commission Communication in 2002 covers the collection and use of expertise, and includes some general principles such as independence, excellence and transparency[23]. 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.

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

The Commission's Better Regulation Guidelines in 2015 marked an improvement[24]. Whilst they do not focus specifically on scientific evidence, 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[25].

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.

The final problem is the **lack of a consolidated horizontal policy setting out common requirements for the selection of scientific experts and the functioning of scientific committees**. At present, requirements are fragmented and, in some instances, problematic. There are, for example, no common standards for the selection of scientific experts, other than a requirement, in response to an enquiry by the European Ombudsman, to disclose financial conflicts of interest[26]. This has now been reinforced by a Commission requirement, covering the creation and operation of expert groups, for all forms of economic conflicts to be disclosed[27]. Indeed, this focus on financial links as the primary challenge to impartiality of experts is one of the few common themes in this area, and it poses major problems for the quality of scientific assessments.

24 European Commission 'Better Regulation Guidelines' (2015)

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

26 In 2014, the European Ombudsman conducted an own-initiative enquiry into the composition of Commission expert groups. Recommendations were made in 2016.

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

Evidence from international good practice identifies, historically, two types of 'interest' that might challenge impartiality: current financial links and ideological bias. Both should be assessed when considering the suitability of scientists to support regulatory decision-making[28]. This does not, in general, form part of the European Commission's approach to the selection of scientific advisers. Instead the focus is almost entirely on financial conflicts. In practice, this has the effect of targeting and excluding scientists with links to industry. This erodes the quality of scientific assessments because of the importance of industry support for R&D in general and the role of industry knowledge in understanding many of the risks managed by EU laws.

There are, however, some good practice examples at EU-level that could serve as a framework for the development of a future horizontal policy. DG SANTE's independent scientific committees adopted in 2013, for example, common rules of procedure that emphasise the importance of relevance, excellence and balance in the selection of scientific advisers, and recognise that values, along with political, and ideological stances, threaten independence[29].

4.3. Operation of EU Scientific Assessment Process

Many of the scientific assessments carried out by the EU institutions are of high quality, and a number of good practices have been developed to try and improve consistency and utility, as well as, in a number of cases, to share ideas across different parts of the Commission and its EU agencies. Examples include:

- EMA's rigorous, science-based, process requirements for the development of substantive guidance;

- Work by EMA to try and improve the attractiveness of investment economics of new drug development without lowering standards of protection;

28 Academic research in this area has advanced recently and suggests that biased behaviour, whereby impartiality is challenged, results from a wide range of conflicts of interest. These include economic factors, as well as non-material factors including ideology, values, experience, status, power, personal commitments, and professional ambitions. This suggests that the causes of bias may be more widespread than has been considered traditionally, and that future policies for the selection of scientific experts should reflect this. See for example, Shalvi S., Gino F., Barkan R., and Ayal S. 'Self-serving justifications. Doing wrong and feeling moral' (Current Directions in Psychological Science, 2015)

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

- Use of peer review by EMA to assure the quality of scientific assessments of new medicines;
- Principles of scientific integrity for researchers developed by the JRC;
- Use by ECHA of "real world" experience to inform the development of substantive guidance;
- Rules of Procedure adopted by DG SANTE's independent scientific committees;
- EU-ANSA network of regulatory scientists in EU agencies;
- ECHA guidance on nanotechnology, based on scientific evidence, that regulates on the basis of applications and not technologies;
- Easy to understand science fact sheets produced by the Scientific Committees of DG SANTE; and,
- Emerging network of national science advisers.

The risk communication undertaken by EFSA in 2015 after its scientific assessment of the health risks posed by bisphenol-A (BPA), is also seen to be an example of good practice. Indeed the study concluded that there was no health risk at current exposure levels, and this was extensively explained to citizens using a variety of communication techniques.

All of these initiatives and examples demonstrate the potential for adopting best practice and for achieving excellence that lies within the EU institutions.

Whilst there are clear examples of excellent scientific assessments, and of the adoption of best practices by parts of the Commission, there remains a clear lack of consistency, transparency, and predictability. In too many cases, scientific assessments do not meet world-leading standards. Specific problems include:

- **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 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 are used to provide scientific assessments. This enables 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.

  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 as an independent scientist; appointment on the basis of criteria other than excellence; and 'ad hominem' criticisms of independent 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 industry.

- **Exclusion of 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.

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.

This problem has its origins in the response of officials to public concern about potential conflicts of interest undermining the quality and credibility of scientific assessments. In response, the European Commission, supported by the EU Ombudsman, has implemented policies for the selection of scientific experts that focus primarily on financial conflicts as a challenge to impartiality. And, to achieve this, it conflates academic employment with 'independence'. This has the effect of focusing on who produces scientific evidence rather than the process through which it is produced and the quality of the evidence itself. It is, moreover, anachronistic because it fails to recognise the nature of modern relationships between academia and business.

- **Failure to ensure impartiality of all scientific experts** – good practice requires both ideological bias and financial conflict of interest 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 ideological bias 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.

- **Undue influence of old or low quality or unscientific studies** – 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 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.

  Final scientific assessments by the EU's scientific advisory processes, however, are not always based solely on scientific studies of the same 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.

  Examples of low quality evidence include out-of-date studies that fail to reflect modern scientific understanding or have been discredited or even retracted; environmental impact models without publicly available data or assumptions; weak epidemiological studies that fail to meet well-established standards of quality and utility; inaccurate statistical analysis; failures to differentiate adequately between correlation and causation; and hypothesis-forming assumptions without robust scientific justification.

- **Unpredictability of test requirements** – substantive guidance, determined by EU risk assessment agencies and other advisory mechanisms, prescribes the tests that companies must perform to demonstrate that new or existing technologies meet agreed standards of safety. Ideally, such requirements reflect the outcome of a high quality scientific assessment and remain stable over time, providing certainty and predictability for investors, unless there is significant scientific or technical progress.

  This standard of good practice is not always met by the EU institutions, leading to rapid revisions of guidance not justified by scientific evidence and creating "data gaps" that companies cannot fill without significant, unanticipated additional expense. When this occurs it erodes incentives to invest in innovation.

- **Inappropriate application of the Precautionary Principle** – 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[30].

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

  Examples include "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; reliance on models and academic studies unrelated to real world experience; and the application of excessively conservative defaults and other bridging assumptions not justified by scientific evidence.

- **Undue influence of public opinion on selection and interpretation of scientific evidence** – when implementing risk management laws, evidence from throughout the OECD area suggests that the most effective decisions are based on the outcomes of scientific assessments derived from the best available science. Risk managers use this evidence to design effective solutions to ensure that benefits justify costs.

  Risk management decisions at EU-level do not always meet this standard. On too many occasions, the selection and interpretation of evidence by risk managers has been influenced by public opinion and social concern, rather than the findings of scientific assessments.

- **Politicisation of mandates** – the scope of a scientific assessment is determined by a mandate from the risk manager. In some cases this is determined by legislation, whilst

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

in others it reflects a specific, current need. Good practice suggests that mandates for scientific committees should be confined to questions that can be answered solely by scientific evidence, and that they should preclude value judgements or opinions.

In a number of cases, scientific assessments for EU institutions have been undertaken on the basis of mandates that embed values or that require the exercise of non-scientific judgements. This undermines the credibility of the process of scientific assessments.

- **Lack of a "public record" requirement** – most EU member states require the actions of the executive function of government to meet legally defined standards of good administration. This protects citizens from abuses of power, increases openness and predictability, and helps make decision-making consistent.

  At EU-level there is a lack of legally enforceable standards of good administration, hence there is no requirement for a "public record" that includes all of the scientific evidence used to justify an implementation decision. Without this, scientific assessors and risk managers are able to include, within their deliberations, low quality studies or unscientific studies that have not been the subject of an expert Systematic Evidence Review.

- **Poor risk communication** – good administration places significant emphasis on transparency in the exercise of executive power, including the communication of the findings of significant scientific assessments. When this is done well, it helps to build confidence in the effectiveness of government and, where appropriate, manage public concerns.

  On too many occasions, communication of the results of scientific assessments to risk managers and to the public by EU institutions prompts stigmatisation. When results are not explained contextually or when undue influence is placed on uncertainties that cannot be resolved by science, then there is scope for misunderstanding and for the social amplification of risk.

- **Failure to defend science and scientists** – risk management decisions, even when implementing laws, do, on some occasions, reflect non-scientific factors. This is a political judgement by the executive function, for which it is accountable. When this occurs,

good practice suggests that it should not be justified by uncertainties or by judgements within a scientific assessment, unless there is manifest error. Instead, officials should explain the influence of non-scientific factors in their decision-making. If, for example, they are seeking to assuage 'concerns' then they should state this.

Too often this does not occur at EU-level, thereby undermining the credibility of the wider scientific assessment process. It also sends negative signals to investors in innovation. Over time, it further reduces incentives for eminent scientists to contribute to scientific assessments at EU-level.

5. Conclusions

Over the last two decades, significant improvements have been made in the way in which the EU institutions collect and use scientific evidence to assess and manage the risks to humans and the environment posed by technologies and lifestyle choices. In some policy areas, this has stimulated the development of policies and processes that deliver widely-respected high quality scientific assessments on a regular basis.

Despite this, the process of reform remains incomplete. Looking 'horizontally' across a wide range of risk management processes and programmes, standards of scientific assessment and risk management are inconsistent and unpredictable, and too many scientific assessments fail to meet globally-accepted standards of excellence. Specific problems include inadequate expertise; failure to ensure impartiality of scientific experts; undue influence of low quality studies; unpredictability of test requirements; inappropriate application of the Precautionary Principle within scientific assessments; lack of transparency of scientific assessment and risk management; poor risk communication; and an unwillingness of regulators to defend science, the scientific method, and scientists.

Failings such as these in the governance of one of the world's largest trading areas are the result of complex causes. Most obviously, they reflect the way in which the system of scientific advice used to inform risk management decision-making at EU-level has developed.

Over more than three decades, this process has taken place on a piecemeal basis. Today, it reflects the specific goals and requirements of a series of risk management laws, combined with the bureaucratic practices and cultures of different parts of the European Commission. It lacks, as a result, powerful horizontal institutions, policies, and guidance designed to ensure that the best available science is used to inform and guide throughout the policy cycle; and, that standards of good administration are met. Political commitments to base decisions on the best available scientific evidence are limited, ambiguous, and inconsistent. No central oversight mechanism exists and there are, for example no common policies and standards for the collection and use of scientific evidence, selection of scientific experts, functioning of scientific committees, and risk

analysis. Critical 'horizontal' guidelines, dealing with issues such as the characteristics of best available science or the best practices for Systematic Evidence Review, are missing too.

There are deeper, underlying causes as well. Some, such as the structural politicisation of implementing decisions or the mismatch between legislative aspiration, scientific capability, and technical capacity, are the result of decisions taken at EU-level, whilst others reflect wider changes in the context within which risk management decisions are made and their impact on EU-level decision-makers.

Trust in public institutions has declined, reflecting a shift in social attitudes and the impact of a series of regulatory failures in the 1980s and 1990s. Governance mechanisms continue to evolve in response to this, leaving many risk management processes embryonic or over-focused on process transparency and citizen involvement rather than ensuring the excellence of inputs as well as predictable and effective outcomes. It is all too easily forgotten that 'participatory' regulatory processes lack legitimacy, and that public trust depends, in part, on the effectiveness of government action.

Finally, the position of scientific evidence as a privileged knowledge input is threatened. Some citizens have little trust in science or in politicians. Others, taking a more intellectual perspective, argue that science is just opinion because there is no such thing as truth, and that all evidence must be biased because it is the product of human judgement. Science is thus elided with scientists. Such concerns and critiques create problems for politicians and regulators and, increasingly, undermine the use of the best available scientific evidence to guide risk management decisions.

Throughout all of this, the scientific method, scientific enquiry and its contribution to human progress is ignored or dismissed.

Whilst expert scientific assessments may not be able to resolve conflicts of values or to establish definitively the absence of all risks, our lifestyles depend on them, our government is based on them, and complex decisions cannot be made without them. There is, moreover, no credible alternative.

The challenge facing the European Union is to recognise this and to undertake the necessary reforms to improve and strengthen scientific assessments. It is the

natural complement to the OECD's regulatory principles that all member governments, including the European Commission, support. **It is the next step for the Commission's much-admired Better Regulation strategy.** It is the means to deliver high standards of protection for Europe's citizens and for the environment, whilst at the same time helping to stimulate risk-takers to invest in the innovations needed to restore growth and prosperity.

6. Recommendations

Reflecting the mandate of the European Risk Forum, a programme of reforms has been identified that focuses on the use of scientific evidence to guide risk management decisions at all stages of the policy-cycle (policy formulation, law-making, and implementation through rules, guidance, and administrative decisions). **They are a set of reforms designed to change behaviours within a complex institutional framework. As such, they target change in political commitment, institutions, policies, and guidelines, and recognise that reforms take time to develop, accept, and implement**.

The reforms build on the many good practices already present within the EU institutions. Taken together, they target the underlying causes of the failings of the current EU-level system, along with the weaknesses in structures and processes identified by the ERF's research.

The programme set out is ambitious. It recommends extensive improvements and changes. Implementation will take time. Some reforms can be implemented within the next 1-3 years; others will take longer. Ideas for immediate reform are also set out in the Executive Summary of this monograph.

Recommendations are included for a range of different actors: EU institutions collectively; the European Commission; the European Parliament; the scientific community; business; and other organisations[31].

If implemented fully, these recommendations provide a means for the EU institutions to build a world-leading process for collecting and using scientific evidence to assess and manage risk: one of the most important areas of public policy. Standards of protection will be enhanced as a result, and innovation, the single most important process for delivering the social and economic objectives of citizens, will benefit too. Predictable risk management processes anchored in world-class scientific evidence provide powerful incentives for investors to support innovation and hence contribute to Europe's prosperity.

31 It is important to note that responsibility for ensuring the quality of individual studies rests with the scientists who undertake the research. Governments, however, are responsible to developing structures, processes, and policies for ensuring that the best available science guides and informs risk management decision-making.

6.1. EU Institutions and Risk Management

6.1.1. Political Commitments

Recommendation 1: Collectively, the EU institutions should, through a revision of the Inter-Institutional Agreement on Better Law-Making, make a formal commitment to:

- Make and implement laws on the basis of high quality evidence, using globally-accepted standards of regulatory management and good administration;
- Design and implement risk management measures that protect human health, public safety and the environment while 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.

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.

6.1.2. Legislation

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.

6.2. European Commission – Political Commitments

Recommendation 4: Political responsibility for the quality and effectiveness of the overall process of collecting and using scientific evidence to make risk management decisions should rest with the First Vice-President in charge of Better Regulation. This portfolio, which aims to improve the quality of regulatory decision-making, is a logical complement to the existing Better Regulation policy, and should be closely co-ordinated with the Commissioner for Research, Science and Innovation, and with the Commissioner responsible for the Joint Research Centre.

6.3. European Commission - Institutional Architecture

6.3.1. Central Oversight Body – Scientific Advice Mechanism

Recommendation 5: A central oversight body with responsibility for ensuring the effective functioning of the entire scientific advisory system should be set up. It includes overseeing the quality, objectivity, utility, and integrity of scientific evidence and advice used to guide and inform decision-making in all parts of the EU's executive government, including agencies. It should be adequately staffed with relevant experts and be given strong powers to ensure compliance with common policies and guidelines by all directorates and agencies. It must, moreover, be independent of the Joint Research Centre, EU agencies, and policy DGs.

This could be achieved, for instance, by expanding the scope of responsibilities of the Scientific Advice Mechanism (SAM). This should be a permanent 'horizontal' function of the SAM. Accordingly, the mandate of the SAM 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

6.3.2. Evidence Centre – Joint Research Centre

Recommendation 6: Building on the 2016 strategy for the Joint Research Centre (JRC), this institution should expand its role and capacity as the European Commission's centre of excellence for scientific evidence, including that used to inform the management of risk.

Specifically, the mandate of the JRC should be expanded so as to include responsibility for:

- Providing expert resources, advice and support to scientific advisers and officials using scientific evidence throughout all stages of the policy cycle, including law-making and implementation. This may include providing experts on secondment to policy DGs;

- Co-ordinating a programme of training to enhance the scientific literacy of officials in Commission services involved in risk-management decision-making;

- Promoting the mobility of researchers and policy officers between the JRC and policy DGs;

- Supporting the Regulatory Scrutiny Board by assessing the quality and relevance of scientific evidence used to support legislative and regulatory measures designed to manage risks to human health, public safety, and the environment;

- Becoming the knowledge manager for the European Commission;

- Promoting stronger links between the scientific community and EU agencies. This could include developing programmes that enable scientists to work within EU agencies for limited periods;

- Managing a 'foresight' process designed to examine long-term policy challenges that are likely to cross many traditional departmental boundaries and require scientific input;

In order to achieve these objectives, action is needed to ensure that the JRC has the in-house technical expertise, state-of-the-art laboratories, independence, and flexibility to operate as a research organisation within the Commission's administrative framework.

6.3.3. Directorate-General for Research and Innovation

Recommendation 7: Working in close collaboration with the new institutional architecture for improving the effectiveness, utility, and quality of the scientific advisory process within the European Commission, the Directorate-General for Research and Innovation should be responsible for:

- Designing and funding an extensive investment in regulatory science that makes use of resources from EU research framework programmes' budgets. This should be developed using panels of eminent scientists with relevant experience and independent of the EU institutions.

- Establishing funding conditions that require scientists involved in regulatory science projects to carry out studies using internationally accepted standards (such as GLP and OECD guidelines). Member States should be encouraged, by the European Commission, to establish similar funding conditions;

6.3.4. Directorates-General and Agencies

Recommendation 8: Each Commission policy directorate-general and EU agency with a scientific remit should establish an internal organisational structure to ensure that scientific evidence used to inform and guide decision-making meets the standards set out in Commission-wide policies and guidelines.

- Each policy directorate-general and agency should appoint a senior scientific adviser (or scientific advisory panel), reporting directly to the Director-General or Executive Director, responsible for ensuring the quality, objectivity, utility, and integrity of scientific evidence used to guide and inform decision-making. The scientific adviser (or panel) must also be responsible for identifying future policy issues that will require access to scientific evidence and for commissioning additional research, as appropriate.

- Compliance with Commission-wide policies and guidelines should be described in an annual report produced by the scientific adviser (or panel).

- Officials responsible for collecting, or using scientific evidence should receive regular training. This should cover the broad methodological principles and concepts that underpin scientific evidence; scientific quality; limitations and uses of scientific evidence; risk assessment, understanding of scientific uncertainty in scientific assessments; risk communication; briefing of scientific experts; and compliance with government-wide policies and guidelines.

- All risk assessment agencies should establish transparent, science-based processes for the development and reform of substantive technical and scientific guidance. Processes should meet the standards set out in the Commission's Better Regulation Policy. They should be based on the best available science; they should embed early and regular consultation with stakeholders; and they should be informed fully by a comprehensive understanding of costs and benefits. Processes should be transparent.

6.3.5. Networks

Recommendation 9: EU-ANSA, the informal network of agency scientific advisers, should be placed on a permanent basis and provided with adequate secretarial support. It should seek to ensure effective sharing of operational good practices. Ideas should also be shared with Member State scientific advisory panels and advisors using existing networks.

Recommendation 10: The European Science Advisors Forum (ESAF), the emerging network of science advisors in Member States, should become the main platform for exchanging best practices in scientific assessments between Member States, and between the Member States and the EU institutions. In the longer-term, this network should become a formal Council committee, similar to the European Research Area Committee (ERAC).

6.4. European Commission - Policies

6.4.1. Risk Analysis

Recommendation 11: The European Commission should develop and adopt common principles and minimum detailed standards for risk analysis. This could be achieved through, for example, the adoption of a new Communication. It should:

- Develop the ideas and concepts set out in the EU Food Law;
- Distinguish between risk assessments used for determining policy and designing legislation, where scientific evidence should inform decision-making, and the processes of implementing laws where, unless required otherwise by legislation, decisions should be based on scientific evidence; and,
- Require all risk assessments to be informed fully by real world experience and evidence, and to be based on normal handling and usage.

(A more extensive description of the suggested coverage of a Communication is set out in **Appendix B**.)

6.4.2. Quality, Collection, and Use of Scientific Evidence

Recommendation 12: The European Commission should develop and adopt, in, for example, a new 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 peer review, and provision of an independent right of appeal, prior to dissemination of the findings of significant scientific assessment; and,

- Establish 'excellence', regardless of funding, and relevance as the sole criteria for determining whether or not scientific evidence is included within a scientific assessment.

(Appendix C sets out the suggested coverage and requirements of a new Decision in more detail.)

6.4.3. Scientific Experts and Committees

Recommendation 13: The European Commission should set out, in, for instance, a new Decision, the key principles for the selection of scientific experts and for the operation of scientific committees. These should be minimum standards and should apply to all agencies and directorates, and all forms of scientific committee including Technical Working Groups. The Decision should:

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

- Recognise that industry is an important, and sometimes critical, source of knowledge, expertise, and experience, and that transparent processes should be put in place to ensure that scientific experts have access to this;

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

- Establish transparent selection processes that take due account of and distinguish clearly between two different challenges to impartiality: bias and financial conflict of interest;

- 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;

- Establish standard rules of procedure for scientific committees; and,

- Limit the scope of mandates to scientific experts to questions that are capable of being answered using scientific evidence.

(The suggested coverage and requirements of a new Decision are set out in more detail in **Appendix D**.)

6.5. European Commission - Guidance

Recommendation 14: Working under direction of the central oversight institution, 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. This 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.

Commission-wide guidance should include:

- Catalogue of characteristics of "best available science"
- Design and use of Systematic Evidence Reviews;
- Nature and use of epidemiological evidence;
- Data interpretation and statistical analysis;
- Reporting and communication of scientific uncertainties;
- Nature, quality and use of social science evidence;
- Procedures for identifying and managing conflicts of interests of all types, including ideological bias, when selecting scientific experts;
- Rules of procedure for scientific committees;

- Standards for independent peer review of scientific assessments;
- Mechanisms and procedures for an independent right of appeal, prior to the publication of a scientific assessment;
- Characteristics of poor quality scientific evidence;
- Key concepts and definitions used in science and risk assessment

6.6. European Commission - Better Regulation Guidelines

6.6.1. Consultation

Recommendation 15: Standards and processes for public consultation should be revised to recognise the difference between opinions collected through such processes and the outcomes of scientific assessments. They should recognise explicitly that public consultation is not a substitute for collecting scientific evidence through formal processes of scientific assessment.

6.6.2. Impact Assessment – Intervention Logic

Recommendation 16: Guidelines for impact assessment should be expanded to recognise that the intervention logic for ex ante assessment of measures designed to manage risks posed to human health, public safety, and the environment should be based on the findings of a formal science-based risk assessment. This should meet the requirements for best available science and risk analysis set out in other Commission-wide policies. It should provide a justification for government intervention that distinguishes evidence of hazard from assessment of risk. It should be based on credible real world experience and normal handling and use. As well as identifying the benefits of government action, it should provide, through a science-based analysis of cause-and-effect, a framework for the design of appropriate and effective risk management options

6.6.3. Risk Management – Precautionary Principle

Recommendation 17: Supplementary guidelines should be developed that clarify the role of the Precautionary Principle in regulatory decision-making. These should be in addition to and should not replace the existing Commission Communication. 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. It should remind all agencies and directorates of these requirements.

The guidelines should 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.

6.6.4. Regulatory Scrutiny Board

Recommendation 18: The Regulatory Scrutiny Board (RSB) should ensure that all sections of ex ante impact assessments fully meet the relevant requirements set out in the Better Regulation guidelines. The RSB should also review, using support from JRC experts, the scientific evidence used to support Commission initiatives designed to protect human health, public safety, or the environment.

6.6.5. Ex Post Evaluation

Recommendation 19: Measures designed to protect human life, public safety, or the environment should be required to re-assess the original scientific evidence and risk assessment used to justify intervention, as well as examining new scientific evidence, within an appropriate time horizon. Reviews should encompass legislative and implementing measures and should be carried out in accordance with Commission-wide policies for the quality of scientific evidence, and risk analysis.

6.6.6. Substantive Technical and Scientific Guidance

Recommendation 20: Recognising the major role that technical and scientific guidance plays in implementing measures to protect human health, public safety, and the environment, all major guidance proposals should be brought within the scope of the requirements of the Commission's Better Regulation Policy.

6.7. European Parliament

6.7.1. Science and Technology Assessment Panel (STOA)

Recommendation 21: The focus of the STOA Panel should be expanded to promote debate amongst MEPs about the following:

- Importance of scientific evidence as a pre-eminent knowledge input for decision-making;
- Characteristics of the best available science and the dangers of basing decisions on poor quality scientific studies;
- Benefits of using the best available science when managing risks posed by technologies; and,
- Governance within the European Parliament to ensure that advice provided to MEPs is based on the best available science

6.7.2. European Parliament Research Service (EPRS)

Recommendation 22: Scientific evidence provided to legislators by the EPRS should meet uniform standards that are directly derived from or made equivalent to relevant Commission-wide policies and guidelines for the quality, collection and use of scientific evidence and for scientific experts and committees. Standards should be transparent, and they should include independent peer review of the findings of reports, prior to their dissemination to legislators. They should apply to research conducted using in-house resources and to outsourced studies.

6.7.3. European Parliament Group on Risk

Recommendation 23: Additional resources should be provided by the European Parliament to support the work of the EP Group on Risk. The group should also be encouraged to continue to seek multi-group political representation, and to seek active collaboration with other EP inter-groups, such as those focused on promoting research and innovation.

6.8. Scientific Community

Recommendation 24: Eminent scientists, academies of science and learned societies, research-performing organisations, and higher education institutes that promote science standards should support independent activities and institutions designed to support, promote and oversee the use of the best available science by the EU institutions. Specifically, they should take action to:

- Engage in robust public debate to explain and promote the scientific method, and its contribution to progress; to counter critiques of science, scientific enquiry, the scientific method, and scientists; and to ensure a more informed debate about the consequences for citizens of policy-makers endorsing abstract risk management goals, such as the pursuit of zero risk or a toxic free world. They should also provide evidence to citizens of the benefits for health, safety, and the environment of basing risk management measures on the best available science.

- Provide expert scientific evidence on important or controversial issues to journalists and media outlets.

- Develop specific proposals to define methodological guidelines for improved scientific assessment. These should be drawn up independently of initiatives of the EU institutions, and should include guidelines such as a catalogue of characteristics of best available science; Systematic Evidence Review, possibly drawing on the work of the Cochrane Collaboration; use and interpretation of epidemiological evidence; and statistical analysis and interpretation.

- Participate in expert committees to assist the central oversight institution, Joint Research Centre, the EU's risk assessment agencies, and the European Parliament Research Service, as well as equivalent institutions at national level;

- Build relationships with editors of major scientific journals so as to widen the stock of good scientific studies by publishing a greater number of "no effect' studies;

- Work with independent institutions, including Think Tanks, to develop quality standards for the use of social science in risk management decisions. Proposals should recognise the structural weaknesses of much existing social science research used in regulatory processes most notably the lack of verifiability and reproducibility; the failings of peer review, designed for natural science, in these academic domains; the nature of evidence used by the private sector when investing in understanding attitudes, intentions, and usage of customers; and the expertise available within the professional market research industry.

6.9. Business

Recommendation 25: Major businesses, trade associations, and business organisations should develop a series of programmes to build trust in the contribution of industry knowledge to the effective management of risk. This is likely to include:

- Participating financially in transparent programmes, jointly with the EU institutions, to improve regulatory science in important areas, such as complex hazards and the impacts of new technologies;

- Engaging with EU institutions to develop common methodologies for scientific assessments, including risk assessments;

- Publishing the outcomes of investments in regulatory science in high impact, peer reviewed scientific journals using the open access "gold standard", where this does not compromise confidential business information;

- Drawing up codes of scientific integrity at a sectoral-level and establishing transparent audit procedures;

- Investing in education and communication programmes at EU, national and community-level to explain more thoroughly the role the industry plays in funding R&D in general and regulatory science in particular; and,

- Investing in socio-economic studies that demonstrate the public gains from innovation and other forms of economic activity. These should highlight the benefits for societies from products and technologies, as well as wider corporate investment in communities, research structures, and the business environment.

6.10. Other Organisations

Recommendation 26: Other organisations involved in generating and assessing scientific studies, so as to participate in risk management debates, should make public commitments to maintain the highest standards of excellence; to act in a manner that is consistent with the requirements of the scientific method; to enforce quality standards rigorously; and, when reporting findings, to distinguish clearly between scientific evidence and value judgements.

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.

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Appendix A

Good Practice Framework

1. Political Commitments

Politicians at the highest level of government make formal, public commitments to:

- Make and implement laws on the basis of 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 while 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;
- Ensure that scientific assessments, including risk assessments, reflect fully real world experience and normal conditions of usage and exposure; and,
- Communicate fully, openly, and objectively the potential risks posed by technologies, whilst recognising explicitly that a zero risk society is neither possible nor desirable.

2. Legislation

The legal framework includes a Law of Administrative Procedures (LAP) or equivalent. This recognises the central role that risk assessment, and other forms of expert scientific assessment, plays in the implementation of laws. These activities fall within its scope. The LAP establishes 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.

At a sectoral-level, legislation requires officials to base risk management decisions on the best available science and high quality risk assessments that fully reflect a "real world" understanding of exposures.

3. Institutional Architecture

3.1. Central Oversight Body

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 and advice. This is a permanent 'horizontal' function with responsibility for the quality, objectivity, utility, and integrity of scientific evidence and advice used to guide and inform decision-making in all parts of government, including agencies. It is adequately staffed with relevant experts and has strong powers to ensure compliance with common policies and guidelines by all departments and agencies.

*3.2. Departments and Agencies*32

Each department and agency establishes an internal organisational structure to ensure that scientific evidence provided by experts and scientific advice used to inform and guide decision-making meets the standards set out in government-wide policies and guidelines.

3.3. Networks

Formal networks of departmental and agency scientific advisers are in place, supported by the central oversight body. These share good practice and identify scientific and technical issues that have 'horizontal' implications.

3.4. Investment

There is a well-resourced, long-term programme of investment in the development of regulatory science. The central oversight body oversees this, working, where relevant, with

32 There is a clear distinction between "science advisers" and "scientific experts". Science advisors mediate between politicians and regulators and the processes designed to generate scientific evidence. They are part of the structure of regulatory process management. In contrast, scientific experts provide evidence.

agencies and government departments to identify research priorities. Relevant experts from outside government are involved in the development programme.

3.5. Legislature

A well-resourced body, either internal or in-house but politically independent, provides scientific evidence, based on the best available science and scientific assessment, to help inform the work of the legislative function. All scientific evidence provided to legislators by this body meets uniform standards that are directly derived from or made equivalent to the government-wide policies and guidelines established by the executive function.

3.6. Scientific Community

Eminent scientists, academies of science and learned societies, research-performing organisations and higher education institutes contribute to independent activities and institutions designed to support, promote and oversee the use of best available science by governments. This includes the provision of expert scientific evidence on important or controversial issues; design of technical guidance for scientific assessments; support for journalists and the media; and provision of objective information for policy-makers and opinion-formers, explaining science, the scientific method, scientific excellence, and the benefits for citizens of basing decisions on science.

4. Policies

4.1. Quality, Collection and Use of Scientific Evidence

A government-wide policy recognises that science possesses unique characteristics as a form of evidence for guiding the development and implementation of measures to manage risks to human health, public safety, and the environment. To that end, it requires government decision-making to be guided by the best available science that is gathered using widely accepted, consistent, open and transparent processes, and subject to robust quality controls.

The policy sets out the objectives and principles that determine the quality of scientific evidence that is used to guide policy, legislative, and implementation decisions, as well as

its collection and use. It states explicitly that 'excellence' and relevance, regardless of the source or funding, are the only criteria for determining whether or not scientific evidence is included within a scientific assessment.

Finally, the policy establishes that before the findings of a significant scientific assessment are disseminated, they are subject to an independent peer review.

4.2. Scientific Experts and Committees

A 'horizontal' policy, covering all departments and agencies, sets out key principles for the selection of scientific experts and for the operation of scientific committees. It requires scientific evidence used to guide the decisions of governments to be provided by groups of highly qualified, eminent scientific experts able to bring together insights from different scientific disciplines, where this is appropriate, and to draw on relevant scientific expertise from any source. There is a clear, transparent distinction between findings and conclusions derived from scientific assessments and those from other sources of knowledge. This ensures the integrity of scientific advice.

The policy states that all relevant scientific experts who meet agreed criteria of eminence, excellence, and relevance are eligible for selection. Through a transparent selection process that uses peer group nomination and self-identification, experts are chosen who meet agreed standards of excellence and relevance, and who are also impartial and thus able to act objectively in the public interest. Selection processes, moreover, take due account of and distinguish clearly between two different challenges to impartiality: bias and financial conflict of interest.

Finally, a clear process is in place to identify and highlight the potential for bias. It recognises that bias is, in general, intellectually motivated or the result of a close identification with a particular point of view or group. It accepts that on some occasions the group of expert scientists may be able to balance certain forms of bias but recognises that some potential sources of bias may be so substantial that they preclude committee service.

4.3. Risk Analysis

A government-wide policy sets out common principles for risk analysis. This requires a clear distinction between three phases of activity: "risk assessment", the structured process of assessing scientific evidence; "risk management", the process for determining legislative or regulatory measures guided by the findings of risk assessment; and "risk communication", the process of explaining the findings of assessment and management to decision-makers and citizens.

The policy distinguishes between risk assessments used for determining policy and designing legislation, where scientific evidence informs decision-making, and the processes of implementing laws where, unless required otherwise by legislation, decisions are based on scientific evidence.

4.4. Regulatory Process

Government-wide regulatory process principles, standards, and guidelines require the use of the best available science, and expert scientific assessment, for the ex ante and ex post evaluation of measures designed to manage potential risks to human health, public safety, or the environment. They recognise explicitly, moreover, that public consultation is not a substitute for collecting scientific evidence through formal processes.

Intervention logic for ex ante assessment of measures designed to manage risks posed to human health, public safety, and the environment is based on the findings of a formal science-based risk assessment. This meets the requirements for best available science and risk analysis set out in other government-wide policies. It provides a justification for government intervention that distinguishes evidence of hazard from assessment of risk. It is based on credible real world experience and normal handling and use. As well as identifying the benefits of government action, it provides, through a science-based analysis of cause-and-effect, a framework for the design of appropriate and effective risk management options.

Quality assurance of ex ante impact assessments includes a formal review of the scientific evidence, and expert risk assessment, used to justify government action. Appropriately

qualified experts, participating in formal regulatory oversight institutions, undertake this review.

Ex post evaluations of risk management measures are required to re-assess the regulatory (risk management) option chosen in the light of the original scientific evidence and risk assessment used to justify intervention, as well as examining new scientific evidence. This is carried out in accordance with government-wide policies for the quality of scientific evidence, and risk analysis.

5. Guidance

Committees of eminent scientists, who are independent of government, are responsible for drawing up all significant, detailed technical guidelines required to support the government-wide policies for the quality of scientific evidence and risk analysis. This ensures 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.

Appendix B

European Commission: Recommendation on Risk Analysis Policy

A new Commission Communication should set out common principles for risk analysis. This should require a clear distinction between three phases of activity: "risk assessment", the structured process of assessing scientific evidence; "risk management", the process for determining legislative or regulatory measures guided by the findings of risk assessment; and "risk communication", the process of explaining the findings of assessment and management to decision-makers and citizens.

The Communication should distinguish between risk assessments used for determining policy and designing legislation, where scientific evidence informs decision-making, and the processes of implementing laws where, unless required otherwise by legislation, decisions are based on scientific evidence.

Specifically it requires:

Risk Assessment:

Risk assessors only employ the best available science, which meets standards for quality, collection, and use set out in the relevant policy, to assess risks to health, safety, and the environment. This applies to scientific assessments carried out for each individual stage of a risk assessment: hazard identification; dose-response relationship; exposure; and risk characterisation;

- Risk assessments describe clearly the scope of work – agent, technology, or activity; hazard of concern; affected entities; exposure or event scenarios; and, event-consequence or dose-response relationship for the hazard of concern;

- Risk assessments, unless required otherwise by law, encompass all appropriate hazards, and, as well as considering the full population at risk, pay attention to sub-populations that may be particularly susceptible to such risks or may be more highly exposed;

- Characterisation of risk and changes in the nature or magnitude of risks is broad enough to inform risk management decisions made by government. To achieve this, it is likely to be qualitative and quantitative, consistent with available data;

- Unless otherwise required by statute, assessments of exposure are informed fully by real world evidence and based on normal handling and use;

- Judgements used in developing a risk assessment such as assumptions, defaults, and uncertainties should be stated explicitly, and the rationale for these judgements, and their influence on the assessment, should be explained;

- Approaches to evaluating risks posed by hazardous agents or events are consistent

Risk Management:

Risk management decisions are guided by government-wide regulatory management principles. These cover design of legislative measures and their implementation through a mix of rules (regulatory decisions), substantive guidance, and administrative actions. Scientific evidence is used to help officials analyse the distribution of risks, to identify the benefits of action; to evaluate reasonable feasible risk management strategies; and to help officials limit the likelihood of regulatory failure.

Risk Communication:

Communication of the findings of risk assessments to risk managers is consistent with its purpose and is timely, comprehensive, informative, and understandable. Specifically, good presentation ensures that:

- Each population addressed by any estimate of risk and each risk assessment end-point is identified, along with the expected and (appropriate) upper and lower bound estimates of human health or environmental risk;

- Excellent studies and data that support, are directly relevant to, or fail to support any estimate of risk are highlighted;

- Components of the advice that depend on widely accepted facts, judgement, and opinion are distinguished clearly;
- Methodologies used to reconcile inconsistencies in scientific data are explained fully;
- Assumptions or analytical methods on which conclusions rest are described fully;
- Significant uncertainties are identified and explained;
- New evidence that might alter conclusions is highlighted; and,
- Value judgements are avoided and comments restricted to science and scientific advice;

Communication of the findings of the overall process of risk analysis to citizens is a two-way exchange of information. It ensures that:

- Risk management goals are stated clearly;
- Significant assumptions, data, models and inferences used or relied upon in the assessment, or in the risk management decision, are explained fully;
- Sources, extent, and magnitude of significant scientific uncertainties associated with the assessment or risk management decision are described. A clear distinction is drawn between uncertainties that further scientific evidence may be able to resolve and those that are, in effect, scholastic or ideological in origin or represent a clash of values;

Appendix C

European Commission: Recommendation on Quality, Collection and Use of Scientific Evidence Policy

The Commission should draw up and adopt a Decision that sets out the objectives and principles that determine the quality of scientific evidence that is used to guide policy, legislative, and implementation decisions, as well as its use and collection.

Specifically, it should require:

Objectives:

- Decision-making is guided by the best available science gathered using widely accepted, consistent, open and transparent processes, and subject to robust quality controls.

General:

- Application of the policy is comprehensive. It should cover all scientific assessments carried out by, and on behalf of, all directorates or agencies to guide policy-making, legislation, implementation of laws (including regulation and substantive guidance), and ex post evaluation.

- Science is recognised as possessing unique characteristics as a form of evidence for guiding the development and implementation of measures to manage risks to human health, public safety, and the environment. Its benefits for effective decision-making, for protecting citizens and the environment from risks, and for promoting innovation are explained fully. Science, as a result, is the pre-eminent knowledge input in these policy areas;

- Important concepts and definitions, necessary for the understanding by officials of scientific evidence, are explained. Conceptual information acknowledges fully the limitations of the scientific method. Definitions include "best available science", "the scientific method", "scientific uncertainty', "hazard", risk", and "risk assessment". Key

activities that underpin the process of collecting and assessing scientific evidence are also described;

- Scientific evidence is only collected through expert, transparent, open processes, unless otherwise required by statute. Consultants and other similar 'ad hoc' sources of scientific information should not be used. Where this is unavoidable, due to the need to acquire specific expert evidence, then the reasons for doing this should be documented and the process used should be fully transparent and subject to external scrutiny, including independent peer review. In the event that this occurs, moreover, then the requirements of the Commission Decision on Scientific Experts and Committees must apply;

- Assurance of the quality of scientific evidence is critical for ensuring that government decisions are effective and guided by excellent science. Robust quality controls are required to ensure this, including peer review of significant scientific assessments

- Not all studies are of equal quality: some are flawed; others are as yet unverified or have not been replicated; and some are misleadingly or erroneously interpreted. Poor studies are excluded, using explicit and transparent criteria and processes, from scientific assessments.

Quality:

- 'Excellence', regardless of the source or funding, and relevance are the sole criteria for determining whether or not scientific evidence is included within a scientific assessment;

- Detailed guidance provides definitions of "best available science" (the traditional meaning of excellence) in general, for different types of scientific evidence, and for its interpretation, based on a presumption favouring studies carried out using internationally accepted and validated approaches that meet the demanding requirements of the scientific method;

Collection:

- Unless otherwise required by statute, scientific evidence is collected using the well-established process of Systematic Evidence Review, focusing on a "bottom up" process of assessing all relevant studies that meet tests of quality and relevance. Detailed guidance provides a description of modern requirements. In general, however, this requires

    - Agreement of a protocol for the process that is capable of being peer reviewed and that would enable a similarly qualified group to reach the same conclusions;
    - Collection of all relevant published and unpublished evidence;
    - Selection of evidence on the basis of defined and reported criteria;
    - Elimination of evidence that is irrelevant or of inadequate quality;
    - Synthesis and interpretation of evidence in an unbiased way, with a presumption favouring quality and weight-of-evidence;
    - Presentation of findings in a complete, transparent, and unbiased way with due consideration to their limitations

Use:

- Before the findings of a significant scientific assessment are disseminated, they are subject to an independent peer review, unless precluded by statute. This examines the process carried out and the substance of the findings of the assessment. It is undertaken whenever an assessment is based on novel or hypothesis-forming science or if the findings will have a clear and substantial impact on important public policies or private sector decisions. Reviews are, moreover, carried out independently of scientific committees or technical working groups overseeing the formulation of scientific assessments;

- After completion of peer review and formulation of draft scientific assessment, affected parties have the right of scientific appeal. This is exercised prior to publication of the draft assessment and focuses solely on the processes of assessment and the interpretation of scientific evidence. Appeal processes are established to facilitate this;

- Scientific evidence provided to policy-makers and officials is published, subject only to necessary restrictions to protect the confidentiality of commercially sensitive data.

Appendix D

European Commission: Recommendation on Scientific Experts and Committees Policy

A 'horizontal' Decision, covering all departments and agencies, should be adopted by the Commission that sets out key principles for the selection of scientific experts and for the operation of scientific committees. It should apply to all parts of the policy-cycle: policy, legislation, implementation (rules, guidance, administrative decisions), and ex post evaluation.

Specifically, it requires:

Objective:

Scientific evidence used to guide the decisions of governments is provided by groups of highly qualified, eminent scientific experts able to bring together insights from different scientific disciplines, where this is appropriate, and to draw on relevant scientific expertise from any source;

General:

Scientific committees provide expert advice to governments. They comprise leading eminent scientists. They are balanced, containing scientists from different scientific disciplines or perspectives, where this is appropriate;

Guiding principles for the assessment and provision of scientific evidence are established. These include rationality, excellence, impartiality, transparency, reasonableness, public duty, consistency, and proportionality. Unless otherwise guided by statute, they require assessments of exposures or usage to be informed fully by real world evidence and to be based on normal handling and use. They also require the use of the Precautionary Principle to be confined to risk management decisions;

Industry is an important, and sometimes critical, source of knowledge, expertise and experience. Transparent processes are in place to ensure that scientific experts have access to this;

Appropriately qualified scientists with relevant expertise, who meet agreed standards of excellence, carry out scientific assessments. Moreover, there is a clear, transparent distinction between findings and conclusions derived from scientific assessments and those from other sources of knowledge. This ensures the integrity of scientific advice;

A clear distinction is drawn between expert groups that provide scientific assessments and those that provide other forms of advice. Whenever groups are asked to provide scientific assessments then membership of the group should be limited to appropriately, excellent scientists;

Scientific assessments do not recommend specific regulatory practices or risk management options, or answer questions that involve economics, ethics, values or other matters of policy, unless specifically required to do so in a written mandate;

Scientists, when carrying out scientific assessments, are insured against all forms of liability related to their work, findings, and conclusions.

Scientific Experts:

- Whilst all scientific experts must be highly qualified and possess relevant expertise; they should also be eminent, excellent, and recognised by their peers. These are the primary criteria used to select them;

- All relevant scientists who meet agreed criteria of eminence, excellence, and relevance are eligible for selection. This includes scientists from outside the EU and those employed by, or working with, stakeholders;

- Scientific experts are not appointed to represent a particular point of view or group;

- Where experts are independent of government, they receive remuneration and expenses for their work based on rates payable to similarly qualified consultants, so as to attract eminent scientists;

- Through a transparent selection process that uses peer group nomination and self-identification, experts are chosen who meet agreed standards of excellence and who are also impartial and thus able to act objectively in the public interest;

- Selection processes take due account of and distinguish clearly between two different challenges to impartiality: bias and financial conflict of interest;

- All scientific experts are required to commit themselves formally to act impartially, and in the best interests of citizens, when providing advice to government;

- A clear process is in place to identify and highlight the potential for bias. It recognises that bias is, in general, intellectually motivated or the result of a close identification with a particular point of view or group. It accepts that some potential sources of bias may be so substantial that they preclude committee service;

- Relevant financial conflicts of interest are required to be disclosed. These are clearly defined and relate primarily to current activities of the prospective expert, and relevant immediate family members. Financial conflicts are primarily managed through disclosure but may preclude committee service if they are current, relevant, substantial, and can reasonably be shown as being likely to impair an individual's impartiality.

Operation of Scientific Expert Committees:

- Membership of scientific committees is structured such that policy-makers have access to a relevant range of different types of appropriate scientific experts from different scientific disciplines;

- Scientific committees operate on a consistent basis following transparent written rules of procedure, and the roles of committee members, secretariat, and committee chairperson are described fully. Rules of procedure followed by all scientific expert committees meet the minimum standards set out in guidance;

- Meetings of committees are, if required, held in private, and comments by committee members are made in confidence, so as to assure objectivity and candour of advice;

- Information about the membership, activities, and outputs of scientific committees is provided to citizens on a timely basis with a presumption of openness. Scientific opinions provided to policy-makers are published, although information provided by private companies in confidence is not, in general, made available.

Briefing and Utilisation of Scientific Experts:

- Scientific committees operate within a transparent framework established by clear terms of reference that are set by policy-makers and agreed with committee members. Terms of reference are made available to citizens;

- Officials consult widely with stakeholders when framing the content and scope of policy-related questions to be answered by scientific experts;

- When dealing with issues characterised by high levels of scientific uncertainty, scientific experts help policy-makers frame the scope and content of questions;

- Use of scientific experts is confined to questions that are capable of being answered using scientific evidence. Scientific experts are not asked to express value judgements or to make policy recommendations.

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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