EUROPEAN RISK FORUM – COMMUNICATION 08

STAKEHOLDER CONSULTATION ON SMART REGULATION IN THE EU – EUROPEAN COMMISSION CONSULTATION

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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);

- 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, the Forum believes, 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 practioners 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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EXECUTIVE SUMMARY

The European Risk Forum (ERF) is a think tank committed to improving the way that legislative and regulatory decisions are made at EU-level, particularly decisions about the best way to manage risk. The ERF focuses on regulatory decision-making principles, processes, and mechanisms. It serves as a platform for high-level debate between senior officials, representatives of corporate businesses and associations as well as academics. It focuses on issues such as science and decision-making; impact assessment; consultation; lifestyle risks; regulations of new technologies; agencies; comitology; and international regulatory co-operation. The Forum also addresses risk assessment, risk management, and risk communication in a 'horizontal, cross-sectoral approach.

As a part of its work, the ERF contributes ideas to all of the EU's institutions, including participating in relevant public consultations. The Commission has set up a stakeholder consultation to examine ways of improving its Smart Regulation initiative.

The Commission's Smart Regulation initiative builds on earlier programmes designed to improve the quality of legislative and regulatory decision-making at EU-level. Taken together, these activities have generated significant improvements in the way in which the EU's institutions seek to manage risks.

Major beneficial changes include an increased focus on evidence-based decision-making, including seeking to take a comprehensive approach to understanding all of the costs and benefits of proposed government actions; comprehensive policies, processes, guidelines, and institutions for undertaking the 'ex ante' evaluation of legislative and regulatory proposals; strong, central oversight of 'ex ante' impact assessment by the Commission's widely-respected Impact Assessment Board; transparent minimum standards for consulting parties affected by regulatory interventions – indeed, the Smart Regulation has furthered improved these, lengthening the minimum period of formal consultations; and, clear commitments to establish a wide-ranging programme to evaluate the impact of regulatory decisions on an 'ex post' basis;

The ERF welcomes the opportunity to contribute to the development of the Commission's Smart Regulation initiative. Our comments focus on identifying ways of enhancing the quality of EU legislation, with particular emphasis on risk management.

Possible improvements have been identified in the following areas:

- An EU-level Administrative Procedures Act;
- Impact Assessment – General Approach;
- Impact Assessment – Risk Management Measures;
- Science and Decision-Making;
- Risk Assessment;
- Use of Precaution to Manage Risks;
- Cost Effectiveness Analysis;
- Benefits of Regulatory Action;
- Technical Guidelines and Risk Management;
- Implementation of Legislation; and,
- Ex Post Evaluation of Regulatory Decisions

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1. EUROPEAN RISK FORUM[1]

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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.

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Achieving these goals is, the Forum believes, 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 principles and requirements form part of the approach to regulatory decision-making set out by the OECD since 1995. The approach to risk regulation promoted by the WTO also makes explicit reference to these principles and practices.

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[1] For more information, please refer to the ERF website: www.riskforum.eu

A number of distinguished speakers have addressed the Forum in the past, including Members of the European Parliament, senior officials in the European Commission and EU agencies, members of the European Court of Justice, and world-leading academics.

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2. PUBLIC MANAGEMENT OF RISK

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Today, it is most readily associated with government actions to protect people at work and to protect citizens and the environment from harm. But as a core function of government, risk management has been a potent and pervasive form of public policy for more than 200 years. In that period it has been used to support a range of varied policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment; protecting industrial workers from the impacts of economic activity; and protecting citizens and the environment from undesirable risks.

Public risk management can be broadly defined as any government action designed to prevent, reduce, or re-allocate risk. It includes actions to manage risks posed by technologies, economic activity, and lifestyle choices.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their risk management responsibilities. These now encompass issues such as product safety, food safety, pharmaceuticals, chemicals, environmental protection, public health, occupational health and safety, and consumer protection.

EU-level risk management decisions are taken through two distinct and different mechanisms: the creation of new (or the revision of) secondary legislation; and the implementation of existing legislation through technical regulatory decision-making processes (including agencies, specialist advisory or scientific committees, guidelines, and implementing processes, such as 'new' comitology[2]).

Effective risk management policy requires decision-makers to strike a balance between fostering prosperity on the one hand and maximising security and equity on the other – a balance that changes over time. To ensure that risk management policies are successful, the EU's institutions need to be able to make decisions that will deliver intended economic and social goals without major, unintended negative side-effects, whilst also meeting ever rising standards of good governance.

In recent years, achieving these goals has become more difficult. Traditional decision-making models for assessing and managing risks face major challenges, which include declining public trust; increasing dissent; greater uncertainty; and increasing risk

[2] The Lisbon Treaty sets out two processes for implementing legislation: Delegated and Implementing Acts. These replace the previous process, known as 'comitology'.

aversion. At the same time, policy goals and risk management objectives have become more complex, and new ideas about the best way to manage risks have emerged.

At EU-level, these challenges have triggered a number of major changes. New risk assessment institutions have been set up; new policy objectives have been established; the scope of risk management policy-making has been expanded (to encompass lifestyle risks); and major changes have been made in technical regulatory decision-making processes. Alongside these risk-specific changes, the EU's commitment to improved governance and better quality decision-making ("Better Regulation" and now "Smart Regulation") has led to the introduction of new regulatory process management tools, most notably consultation and impact assessment.

Over the last decade, the EU's "Better Regulation" and "Smart Regulation" initiatives have led to remarkable progress. However, more needs to be done to strengthen the robustness of the tools and the accountability of the processes, as well as sustaining momentum in a number of areas, in particular the collection and use of scientific advice for decision-making.

3. SMART REGULATION

The Commission's Smart Regulation initiative builds on earlier programmes designed to improve the quality of legislative and regulatory decision-making at EU-level. Taken together, these activities have generated significant improvements in the way in which the EU's institutions seek to manage risks. Major beneficial changes include:

- Increased focus on evidence-based decision-making, including seeking to take a comprehensive approach to understanding all of the costs and benefits of proposed government actions;

- Comprehensive policies, processes, guidelines, and institutions for undertaking the 'ex ante' evaluation of legislative and regulatory proposals;

- Strong, central oversight of 'ex ante' impact assessment by the Commission's widely-respected Impact Assessment Board;

- Transparent minimum standards for consulting parties affected by regulatory interventions – indeed, the Smart Regulation has furthered improved these, lengthening the minimum period of formal consultations;

- Clear commitments to establish a wide-ranging programme to evaluate the impact of regulatory decisions on an 'ex post' basis;

4. ENHANCING THE QUALITY OF EU LEGISLATION – IDEAS FROM THE EUROPEAN RISK FORUM

The ERF welcomes the opportunity to contribute to the development of the Commission's Smart Regulation initiative. Our comments focus on identifying ways of enhancing the quality of EU legislation, with particular emphasis on the management of risk.

Possible improvements have been identified in the following areas:

- An EU-level Administrative Procedures Act;
- Impact Assessment – General Approach;
- Impact Assessment – Risk Management Measures;
- Science and Decision-Making;
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- Implementation of Legislation; and,
- Ex Post Evaluation of Regulatory Decisions

4.1. AN EU-LEVEL ADMINISTRATIVE PROCEDURES ACT

Part of the body of administrative law, an Administrative Procedures Act is an essential institutional feature of modern, democratic governments. It enshrines in law the principles of good administration: transparency and consistency; public participation; public record (ensuring that decisions are based solely on information set out in public); and accountability. It clarifies and protects the rights of citizens and businesses when governments take actions that affect them directly, establishing clear procedural due process and strengthening judicial review.

A well-designed Administrative Procedures Act increases the predictability, transparency, effectiveness, and legitimacy of government decisions. It ensures that a systematic and consistent approach is taken to decision-making, ensuring higher quality decisions and reducing the risk of regulatory failure. Judicial review mechanisms are also strengthened, contributing to greater accountability in decision-making.

In contrast, at EU-level there is no formal, codified law that places legally enforceable limits on the way in the EU institutions make decisions or that establishes procedural due process standards. Instead, there is an incoherent and inconsistent approach that fails, in general, to provide general procedural rights.

A working group of MEPs, reporting to the Committee on Legal Affairs, has reviewed the current situation. It proposes the introduction of a single general administrative law (an EU Administrative Procedures Act) based on Article 298 of the Lisbon Treaty. It should be binding on all of the Union's institutions, bodies, and agencies, and should provide a minimum safety net of guarantees to citizens and businesses in all of their direct dealings with the EU's institutions.

The ERF has identified a series of additional ideas that could help develop the general principles to be included in an Administrative Procedures Act (APA):

- **Place into EU law an Administrative Procedures Act that enshrines the four key principles of good administration**[3] (transparency and consistency; public participation; public record; and accountability);

- **For each of the key principles of good administration establish, within the EU law, clear legally-binding, procedural standards**;

- **Ensure that the EU-level Administrative Act includes clear and extensive judicial review standards,** ensuring that the principles of good administration can be fully enforced by citizens and affected entities;

- **Require <u>all</u> rule-making and adjudication decisions that implement secondary legislation to adhere to the standards of good administration set out in an EU-level Administrative Procedures Act.** This should include technical guidance where this is a disguised form of rule-making or regulation;

- **Ensure that all EU institutions involved in the implementation of secondary legislation are included within the scope of an EU-level Administrative Procedures Act.** Where appropriate this should encompass EU-level agencies as well as technical and other committees involved in the new implementing processes established by the Lisbon Treaty.

- **Require the Secretariat-General of each EU institution to establish internal enforcement procedures,** ensuring compliance with the provisions of an EU-Level Administrative Procedures Act.

- **Mandate the EU Ombudsman to provide annual performance reports to the European Parliament,** demonstrating compliance and ensuring accountability;

[3] These are described in greater detail in Appendix A.

4.2. IMPACT ASSESSMENT - GENERAL

Regulatory Impact Analysis (RIA) is one of the most widely-used processes for improving the quality of regulatory decisions. In a wide range of different legal and regulatory settings, it helps regulators improve the effectiveness of regulatory outcomes, whilst, at the same time, reducing the costs of regulatory decisions.

The EU's institutions have taken a series of steps to improve the quality of regulatory decision-making over the last 20 years. However, the most important changes have been introduced by the European Commission, the EU institution responsible for initiating new secondary rules and for implementing existing laws, in the period since 2002. These changes form part of wider series of initiatives designed to both improve governance and instil a "new regulatory culture" at EU-level. Indeed, the Commission has made substantial progress in establishing one of the largest and most comprehensive impact assessment (IA) programmes in the world.

The European Court of Auditors identified in late 2007 the EU's 'Better Regulation' programme and impact assessments as a relevant audit subject. An audit of the programme was then undertaken. Specifically, the audit focused on *"Impact Assessments in the EU institutions: Do they support decision-making?"* In 2010, the Court of Auditors adopted the final report.

The audit provides an extensive analysis of some of the most important strengths and weaknesses of the Commission's impact assessment system. Action needs to be taken to build on these insights. Based on these findings and other research carried out by The European Risk Forum, it is possible to identify a series of reforms that, if implemented together, could contribute significantly to improvements in the quality, utility, and effectiveness of impact assessment at EU-level.

Reforms include:

- **Require the Court of Auditors to audit the IA system every three years**, improving the methodology to examine risk management policies and expanding the issues examined;

- **Establish data quality standards for the use of scientific evidence in IAs**, requiring studies, information, and data to be based on widely-accepted sound and objective scientific practices ("the scientific method") including peer reviewed science;

- **Revise the Commission's technical guidance for assessing the costs and benefits of risk management decisions**, stressing the importance of risk acceptance, basing intervention on the findings of a peer reviewed risk assessment, highlighting the difference between hazard and risk, and recognising the limitations of different regulatory options;

- **Develop new technical guidance for the assessment of complex regulatory costs**, helping officials understand the impact of technical regulatory decisions, as well as secondary legislation, on innovation processes, the diffusion of new technologies, and levels of sales and margins;

- **Amend existing technical guidance to ensure a more rigorous review of the benefits of government intervention**, highlighting the overall value of policy actions ensuring that complex benefits are understood (such as benefit-risk trade-offs), and improving legitimacy;

- **Consult widely on all draft IAs**, requiring processes to meet the Commission's established process standards for consultation;

- **Develop and adopt binding rules of procedure requiring the Council and EP to us IA to examine all substantive amendments to Commission proposals,** ensuring that legislators understand fully the benefits and costs of legislative proposals;

- **Establish an independent capacity to review annually the quality of IAs produced and compliance with agreed processes**, building on existing expertise in a Think Tank and strengthening transparency and accountability.

4.3. IMPACT ASSESSMENT AND RISK MANAGEMENT

After the most recent revisions, the Commission's Impact Assessment (IA) guidelines recognise public risk management as an important 'horizontal' theme of EU-level policy-making. Whilst this is a welcome improvement, the draft guidelines in this area are incomplete and place too much emphasis on the concept of precaution as a basis for making risk management decisions. If these weaknesses are to be rectified and the quality of risk management decisions improved, then further changes to the guidelines are needed.

Specifically, the following improvements could be made to the Commission's IA guidelines:

- **Require all legislative and regulatory proposals designed to manage lifestyle or technological risks to human health, public safety, or the environment to be accompanied by the findings of formal scientific risk assessment**, designed to support analyses of problem definition and regulatory options.

- **Recognise the characteristics of different types of threats (including lifestyle and technological risks)**, define them on the basis of scientific knowledge, and take account of this in assessing problems, identifying risk management options, and assessing the costs and benefits of policy action;

- **Base all scientific risk assessments on the best available scientific and technical information**, and ensure that conclusions about a problem's potential risks to human health, public safety, and the environment assessments take full account of the weight of scientific evidence. Assessments should, moreover, distinguish clearly between 'hazard' and 'risk', identify realistic exposures to hazards; and highlight scientific uncertainties (using appropriate, well-established typologies of different types of uncertainty);

- **Require risk assessments to be subject to peer review** if they are to be used to support major legislative or regulatory decisions;

- **Require objectives for new or revised EU-level risk management rules to recognise the importance of risk-taking** for economic prosperity and long-term improvements in the quality of life; and, to accept that zero risk is neither achievable nor desirable in modern societies and that legislation cannot achieve this;

- **Highlight precaution as one of a number of legitimate and distinctive approaches to risk management decision-making but recognise its weaknesses** and require its use to be cost-effective, based on scientific evidence, proportionate, limited in scope, non-discriminatory, consistent with international agreements, and provisional. The guidelines should, for instance, highlight the limited and specific circumstances in which the precautionary principle should be considered as a potential option for managing risks at EU-level;

- **Require officials to make extensive use of quantitative analyses when assessing the costs and benefits of different risk management options.** These should include, wherever appropriate, monetary analyses and the use of modern cost effectiveness analyses. Assessments of potential benefits and costs should, moreover, recognise potential unintended negative consequences, and the loss of existing benefits, of specific policy options.

4.4. SCIENCE AND DECISION-MAKING

An important challenge facing the Commission's Smart Regulation initiative is ensuring effective integration with other, supporting policies, most notably those involving the management of risk.

In this context, effective use of science by decision-makers lies at the heart of the EU's Smart Regulation initiative. Used well, science provides effective ways of identifying potential risks, protecting citizens, and using resources wisely. It enables decisions to be based on evidence derived from transparent, rational processes designed to enhance legitimacy and trust. Moreover, it provides theories with explanatory and predictive power, enabling policy-makers to anticipate problems and to develop effective solutions.

There is, however, an emerging debate as to the appropriate role of scientific evidence in determining the outcome of legislative and regulatory decisions. Hence, a challenge facing all governments is to ensure that good science retains its central role in policy-making and decision-making processes, whilst taking appropriate account of its limitations.

Considerable progress has been made by the European Commission to improve the quality and credibility of scientific advice to policy-makers, and this is widely recognised by opinion-formers and stakeholders. There are, however, gaps in these reforms, most notably the lack of formal policies and guidelines in key areas (such as the quality of

scientific advice, and risk communication), and weaknesses in the institutional architecture, including a lack of resources.

The recent decision by the President of the Commission to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms carried out by the European Commission, and to create the institutional architecture needed to ensure that reliable, well-founded scientific evidence is used effectively to improve further the quality of EU-level legislative and regulatory decisions.

In view of this, it is recommended that:

- **The Commission's Chief Scientific Adviser should report directly to the President of the European Commission and should be responsible for ensuring the integrity, quality and effective operation of the scientific advisory system.**

- **The position of Chief Scientific Adviser should be at a level equivalent to that of a Director-General of the European Commission.** This will strengthen the importance and legitimacy of the role.

- **The European Commission should establish a central unit in support of the Chief Scientific Adviser.** The unit should build on the work carried out by DG SANCO, and be responsible for:

    - Developing the overall scientific advice policy and the specific guidelines that underpin the operation of the entire advisory system, including Technical Working Groups, Risk Assessment Agencies, and the Commission's independent scientific committees;
    - Providing additional expert resources, advice and support to Scientific Advisory Committees and officials;
    - Enforcing compliance with common guidelines;
    - Auditing the extent to which science is used effectively in policy-making and decision-making processes;
    - Commissioning periodic external evaluations of the operation of the overall scientific advisory system;
    - Producing an annual review of the effectiveness of the scientific advisory system

- **The central unit supporting the Chief Scientific Adviser should ideally be located within the Secretary-General's department of the European Commission,** ensuring an effective link with the implementation and enforcement of other parts of the Better Regulation initiative (most notably the Impact Assessment and Ex Post Evaluation processes).

- **A steering group, chaired by the Chief Scientific Adviser, should be established to oversee and co-ordinate the use of science by the Commission, its agencies, and its Technical Working Groups.** This group should focus on improving the quality, credibility, and utility of scientific evidence used by Commission Services and EU-level risk assessment agencies and Technical Working Groups to support policy-making, secondary legislation and

regulatory decisions (including case-by-case adjudications, guidelines, and rule-making).

- **The Chief Scientific Adviser should establish a new, coherent policy for the collection and use of scientific advice.** The policy should be applied to all stages of the regulatory cycle and to all sources of scientific advice, including formal Scientific Advisory Committees, Risk Assessment Agencies, Technical Working Groups, Comitology Committees (and equivalent bodies set up to implement legislation using the new mechanisms set out in the Lisbon Treaty), and other bodies such as EEA. The policy statement should:

    - Define a set of guiding principles for the collection, assessment and provision of scientific advice;
    - Require legislative and regulatory decisions to be based on the best available science;
    - Describe clearly the benefits and limitations of using scientific evidence to manage risks to human health and the environment; and
    - Provide a comprehensive set of key concepts and definitions used in the provision of scientific advice, including definitions of 'best available science', the 'scientific method', 'uncertainty', 'hazard' and 'risk'.

- **A formal policy for managing risks posed by new technologies should be drawn up by the Chief Scientific Adviser.** This should highlight the important role that well-designed regulation, based on high quality science, can play in supporting innovation. It should, moreover, require risk management legislation to be technologically-neutral and should recognise the negative consequences for citizens of stigmatising new ideas (or products), and locking-in old technologies;

- **A policy for improving public acceptance of the use of scientific evidence in regulatory and legislative decision-making should be drawn up and implemented by the Chief Scientific Adviser.** This should emphasise the role of high quality science in identifying significant risks and in developing effective risk management outcomes. It should also highlight the link between the EU's Better Regulation goals and the use of high quality science as the key knowledge input for risk management decisions.

- **The Chief Scientific Adviser should develop and publish mandatory written principles that define the quality and relevance of studies, information, and data to be used in scientific assessments by the European Commission's scientific advisers and committees** (including EU-level risk assessment agencies, Technical Working Groups, and Rapporteur Member States). These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science. Appropriate guidance should also be developed to ensure effective and consistent implementation. Guidance should encompass all forms of scientific evidence including epidemiological studies and animal testing.

- **The Chief Scientific Adviser should require significant risk assessment opinions to be independently peer-reviewed**, strengthening the processes used to collect and review scientific evidence. Use of peer review should be limited to findings from reviews by scientific advisers, which are likely to have a substantial impact on public policy or the decisions of private companies or the freedoms of citizens.

- **Mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication") should be drawn up by Chief Scientific Adviser.** These should, for example, require written explanations explaining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings, and explaining why some studies were not considered or some findings were rejected.

4.5. RISK ASSESSMENT

Most OECD governments recognise that, in order to make high quality decisions, legislative and regulatory proposals designed to manage lifestyle or technological risks to human health, public safety, or the environment should be accompanied by the findings of formal scientific risk assessment.

A Working Group has been established by the Inter-Committee Co-ordination Group of the Non-Food Scientific Committees serving the European Commission. This group has three objectives: review current risk assessment practices; explore what risk managers and policy managers need from risk assessment; and, identify approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent, and easy to interpret and communicate.

A preliminary review has been completed by the group. The main conclusion of this phase of the study is that the outputs of risk assessment need to be more policy-relevant. This includes describing the outputs of risk assessments in terms of value-relevant impacts on humans and ecosystems.

If implemented, these reforms could, along with other improvements, help improve the quality of all forms of risk management decisions taken at EU-level. Specifically, a better integration of the outputs of risk assessments with the needs of officials responsible for impact analyses and risk management could achieve the following: better analysis of the benefits of risk management; enhanced understanding of the extent to which benefits justify costs when making legislative and regulatory decisions; better informed risk governance; improved impact assessment; and, more utilisation of cost effectiveness analysis.

Alongside the excellent recommendations put forward by the working group, the ERF has identified a series of additional ideas that could improve the utility of risk assessment within the risk management process. These include:

- **Focus on quantification of outcomes initially, recognising that monetisation poses particular conceptual, technical, and ethical challenges.** Quantification includes outcomes such as the impact of health risks

on quality adjusted life years and other direct measures of mortality and morbidity. If monetisation is used then care should be taken to use appropriate discounting methodologies such that timing effects are properly recognised, and that willingness-to-pay measures, such as the Value of Statistical Lives (VSL), are employed, wherever possible.

- **Base quantified estimates of harms and potential benefits on expected outcomes reflecting real world exposures rather than worst case scenarios and/or theoretical exposures.** This limits over-claiming of benefits, enhances the credibility of risk management proposals, reduces the likelihood of negative, unintended economic side-effects, and increases regulatory effectiveness.

- **Introduce detailed guidelines for quantifying estimates of potential harms.** These should be subject to external consultation and reviewed regularly, ensuring that they remain abreast of conceptual and methodological developments.

- **Ensure that estimates of the potential economic and social costs continue to be assessed by risk managers rather than risk assessors.** Identification of the potential costs of regulatory decisions, including measures to manage harms, is a complex that is difficult to undertake. Indeed, it should be undertaken by experts and should be informed fully by extensive consultation processes.

  The most important negative impacts of regulatory decisions are, for example, unlikely to be the burden of paperwork or the initial expense of compliance. Rather, the most significant cost of regulation lies in the distortion of business, individual and societal behaviour triggered by regulatory requirements. This includes changes in investment decisions, innovation activity, technology dissemination, and materials utilisation on the one hand, and stigmatisation of substances or technologies on the other.

  It is also increasingly important to consider the long-term adjustment costs associated with regulatory decisions, especially in regional labour markets.

- **Establish processes to prevent policy-relevant outcomes of risk assessments stigmatising specific materials or technologies, including developing appropriate risk communication techniques.** Whilst new ways of characterising potential harms may improve regulatory decision-making, it could also, unless carefully managed, stigmatise specific materials or technologies.

  Stigmatisation is a form of social amplification of risk. It triggers changes in the materials or technology choices made by private individuals and 'gatekeepers' (such as retailers or 'assemblers' in the manufacturing sector). It occurs when concerns and fears about potential harms are amplified by governments or the media or campaigners.

  Stigmatisation also forms part of new range of risk management tools. It provides governments with a way to influence behaviour of participants in product markets. In the light of the need to separate risk assessment and risk management, and the overall potential of stigmatisation mechanisms to cause

economic harms, risk assessors should take considerable care when estimating policy-relevant outcomes and when communicating them to risk managers.

Use of policy-relevant measures of harm should therefore be based on realistic exposures and expected outcomes. Precaution should not form part of the risk characterisation process, nor should worst case scenarios or equivalent approaches to estimation. Moreover, action should be taken to ensure that internal communication to risk managers places policy-relevant measures within an appropriate context, avoiding creating unnecessary controversy or concern.

- **Establish consolidated mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments** by the European Commission's scientific advisers and risk assessors. These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science, where appropriate. By doing this, risk assessors will also act as guardians of good science for the Commission, increasing the credibility, effectiveness, and legitimacy of decision-making.

- **Expand the proposed guidelines for the presentation of scientific advice to risk managers and policy-makers to require written explanations outlining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings.** ECJ case law has identified this as an area where risk assessment needs to be made more transparent, particularly when undertaking assessments as part of the implementation of framework risk management legislation.

- **Require significant risk assessment opinions to be independently and publicly peer-reviewed**. This recognises the role that risk assessments can play in framing public policy and helps increase public confidence in the quality of opinions.

4.6. PRECAUTION AND RISK MANAGEMENT

For over a century, the concept of precaution, the idea of taking preventative action in advance of harm, has informed the development of strategies used by governments to manage risks to human health, public safety, and the environment. Supported by scientific evidence and an understanding of costs and benefits, the precautionary approach has enabled governments throughout the OECD area to design effective risk management strategies for complex problems that, moreover, take account of differing levels of scientific uncertainty and social acceptance of risk.

In recent years, however, a new form of precautionary risk management has emerged. Based on the concept of a formal "Precautionary Principle", this approach seeks to institutionalise the use of precaution to manage risks. To many citizens and governments, a Precautionary Principle, as a tool for managing complex, modern risks, seems to be a statement of common sense. The problems lie, however, in implementing it.

The Precautionary Principle is one of the main tools used by the EU institutions to manage potential risks to human health, public safety, and the environment. Evidence from its widespread use in the EU and throughout the OECD suggests that, as a mechanism for ensuring high quality regulatory decisions, it is substantially flawed. Actions taken by the Commission have addressed some of the well-established weaknesses of the Precautionary Principle, but these steps do not go far enough. Possible additional reforms include:

- **Undertake an independent evaluation of the use of the Precautionary Principle by the EU institutions**, focusing on the scope of application, justification for action, overall negative and positive impacts, and processes;

- **Develop additional guidance for the application of the Precautionary Principle by the European Commission** focusing on limiting the scope of application and defining clearly the evidential thresholds and standards needed to justify its use;

- **Require the application of the Precautionary Principle to be subject to additional impact assessment 'tests'.** These should examine the following issues:

    - The risk/risk trade-off – banning of substances should not lead to the greater use of a less safe alternatives or practices or processes;
    - The risk of irreversibility – restrictions on use of products or technologies should not have the effect of closing off branches of science that may have great value in ways yet to be discovered;
    - Effects on trading relationships with major partners – regulatory interventions should not create barriers to trade, unless they meet the standards set out by the WTO;
    - Risk for the science base in Europe – risk management measures should not trigger the "hollowing out" of scientific activity;
    - Known risks/unknown risks – the known risks of regulatory intervention should be rigorously compared with the unknown risks to health and safety

- **Establish new procedures for assessing the plausibility of evidence used to justify the application of the Precautionary Principle**, emphasising transparency, the importance of high quality science, and independent, peer review of assessments;

- **Establish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments** by the European Commission's scientific advisers. These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science.

- **Require all applications of the Precautionary Principle to specify the degree and type of scientific uncertainty and how it is to be clarified.** If the PP is applied to gaps in the scientific knowledge, it is vital that these gaps be capable

of being proven. Precautionary action should not be based on hypothetical or perceived risks. Moreover, it should be made clear whether uncertainties are to be clarified by science or from experience.

- **Develop a Commission Communication on the use and implementation of the Proportionality Principle**, ensuring that this is used to counter-balance the application of Precautionary Principle;

- **Revise the impact assessment guidelines for risk management decisions**, highlighting the limited role the Precautionary Principle plays in managing risks, its costs and limitations, and the need for plausible justifications of its application;

- **Require all uses of the Precautionary Principle to be documented and included in the Commission's annual report on law-making**, highlighting the justification for the use of the Principle including an independent assessment of the plausibility of the evidence of harm and nature of the risk to be managed;

4.7. COST EFFECTIVENESS ANALYSIS

Cost Effectiveness Analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of policy actions with their costs. Used well, CEA forces policy-makers and regulators to quantify rigorously the health or environmental benefits of prospective government actions to reduce risks. When properly constructed, CEA provides clear metrics for decision-makers, facilitating comparisons between different ways of managing the same problem, such as reducing risks to human health or public safety. CEA data, derived from a range of risk management actions, can also play a major role in the governance of risk, helping to identify the most efficient ways in which resources can be used to save or improve lives.

CEA is most often used as part of a structured process for making legislative or regulatory decisions. In many leading countries within the OECD area, it is widely used when policy-makers and regulators examine ways of reducing risks to human health or public safety. It focuses on the ultimate outcomes, such as lives saved or improved, rather than intermediate reductions in emissions or exposures. It helps to inform ex ante impact assessment, facilitating the selection of policy options. It provides policy-makers, moreover, with an important analytical tool when benefits are difficult to monetize or when there are barriers to placing values on health or environmental benefits.

Since 2002, the Commission has begun the process of encouraging regulators to make greater use of modern forms of CEA. More needs to be done to build on this and to require greater use of CEA, so as to improve the quality of risk management decisions and of risk governance at EU-level. Specific improvements could include:

- **Make it mandatory for all EU-level Impact Assessments of measures designed to manage risks to health; safety, or the environment to be supported by a full CEA,** improving the formal review of policy options;

- **Revise the IA guidelines to establish clear tests of cost effectiveness to demonstrate that proposed interventions do more good than harm,**

developing appropriate methodologies and processes for the monetization of benefits and of the "health-health analysis";

- **Recognise within the impact assessment process the need to base estimates of the benefits of risk management decisions on the weight-of-scientific evidence,** avoiding over-claiming through worst case scenarios;

- **Require IA reports to include comparative cost effectiveness analyses that examine other interventions,** highlighting the relative costs of achieving improvements in mortality, morbidity, or the environment;

- **Require the IAB to verify that the benefits of regulatory proposals are fully identified, credible, measurable, and capable of being assessed on an ex post basis,** creating a formal 'hurdle' before a regulatory proposal is allowed to be considered by the Commission;

- **Use CEA as part of an extensive ex post evaluation of risk management policies designed to protect health, safety, and the environment,** improving the basis for future decision-making and informing the development of risk governance policies

4.8. BENEFITS OF REGULATORY ACTION

Good risk management decisions, along with other public policy interventions, occur when benefits justify costs. Evidence from work by the OECD and others suggests that in too many instances, risk management decisions are based on an incomplete or inadequate assessment of the potential benefits of government intervention.

The development of a thorough, evidence-based understanding of the benefits of government action, combined with rigorous measurement, is an essential pre-condition for making high quality risk management decisions. It helps improve effectiveness, highlighting "cause-and-effect" relationships, facilitating comparison of regulatory options, and ensuring that government interventions are likely to be successful. It strengthens legitimacy by providing credible evidence that the benefits of government action are likely to exceed its costs. Finally, it provides the basis for effective ex post evaluation of regulatory decisions, strengthening further the utility, transparency, and accountability of modern regulatory processes.

Since 2002, the European Commission has built an extensive and well-respected system of ex ante assessment of regulatory impacts. Successive improvements in the supporting guidance notes, combined with process and institutional reforms, have delivered higher quality regulatory decisions. Despite these advances, more needs to be done if to ensure that the benefits of all regulatory and legislative proposals are fully identified, quantified, and supported by robust, credible evidence. This could include a number of possible improvements:

- **Strengthen the overall impact assessment policy by requiring regulators to only select policy options if benefits justify costs**, and to ensure that the final policy option chosen maximises overall net benefits;

- **Amend the impact assessment guidelines by requiring regulators to produce a formal statement of benefits**, basing the statement on robust, credible evidence;

- **Revise the impact assessment guidelines by mandating regulators to quantify, and wherever possible monetise, the benefits of risk management rules designed to improve health, safety, or the environment**, ensuring that any non-compliance with the requirement is explained explicitly and fully;

- **Improve the technical guidance for the monetization of health, safety, and environmental benefits,** requiring the use, wherever possible, willingness-to-pay techniques, including Value of Statistical Life measures;

- **Require the IAB to verify that the benefits of regulatory proposals are fully identified, credible, measurable, and capable of being assessed on an ex post basis,** creating a formal 'hurdle' before a regulatory proposal is allowed to be considered by the Commission;

- **Draw up new impact assessment guidance for risk management decisions,** recognising the distinctive nature of such policies, highlighting the importance of science and risk acceptance, placing the use of precaution in an appropriate context, and emphasising the need to assess risk-benefit trade-offs;

- **Recognise within the impact assessment process the need to base estimates of the benefits of risk management decisions on the weight-of-scientific evidence,** avoiding over-claiming through worst case scenarios;

- **Widen the scope of the guidance for assessing the costs of risk management decisions,** ensuring that any prospective loss of existing social benefits from risk acceptance is recognised as an opportunity cost of government action;

4.9. TECHNICAL GUIDELINES AND RISK MANAGEMENT

At EU-level and throughout the OECD area, non-legally binding 'guidelines', issued by risk assessors and managers, form an important part of most technical regulatory decision-making processes. They set out policies on statutory, regulatory, or technical issues, or provide an interpretation of a statutory issue, or furnish advice on the best or most appropriate way to fulfil an obligation laid down in law. They provide officials with a flexible tool that is able, at its best, to respond rapidly to scientific change and to provide regulatory certainty, without the need for additional legislation.

In contrast, poor quality guidelines can increase costs, reduce innovation, create uncertainty, and erode revenues, without adequate compensating benefits for citizens. In practice, guidelines may also provide agencies or officials with a mechanism for making rules more stringent, without effective oversight or changes in legal requirements. Many guidelines are, moreover, a form of 'soft law'.

At EU-level, non-binding guidelines already play an important role in implementing legislation and managing risks. Over the next decade, their importance and impact will expand substantially. Action is needed at EU-level to ensure that new guidelines are of high quality and are developed using open, transparent processes; and, to assess the effectiveness of existing guidelines. Possible reforms include:

- **Develop a Commission policy statement recognising that guidelines play an important role in assessing and managing risks**, highlighting that they are, in many instances, risk management measures and a form of 'soft law';

- **Include in the EU's Smart Regulation programme a review of the role of guidelines as tool for implementing legislation and managing risk**, identifying ways of ensuring that the costs that guidelines can impose on societies are matched by commensurate benefits;

- **Ensure that inter-institutional debates about future governance models for EU-level agencies recognise the risk management role of guidelines**;

- **Extend the scope of the Commission's regulatory management tools (most notably impact assessment and consultation) to include the development of new guidelines**, including those developed by EU-level risk assessment agencies;

- **Require all EU-level risk assessment agencies to establish common processes and standards for creating new guidelines or amending existing ones**, using the existing procedures established by the EMEA as a benchmark;

- **Ensure that the need for new or revised guidelines is based on well-established, high quality scientific evidence,** setting a rigorous, evidence-based standard for new requirements;

- **Undertake systematic ex post evaluations of the impact and effectiveness of new and existing guidelines**, including assessing the cumulative effect of guidelines at a sector-level;

- **Accelerate the development and implementation of an agreed set of risk assessment principles and procedures for all EU-level risk assessment bodies**.

4.10. IMPLEMENTATION OF EU LEGISLATION

At EU-level and throughout the OECD area, many public risk management objectives are achieved using a complex, multi-stage approach. Framework legislation sets out the social goals to be achieved, identifies the hazards to be controlled, and defines the level of social acceptance of risk. Technical regulatory decision-making processes implement legal requirements and deliver the goals set out in primary law. At EU-level, four different

processes are used to implement framework risk management laws: guidelines; voluntary standards; decentralised decisions by Member States; and 'comitology'[4].

Comitology combines extensive scientific and technical input from the European Commission (the executive function) with political oversight from the EU's Member States and, increasingly, the European Parliament. It is the most widely used form of rule-making at EU-level, providing the EU's institutions with a speedy and flexible process for establishing the detailed and legally binding rules needed to implement framework laws and manage risks, whilst maintaining political consensus. Despite recent efforts to improve the process, comitology continues to exhibit major structural weaknesses. Possible reforms include:

- **Develop a formal Commission policy recognising the role that comitology processes play in the management of risk and defining the procedural rights of participants,** including rights to be consulted, to participate in a structured process with time limits, and to be fully informed of decisions;

- **Establish an administrative right of appeal for persons directly affected by the comitology processes,** covering proposed measures and evidence;

- **Extend the scope of the Commission's minimum standards for consultation to include major comitology decisions,** including risk management;

- **Implement and publish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments that inform the comitology processes**. These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science.

- **Revise the Commission's impact assessment guidelines so that they include methods for identifying 'major' comitology decisions and complex regulatory impacts,** including demand stigmatisation, and set out the main issues that assessments must cover to inform comitology decisions fully;

- **Require all additional scientific, technical and expert information used in the committee phases of the comitology processes to be subject to independent assessment,** including peer review;

- **Publish all scientific and technical evidence used to determine the basis of implementing measures** approved using the comitology processes;

- **Ensure that the existence of all documents, whether confidential or not, is made known to the public via a formal Register**, providing the public with the opportunity to challenge comitology procedures;

[4] The Lisbon Treaty reformed the regulatory comitology process and provided the Commission with two new, implementing mechanisms set out in Articles 290 and 291 (Delegated and Implementing Acts). Throughout this section, the term 'comitology' refers to these two processes.

- **Publish the forward planning programme for comitology decisions and improve the quality of summary records of the meetings** to record all of the issues on the agenda, to accurately record areas of contention during the discussions, and to provide a full and reasoned explanation of their decisions;

- **Allow systematic participation in committee discussions by affected parties**

4.11. EX POST EVALUATION OF REGULATORY DECISIONS

Ex post evaluation is a regulatory process management tool that assesses systematically the outcomes of regulatory decisions after implementation. Used well, it examines the relevance, effectiveness, and impacts of regulatory decisions. At its most successful, it identifies expected outcomes, unintended consequences, reasons for failure, and causes of success.

The progressive introduction of ex post evaluation of regulatory decisions by an increasing number of governments throughout the OECD area forms part of the wider "regulatory performance agenda" being pursued by regulators. It strengthens the "evidence-based" approach to policy-making and complements other regulatory process management tools, such as consultation, simplification, impact assessment, access to documents, and evidential standards.

Systematic and rigorous ex post analysis enhances the quality of regulatory decisions and the processes used to make them. It improves the quality of future regulatory decisions by providing policy-makers and decision-makers with evidence of "real world" effects, unintended consequences, design failings, and compliance weaknesses. It facilitates the reform of existing regulations, identifying outcomes where costs exceed benefits, highlighting areas for improvement and the causes of success or failure, and providing legitimacy for regulatory reform. Ex post analyses also improve the effectiveness of "ex ante" analyses and processes, as well as enhancing accountability and transparency, and reducing the risk of regulatory failure.

In most OECD countries, however, there is relatively little tradition or expertise in systematic ex post evaluation of regulatory decisions. High quality ex post evaluations are, moreover, difficult to undertake: obtaining credible evidence is expensive; and, identifying the distinctive impact of regulatory factors on real-world situations is challenging because of the time lag between implementation and evaluation, combined with the impact of other, non-regulatory events.

Despite these difficulties, substantial progress has been made in some OECD member countries. Taking account of this, it is possible to identify a small number of "success factors" for the effective use of ex post evaluation tools to assess the outcomes of regulatory decisions. These include high level political support (such as the Commission's 2010 Communication and the recent Executive Order from President Obama in the USA); clear analysis of expected outcomes and metrics in ex ante assessments; sunset clauses to force regulators to undertake reviews; systematic review of existing rules after extensive consultation; dedicated policies, tools and

institutions to oversee and undertake implementation; and clear, flexible guidelines for analyses.

The ERF has identified a number of recommendations that, if implemented fully, could help strengthen and improve the ex post evaluation of risk management measures by the EU's institutions. Specifically:

- **Improve the initial quality of risk management measures prior to implementation through the development of specific guidance for the ex ante assessment of such proposals.** Guidance should require the "problem definition" to be based solely on high quality science, supported by peer review of relevant risk assessments. It should ensure that all proposed risk management rules have tangible, measurable objectives. The use of cost effectiveness tools should be encouraged strongly along with the quantification of costs and benefits. Finally, regulators should be required to seek the least onerous risk management option, to ensure that options target the causes of the problem directly, to select only those options based on proven effectiveness and workability, to act proportionately, and to consider unintended consequences.

- **Strengthen the role of the European Commission's Impact Assessment Board** by requiring it to ensure that, for all risk management proposals there are measurable outcomes, quantified metrics of costs and benefits, and a clear link between problem definition and risk management option. Through these reviews, the IAB should verify that effective ex post analysis is feasible.

- **Establish monitoring and early warning mechanisms for existing and new risk management rules** to ensure that potential regulatory failures, unintended consequences, and implementation problems are identified.

- **Make widespread use of high quality scientific assessments to evaluate the relevance and effectiveness of risk management measures.** This should be supported by the introduction of wider evidential and process standards for the use of scientific evidence in decision-making.

- **Ensure the extensive involvement of affected parties during the process of ex post evaluation,** using surveys, formal consultation exercises and other relevant methods.

- **Develop a comprehensive understanding of 'horizontal' (multi-sectoral) unintended consequences of risk management rules, and develop guidance for regulators.** Issues of concern include impacts on innovation, dissemination of new technologies, the loss of existing technologies, demand stigmatisation, and risk-risk.

- **Prevent regulators from introducing replacement risk management measures until ex post evaluations have been undertaken.**

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Appendix A

Principles of Good Administration

Part of the body of administrative law, an Administrative Procedures Act is an essential institutional feature of modern, democratic governments. It places legally enforceable limits on the way in which governments exercise powers, particularly the rule-making and enforcement decisions taken by the executive function to implement complex laws. It clarifies and protects the rights of citizens and businesses when governments take actions that affect them directly, establishing clear procedural due process and strengthening judicial review.

A well-designed Administrative Procedures Act enshrines in law the principles of good administration. These include:

- **Transparency and consistency** – citizens and entities affected by government should know what is going on when actions are planned to be undertaken, so that they can provide input to officials and participate meaningfully in the decision-making process. All inputs to decision-making, whether from government, citizens or entities affected, should, moreover, be collected together and included in a public record. Furthermore, decision-making processes and procedures, including opportunities for public participation, should be easily available, set out clearly in a way that it is understandable, and applied consistently across administrative activities;

- **Public participation** – citizens and affected entities should have a meaningful opportunity to comment on all proposed rules and adjudications. This should not be constrained artificially through the use of information technologies and should maximise the use of public hearings and formal notice and comment procedures.

- **Public record** – decisions should be based solely on the information set out in the publicly available record. This should include all comments submitted by citizens, affected entities, along with all other information the government relies upon and the response of the government to public comments. Decisions should not rely on information that is not available for public comment and public comments should not be ignored[5].

- **Accountability** – citizens and affected entities that have submitted comments should have the right to seek independent judicial review of decisions to ensure that correct procedures have been followed, that decisions are substantially in accordance with authorising legislations, that decisions have been rationally

[5] In decisions involving scientific issues, governments should establish generally applicable criteria for ensuring that scientific evidence is of high quality. Only scientific evidence that meets such standards should be relied upon to support implementation decisions, and failure to meet these standards should be a basis for judicial review.

based on the publicly available record (ensuring that governments cannot justify decisions based on the views of experts or other inputs not subject to public comment), and that comments from the public have been taken into account.

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