European Risk Forum

The ERF Action Plan for Improved Risk Management in the EU

November 2012

Foreword

Europe is today facing unprecedented challenges, which only a conscious, strategic and systematic problem-solving approach can turn to equivalent opportunities for sustainable growth and prosperity. Decision making at the EU level is where much of the stake will be decided. Hence, it is critical that we focus our attention on the quality of the public policy and regulatory decisions taken in Brussels. The Smart Regulation strategy is a promising starting point. But it needs to be complemented and upgraded to fully address one of the most important responsibilities at the EU level, namely the public management of risks.

The European Risk Forum (ERF) is a think-tank committed to improving the way decisions about the best way to manage risk are made at EU-level. The ERF focuses – using a horizontal, cross-sectoral approach – on issues such as science and decision-making; impact assessment; consultation; lifestyle risks; regulations of new technologies; agencies; comitology; and international regulatory cooperation.

As a part of its work, the ERF contributes ideas to all of the EU's institutions, including through participation in the 2012 European Commission's stakeholder consultation to examine ways of improving its Smart Regulation strategy. On that occasion, the ERF expressed general support for the initiatives undertaken by the Commission thus far. The ERF also recommended a number of ways to further enhance the quality of EU regulatory risk management. These include:

- an EU-level Administrative Procedures Act;
- a general approach to impact assessment;
- risk management measures for impact assessment;
- science and decision making;
- risk assessment;
- the use of precaution to manage risks;
- cost effectiveness analysis;
- the benefits of regulatory action;
- technical guidelines and risk management;
- the implementation of legislation; and
- ex post evaluation of regulatory decisions.

The issues addressed in this Action Plan constitute the platform against which the EU's institutions should benchmark their efforts to further improve risk management. The ERF is firmly committed to this "manifesto" and to collaborating with the institutions and private stakeholders towards its realisation. The Forum strives to remain one of the principal fora in Brussels where innovative ideas on regulatory policy and risk regulation are generated and diffused.

I warmly commend this Action Plan to you.

Dirk Hudig
Chairman
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Abbreviations & Acronyms

APA	Administrative Procedures Act
CEA	Cost Effectiveness Analysis
ECJ	European Court of Justice
EEA	European Environment Agency
ERF	European Risk Forum
EU	European Union
IA	Impact Assessment
IAB	Impact Assessment Board
MEP	Member of European Parliament
OECD	Organisation for Economic Cooperation and Development
QALY	Quality Adjusted Life Years
R&D	Research and Development
RIA	Regulatory Impact Analysis
VSL	Value of Statistical Lives
WTO	World Trade Organization

Part 1: Introduction

1.1 Public Management of Risk

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. It 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, products, economic activity, and lifestyle choices.

Today, risk management 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.

The EU's institutions, along with governments in most 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 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[1]).

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 because of declining public trust; increasing dissent; greater uncertainty; and increasing risk aversion. At the same time,

1 The Lisbon Treaty reformed the regulatory comitology process and introduced two new implementing mechanisms set out in Articles 290 and 291 (Delegated and Implementing Acts). Throughout this document, the term 'comitology' refers to these two processes.

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 past decade, the regulatory reform 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.

1.2 Smart Regulation

The European Commission's Smart Regulation initiative[2] builds on earlier efforts 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; and
- clear commitments to establish a wide-ranging programme to evaluate the impact of regulatory decisions on an 'ex post' basis.

2 European Commission, *Communication on Smart Regulation in the European Union*, COM(2010) 543 final.

The ERF supports the progress made so far and seeks to contribute in order to further advance the reform agenda.

Part 2: The ERF Action Plan to Enhance the Quality of EU Risk Management

The ERF has produced an Action Plan that seeks to reinforce the work of the EU's institutions in the remit of the Smart Regulation agenda. The Action Plan focuses 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
- Risk assessment
- Consultation
- Use of precaution to manage risks
- Cost effectiveness analysis
- Benefits of regulatory action
- Technical guidelines and risk management
- Implementation of legislation
- Ex post evaluation of regulatory decisions
- Judicial review and risk management.

The following sections present critical success factors for each of these lines of action.

2.1 An EU-Level Administrative Procedures Act

Part of the body of administrative law, an Administrative Procedures Act (APA) 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 APA 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 the EU's 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. These were some of the conclusions of a Working Group of MEPs, reporting to the Committee on Legal Affairs, after reviewing the current situation[3]. The Working Group proposes the introduction of a single general administrative law (an EU APA) 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 welcomes these developments and has identified a series of additional ideas that could help develop the general principles to be included in an EU APA:

- **Place into EU law an APA that enshrines the four key principles of good administration**[4] (transparency and consistency; public participation; public record; and accountability). The EU APA should be inspired by – but not uncritically mimic – acts adopted in other jurisdictions, reflecting carefully the unique institutional and procedural system of the EU.
- **For each of the key principles of good administration establish, within EU law, clear, legally-binding, procedural standards.**

3 European Parliament Working Group on EU Administrative Law, *State of play and future prospects for EU administrative law, Working Document to be submitted to the Committee on Legal affairs*, 19 October 2011.

4 These are described in greater detail in Appendix A.

- **Ensure that the EU APA includes clear and extensive judicial review standards**, making sure that the principles of good administration can be fully enforced by citizens and affected entities.
- **Establish an accountable and transparent system for selecting which rule-making and adjudication decisions that implement secondary legislation will not adhere to the standards of good administration set out in the EU-level APA.** In addition, technical guidance should be made subject to such a system to avoid it becoming a disguised form of rule making or regulation.
- **Ensure that all the EU's institutions and bodies involved in the preparation, adoption, implementation and repealing of secondary legislation are included within the scope of the EU APA.** 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 and body to establish internal enforcement procedures,** to maximise compliance with the provisions of an EU APA.
- **Mandate the EU Ombudsman to provide annual critical performance reports to the European Parliament,** demonstrating compliance and ensuring accountability and indicating possible corrective actions.

The ERF is the only organisation in Brussels addressing the reform of the administrative procedures at the EU level from the specific perspective of improving the assessment, management and communication of risks. It does so by bridging wide knowledge of international good administrative and regulatory practices with direct access to concrete experiences from the private sector. The ERF believes that the EU APA would improve governance in a number of significant ways. Specifically, it would:

- help the Commission consolidate existing regulatory process management standards. Historically, these have been set out in rules of procedure and other forms of 'soft law' and a majority of the provisions that the EU APA would include have arguably been already codified in the Commission-internal *modus operandi*;
- provide the Commission with more robust evidence, arguments and processes to justify regulatory decisions in its interface with other institutions and public bodies and with stakeholders at the (sub-)national, EU and international levels;
- help the EU's institutions achieve agreed societal goals more effectively and efficiently, whilst at the same time limiting the impact of disproportionate or poor regulatory decisions, including actions designed to limit potential harms;
- improve the overall organisation of risk assessment at the EU level, bringing all existing procedures and standards under the overall framework of good

administrative principles – a way to promote excellence in the collection, validation and use of scientific evidence;

- improve the quality of risk management decisions, one of the EU's largest, most important and most demanded policy areas, and where high quality regulatory decisions must be taken to respond to society's needs and expectations;
- facilitate the task of communicating risks and the role of sound science in decision making, for instance when facing determined public perceptions or (sudden) changes in the level of acceptance of any given risk. In particular, the APA would help explain the recourse to risk-based (rather than hazard-based) approaches to regulatory interventions and better outline substitutions, risk-risk and health-health trade-offs;
- provide support for reformers within the Commission as they seek to standardise good administrative practices across all Services; and
- help bring all institutional actors involved in EU decision making up to the same speed in the Smart Regulation agenda and, over time, ensure consistent standards of good administration when all the EU's institutions are involved in making regulatory decisions.

Achieving improvements in the overall EU governance and administration, and in particular in the area of risk management, citizens will be better protected from potential harms, whilst innovation will be encouraged (for instance through higher predictability in R&D investments and legal certainty). This will contribute to enhancing the legitimacy and effectiveness of the EU's institutions in times of crisis, where trust in public authorities is most required.

2.2 Impact Assessment – General Approach

Regulatory Impact Analysis (RIA) is one of the most widely used processes for improving the quality of regulatory decisions. RIA helps regulators better establish cause-effect mechanisms, set evidence-based baseline scenarios, and improve the effectiveness of regulatory outcomes, whilst 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 past 20 years. Indeed, the Commission has made substantial progress in establishing one of the largest and most comprehensive impact assessment (IA) programmes in the world.

The ERF record of contributions to the Commission's impact assessment system is long and it has critically informed progress so far. The establishment of the internal Impact Assessment Board (IAB) in 2006 is a case in point[5]. The ERF believes that a series of reforms would yield significant further improvements in the quality, utility, and effectiveness of impact assessment at EU level. Reforms include the following:

- **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 investment and 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.
- **Develop structured procedures and standards for the use of external expertises during the preparation of the IAs**, allowing the IAB, for example, to make greater use of qualified experts in an open and transparent manner.
- **Publish and consult widely on all draft IAs**, requiring processes to meet the Commission's established process standards for consultation.
- **Extend the scope of mandatory application of the Commission IA Guidelines to all agencies and bodies** intervening in the EU's decision making, through autonomous rule-making activities.
- **Adopt binding rules of procedure requiring the Council and European Parliament to use IA to examine all substantive amendments to Commission proposals, and enhance the related capacity in these institutions**, ensuring that legislators understand fully the benefits and costs of legislative proposals.

5 See Appendix B at the end of the present Action Plan.

- **Require the European Court of Auditors to audit the IA system as a whole every three years**, improving the methodology to examine risk management policies and expanding the issues examined.
- **Promote capacity building for independent review of the quality of IAs produced and compliance with agreed processes**, building on expertise amongst think-tanks, academia, and stakeholders, and thereby strengthening transparency and accountability of the system.

2.3 Impact Assessment and Risk Management

After the revisions in 2009, the Commission's 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 in relation to risk:

- **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 the most advanced scientific knowledge, and take account of this in assessing problems, identifying risk management options, and estimating the costs and benefits of policy action.
- **Base all scientific risk assessments on the best available scientific and technical information**, ensuring that conclusions about a problem's potential risks to human health, public safety, and the environment 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.

2.4 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 meet societal expectations in an effective and efficient manner. This, in turn, enhances legitimacy and trust. Moreover, science 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 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 decision by the President of the Commission in 2011 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, the ERF recommends that:

- **the Commission's Chief Scientific Adviser, reporting directly to the President of the European Commission, 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 the Health and Consumers Directorate-General (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; and
    - 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 design, implementation and enforcement of other parts of the Smart Regulation initiative (most notably the Impact Assessment and Ex Post Evaluation processes);

- **a steering group, chaired by the Chief Scientific Adviser and reporting to the latter, should be established to oversee and coordinate 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 any bodies set up to implement the equivalent provisions enshrined in the Lisbon Treaty). The policy should:
    - consolidate all guiding principles for the collection, assessment and provision of scientific advice;
    - oversee the enforcement of the obligation to base legislative and regulatory decisions on the best available science;
    - describe clearly the benefits and limitations of using scientific evidence to manage risks to human health and the environment;
    - 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'; and
    - 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;
    - issue and publish mandatory guidelines for the presentation of scientific advice to risk managers and policy makers ('internal risk communication'). Such guidelines should, for example, require written explanations of conclusions,

particularly with regard to the acceptance or applicability of specific studies and findings, and explain why some studies were not considered or some findings were rejected.

- **the Chief Scientific Adviser should draw up formal policy for managing risks posed by new technologies.** 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;
- **the Chief Scientific Adviser should also work towards improving public acceptance of the use of scientific evidence in legislative and regulatory decision making.** 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 Smart Regulation goals and the use of high-quality science as the key knowledge input for risk management decisions; and
- **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, the decisions of private companies, or the freedoms of citizens.

2.5 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 Coordination Group of the Non-Food Scientific Committees serving the European Commission. This group has three objectives: First, to review current risk assessment practices; secondly, to explore what risk managers and policy managers need from risk assessment; and, finally, to identify approaches to risk assessment that can provide results based on the best available science and that are informative, consistent, transparent, and easy to interpret and communicate.

A preliminary review was completed by the group in 2011[6]. 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.

The ERF believes that these reforms can contribute to improving 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 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 the following:

- **Focus on quantification of outcomes, 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 (QUALY) and other direct measures of mortality and morbidity. Metrics such as willingness-to-pay, cost of illness as well as the Value of Statistical Lives (VSL) should be employed, wherever possible. If monetisation is used, then care should be taken to use appropriate discounting methodologies so as to properly recognise timing effects.
- **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 task that is difficult to undertake. Indeed, it should be undertaken by experts and should be informed fully by extensive consultation processes.

6 See http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_consultation_07_en.htm

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.** European Court of Justice (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.

2.6 Consultation

Consultation is a two-way process. It involves dialogue and feedback between governments and citizens. Used well, it lies at the heart of Smart Regulation and is an essential pre-condition for high quality regulatory decision making. Consultation with citizens throughout the legislative cycle helps governments to enhance the quality, credibility and legitimacy of public policy.

Specifically, high quality consultation processes enable policy makers and regulators to:

- tap new sources of policy-relevant ideas, information, and resources, improving the evidential base for decisions;
- integrate public input into policy making, giving citizens, economic operators, and organised interests more of a stake in decision making;
- strengthen public trust, building confidence in the quality and openness of policy-making processes;
- ensure greater acceptance of legislative and regulatory decisions, improving compliance and legitimacy; and
- respond to calls from citizens for greater transparency, predictability and accountability.

Effective consultation requires governments to consult with all significantly affected and potentially interested parties, whether domestic or foreign. Consultation should take place at the earliest possible stage, and should be based on a transparent and, as far as possible, standardised, process. The scope of consultation processes should be clearly understood.

Since 2002, the European Commission has taken major steps to improve its consultation practices, through the implementation of minimum process standards. This has contributed

to an improvement in transparency and predictability within EU-level policy-making processes. Although the Commission's minimum standards meet many of the good practices for effective consultation identified by the OECD and others, there are important gaps in a number of areas. Moreover, consultation practices by the European Parliament and the Council are still not outlined systematically and explicitly, and there is great margin for enhancing transparency and accountability.

There are a number of areas where improvements could be made. Specific ideas for improvement include the following:

- **Make the Commission's minimum standards for consultation legally binding**, creating enforceable rights for affected parties and creating powerful incentives for regulators to comply with agreed requirements.
- **Widen and tailor the scope of the Commission's minimum standards for consultation to include all major technical regulatory decisions taken by the Commission and its agencies.** Technical regulatory decisions subject to consultation should include guidelines drawn up by EU agencies; major decisions by EU agencies that embed risk management assumptions; comitology decisions that affect multiple products, substances, or processes, and comitology decisions subject to detailed and regular scrutiny by the European Parliament.
- **Develop and publish a set of guidelines for the application of the Commission's minimum standards for consultation.** These should be produced by the Secretary-General and should be subject to external peer review.
- **Make greater use of formal public hearings, as a mechanism for enhancing the transparency and effectiveness of consultation by all the EU's institutions.**
- **Improve compliance with minimum standards by requiring each Commissioner to report publicly on the issue.** Moreover, the Secretariat-General should monitor, using key performance indicators, how well each Directorate and Agency complies with the Commission's minimum standards for consultation. The results should be reported annually to the European Parliament by the Commission.
- **Undertake a formal, independent evaluation of the effectiveness and application of the Commission's minimum standards.** Results of the evaluation should be published.
- **Widen the minimum standards to require objectives for consultations to be well defined from the outset.** Moreover, the standards should make clear the respective roles of citizens (providing inputs) and governments (making decisions and protecting the public interest).

- **Ensure that all written submissions received during consultation processes are published.** Exceptions should be made, however, for issues of significant commercial confidentiality.
- **Ensure that services account publicly and specifically for the use they have made of inputs received through consultation processes**, including explaining why relevant recommendations provided by citizens and stakeholders have been rejected.
- **Develop and publish equivalent consultation minimum standards applying to the legislative and regulatory activities of Parliament and the Council.**

2.7 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 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. For 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's 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 countries suggests that, as a mechanism for ensuring high-quality regulatory decisions, it may also lead to significantly inefficient regulatory outcomes. 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 the following:

- **Undertake an independent evaluation of the use of the Precautionary Principle by the EU's 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 risk/risk trade-off – banning of substances should not lead to the greater use of a less safe alternatives, practices or processes;
  - the risk of irreversibility – restrictions on the 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; and
  - 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-reviewed 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 principle is applied further 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 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.

2.8 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 monetise, 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 the following:

- **Make it mandatory for all EU IAs 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 monetisation of benefits and of the 'health-health analysis'.

- **Recognise within the IA 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 Commission's Impact Assessment Board 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.

2.9 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 (IAs). 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 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 as follows:

- **Revise the Commission IA 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 monetisation of health, safety, and environmental benefits**, requiring the use, wherever possible, willingness-to-pay techniques, including VSL measures.
- **Strengthen the scrutiny by the Commission's Impact Assessment Board 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 IA 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 IA 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.

2.10 Technical Guidelines and Risk Management

At EU level and throughout the OECD countries, 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 (developed using open, transparent processes) and to assess the effectiveness of existing guidelines. Possible reforms include the following:

- **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 strategy 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 (European Medicines Agency) 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.**

2.11 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'.

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 the following:

- **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 IA 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 is made known to the public via a formal Register**, providing the public with the opportunity to challenge comitology procedures.
- **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.**

2.12 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, whilst 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 on Smart Regulation and the 2011 Executive Order from US President Obama[7]); clear analysis of expected outcomes and metrics in ex ante assessments; 'sunset' clauses to force regulators to undertake reviews; systematic reviews 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, these include the following:

- **Draw up and publish a plan**, based on transparent criteria and informed by consultation, describing the programme of ex post evaluation of all existing and future regulatory decisions.
- **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

7 Executive Order 13563 on *Improving regulation and regulatory review*, of 18 January 2011.

between problem definition and risk management option. Through these reviews, the Board 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.
- **Revise the scope of the application of the evaluation policy to encompass major technical implementation decisions**, specifically guidelines drawn up by EU agencies; major decisions by EU agencies that embed risk management assumptions; comitology decisions that affect multiple products, substances or processes; and comitology decisions subject to regular and detailed scrutiny by the European Parliament.
- **Expand the responsibilities of relevant European Parliament legislative committees** to include the periodic review of ex post evaluations of relevant legislative decisions.
- **Prevent regulators from introducing replacement risk management measures until ex post evaluations have been undertaken.**

2.13 Judicial Review and Risk Management

Judicial review refers to the power of the judiciary to annul acts of the Executive or Legislature, if in breach of the established legal framework. In open, democratic societies it is one of the most important mechanisms for protecting the rights of individuals (including businesses).

Decisions by judges, made through the process of judicial review, can influence the procedures and standards used by governments to make major administrative decisions, including the implementation of primary risk management laws. In some jurisdictions, such as the US, courts have been instrumental in requiring Federal Agencies to undertake rigorous and rational reviews of the risks posed by new products and technologies, and to base risk management decisions on high quality scientific evidence. Whilst EU courts have tended traditionally to permit the EU's institutions wide-ranging discretion when making risk management decisions, and have avoided detailed involvement in technical and scientific issues, their approach seems to have changed in recent years.

The EU regulatory decision making when managing risks has tended to be based on a combination of Treaty requirements (such as taking account of scientific information), problem-specific secondary legislation, the comitology process for making implementation decisions, and horizontal regulatory tools such as consultation and impact assessment standards, guidelines, and scientific committees. In general, this approach ensures that science plays a role in decision making, that rules are based on acceptance of risk, and that risk management rules are tailored to deal with specific hazards and exposures. On the other hand, the system suffers from the risk of politicisation of implementation decisions and lacks scientific standards.

Recent trends in judicial review by EU courts pose a potential challenge to this approach. Traditionally, such reviews have been limited to questions of whether or not regulatory discretion has been exercised in an arbitrary or unjustifiable manner, and have avoided scientific or procedural issues. This approach is changing. In recent cases (e.g. vitamins, animal antibiotics, crop protection, and flame retardants) EU judges have taken an interest in scientific and technical issues, and in the way that risk management decisions are taken. Important risk management decisions have been annulled. Criticisms have been made of the procedures used for the collection, assessment, and use of scientific evidence, and of the comitology process. And, moreover, judges have begun to assess the procedures and standards used to determine whether or not specific risks (or risk management measures) are acceptable to citizens. In so doing, they have in certain cases interpreted the nature and purpose of the Precautionary Principle in such a way that it may create a new and 'risk averse' attitude to EU regulatory risk management.

The EU's institutions in general, and the European Commission in particular, need to recognise this process and help shape its evolution. Without action, it is possible that greater judicial review of the EU's risk management decision-making process could trigger the emergence of institutionalised aversion to risk, and increase regulatory unpredictability. Alternatively, judicial involvement could be used to provide a stimulus towards enhanced regulatory quality.

Possible reforms include the following:

- **Introduce a Commission-wide policy for new risk management laws, designed to improve quality** by improving definitions, reducing ambiguity, highlighting social acceptance of risk, and recognising explicitly that zero risk is unattainable.
- **Develop an assessment, based on scientific evidence, justifying the use of existing risk assessment and management 'models'.** Public interest benefits should be highlighted and compared to the likely negative impacts of alternative, more precautionary approaches.
- **Draw up mandatory guidelines for the presentation of scientific advice to risk managers and policy makers.** These should, for example, require written explanations explaining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings.
- **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 significant risk assessment opinions to be independently peer reviewed.**
- **Establish more rigorous procedural standards for the operation of the Commission's Regulatory Standing Committees.** These should ensure that all scientific evidence taken into account by a Standing Committee is fully disclosed, properly written up, and formally reviewed by experts.
- **Develop new guidance to ensure that scientific advisers focus only on risk assessment.** This should identify risk assessment practices (such as the use of 'worst-case scenarios') that embed implicit decisions about risk acceptance.
- **Undertake an ex post evaluation of the operation of the Precautionary Principle by the EU's institutions**, including its application by the ECJ, and the use, effectiveness, and impact of the Commission's operational guidelines.

European Risk Forum
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This Action Plan was written by Richard Meads, the European Risk Forum's Rapporteur. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.

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 the following:

- **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[8].
- **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

8 In decisions involving scientific issues, governments should establish generally applicable criteria to ensure 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.

accordance with authorising legislations, that decisions have been rationally 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.

Appendix B

What is the 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's 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 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.

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.

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.

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.

Rationale for the European Risk Forum

The regulatory problem

Governments' regulatory decisions play an increasingly important role in influencing competitiveness. They can determine the speed, risk, and cost of innovation; they can create barriers to market entry or to the use of certain technologies, substances or materials; they can restrict the use of specific marketing techniques; and they can undermine the scale and profitability of markets for existing products.

There is wide recognition that in many regulatory areas, including, most notably, the management of health, safety, and environmental risks, the EU has become the 'global regulator' and 'thought leader'.

As well as its expanding role as an influencer of regulatory activity, policies, and philosophies worldwide, the EU sets the rules that determine the basis on which companies can operate within one of the world's largest and most valuable markets. This latter process takes place through two political mechanisms: the creation of new, primary laws, involving all of the EU's institutions; and, the implementation of primary laws through a series of complex technical decisions, covering issues such as hazard classification, product approval, acceptable limit values, safety testing requirements, technology licensing, and restrictions on specific commercial activities. Increasingly, these risk management laws also encompass new or emerging hazards and technologies, such as climate change, the impact of environmental factors on health, lifestyle-related risks, and the use of nanotechnology.

Whilst EU policy-makers have taken some initial steps to try and ensure that these important decision-making processes operate according to well-established and predictable rules, substantial problems have emerged over the last decade.

These problems include:

- decisions based on hypothetical hazards, rather than a complete and realistic understanding of risks;
- greater emphasis by policy makers on risk aversion, instead of risk acceptance;
- government action justified on the basis of public concern, poor science, controversy, and other non-scientific criteria, as opposed to a through review of high-quality evidence;
- unjustified use of 'precaution' as a formal decision-making tool and risk management philosophy, leading to decisions based on ideology and politics (instead of evidence);
- inadequate consultation with affected parties;
- incomplete or inadequate understanding of the impacts of regulatory decisions (including benefits and costs) prior to government action;
- politicisation of technical, implementing decisions, because of the increased involvement of EU Member States and the European Parliament in the 'comitology' process; and
- high levels of unaccountable technical decision making by officials ('administrative discretion') due, in part, to the poor quality and over-complex nature of many of the EU's most recent risk management laws.

As a result of these trends there is great risk of poor quality regulatory outputs. Regulatory decisions can bedisproportionate, they create uncertainty, they undermine competitiveness, and they lead, increasingly, to economic losses. Such regulatory failures, moreover, limit the ability of the EU to promote risk-taking, innovation, and entrepreneurship, reducing the impact of the 'Innovation Union' and 'Europe 2020' strategies.

These problems are likely to continue, unless opinion formers and policy makers are made aware of better and more effective ways of making regulatory decisions that are able to achieve social goals, without creating substantial negative impacts for citizens and business.

What are the ERF's Goals?

The ERF promotes improvements in the way in which the EU's institutions make risk management decisions. To achieve this, **it seeks to persuade the EU's institutions**

to adopt 'horizontal' decision-making standards and rules, supported by appropriate policies, mechanisms and institutions, designed to ensure that:

- risk management decisions 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 ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;
- risk management decisions 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 structured is consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Why is the ERF an Effective Think-Tank?

The impact and effectiveness of the ERF, and of the ideas it promotes, is underpinned by five important factors:

Track Record - The European Risk Forum is led by Dirk Hudig from Fipra International (as Chairman), Richard Meads from Business Decisions Limited (as Rapporteur), and Lorenzo Allio, from allio|rodrigo consulting (as Senior Policy Analyst). This small group, supported and advised by the ERF members and a wide range of academic advisers in the EU and USA, has extensive experience of risk-related policy issues at EU-level, and successfully built up the risk-based activities carried out at the European Policy Centre over a period of 10 years.

Since 1996, this small group has played an important role in:

- establishing formal requirements for cost-benefit analysis at EU level in the Amsterdam Treaty;
- persuading the Commission to adopt its modern system of impact assessment;
- designing the guidelines used by the Commission to structure the process of impact assessment;
- shaping the content of the Commission's guidelines for the use of the Precautionary Principle;

- promoting dialogue and shared understanding between high-level EU and US regulatory officials on a range of issues including the use of precaution in decision making, managing the risks posed by new technologies, and ensuring food safety;
- persuading the Health and Consumers Directorate-General (DG SANCO) to adopt modern guidelines and institutions to improve the use of science as an input for regulatory decision making;
- defining the coverage and content of Communication used by DG SANCO to collect and assess scientific evidence used to support decision making; and
- designing the form and structure of governance used for EU-level risk assessment agencies.

Reputation – the ERF has developed, amongst many senior decision makers and officials within the EU's institutions, a positive reputation for its technical expertise, the relevance and quality of its work, and for the ERF's emphasis on using evidence (from the EU and elsewhere) to support arguments.

Nature of Expertise – the work of the ERF is based on a unique mix of expertise. Alongside evidence from other OECD countries, academic and other research, the ERF makes use of the extensive regulatory knowledge available within the business community. It derives this from a multi-sector constituency of experts, ensuring that ideas are drawn from as wide a spectrum of experience as possible. These sources of ideas ensure that the ERF's work reflects practical experience, as well as wider theories. This increases the attractiveness of the ERF's ideas to officials within the EU's institutions.

Public Interest – 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 as being in the public interest, and emphasises 'horizontal' rather than 'sectoral' issues. This increases the legitimacy of the ERF's arguments.

Focus – the ERF is the only Brussels-based think-tank that focuses solely on public risk management, and the use of regulatory process management policies, processes and structures to ensure high quality decision making. It is, moreover, expert-based and technically-focused. This makes the ERF the 'natural partner' for experts within the EU's institutions who wish to debate ways in which the EU's horizontal policies for improving regulatory decision making might be improved.

ERF Outcomes

Since its foundation, the ERF has made an important contribution to the regulatory management processes used by the EU's institutions and to the way in which risk is managed at EU level. Specifically:

- to ensure high quality decision making, the ERF focuses its efforts entirely on public risk management, the use of regulatory process management policies, processes and structures.
- amongst officials and senior decision makers, the ERF has garnered a positive reputation for its technical expertise, the relevance and quality of its work and its emphasis on evidence-based argumentation.
- Amongst EU-level opinion formers and decision makers, **the ERF has raised awareness of the importance of the following emerging issues for the effective management of risk**:
  - Role of the EU courts in determining the processes that will be used to make risk assessment and risk management decisions (including the role of science).
  - Role of non-binding guidelines, issued by the Commission and its agencies, as mechanisms for managing risk.
  - Importance of understanding complex impacts of technical regulatory decisions, including demand stigmatisation and restrictions on innovation.
  - Need to reform the comitology process, because of the important role that implementing measures ('technical regulatory decisions') play in managing risks.
  - Need to establish binding standards that determine the quality of scientific evidence used to support risk management decisions, combined with the need to improve the processes used to assess scientific evidence (including peer review).
  - Value of establishing a rigorous system, supported by guidelines and policies, for ex post evaluation of regulatory decisions.
  - Need to develop new policies for the management of risks posed by new technologies, recognising the role they play, in many cases, as 'platform technologies' in disseminating new ideas.
  - Importance of considering the possibility of unintended consequences, including risk-risk outcomes, when assessing the costs and benefits of new risk management rules.

- Need to assess rigorously the benefits of proposed risk management measures, including establishing clear linkages between government actions and improved health and environmental outcomes.
- Value of using cost effectiveness measures to improve impact assessment processes and the overall governance of risk.

- The work of **the ERF has contributed to a number of important changes in the way in which regulatory decisions are made, and risks managed, at EU-level**. Specifically, input from the ERF has influenced the following:
  - Creation and role of the European Commission's Impact Assessment Board.
  - Revision of the operating methods of the Commission Scientific Committees, including greater transparency and more cooperation with risk management agencies, in the latest revision of the Commission's communication.
  - Appointment of a Chief Scientific Adviser in the Commission.
  - Inclusion of specific requirements for assessing the costs and benefits of risk management decisions in the latest revision of the Commission's impact assessment guidelines.
  - Inclusion, in the latest revision of the Commission's IA guidelines, of requirements for impact assessments of risk management measures to take account of scientific risk assessment.
  - Expansion of the scope of the Commission's impact assessment process to encompass comitology and other major implementing measures.
  - Development of detailed guidelines to support the establishment of a Commission-wide policy for ex post evaluation of regulatory decisions.

Further Information

For further details about the work of the ERF, and how to become a member, please contact:

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