EUROPEAN RISK FORUM – POLICY NOTE 05

TECHNICAL REGULATORY DECISION-MAKING AT EU-LEVEL – BACKGROUND AND ISSUES

2007

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

Throughout the OECD area, many public risk management objectives are achieved through a complex, multi-stage approach, involving framework primary laws and technical, implementing processes. Derived through a political process, the legislative framework sets out in the social goals to be achieved, defines the level of social acceptance of risk, and, ideally, specifies the principal characteristics of the implementing process, including risk assessment and risk management mechanisms.

In turn, the objectives of primary risk management legislation are implemented through "technical regulatory decision-making processes". These are used by governments to make large numbers of complex case-by case decisions efficiently and to adapt rapidly and flexibly to technical progress.

Technical regulatory decision-making at EU-level covers a wide range of risks, industries, processes, substances, and products. Examples include 'positive' lists for food additives, food packaging materials, and crop protection products; emission limits; pre-market approval processes for pharmaceuticals, new chemical substances, and genetically-modified foodstuffs; and hazard classification of chemical substances.

Over the last 40 years, the EU has introduced a wide range of different technical regulatory decision-making models. Although a number of older 'models' continue to be used, EU-level technical regulatory decision-making is increasingly dominated by four different, modern approaches: agencies; voluntary standards (or new approach); independent scientific committees; and, the decentralised approach.

In recent years, some steps have been taken to improve the efficiency and predictability of EU-level technical regulatory decision-making processes. Despite these changes more needs to be done, if decisions are to continue to be of high quality. Specifically:

- Establish a formal Commission-wide policy for risk assessment and management decisions made using technical regulatory decision-making processes.

- Include agency guidelines within a formal risk management policy.

- Extend the scope of the Commission's regulatory management tools to include implementing measures, such as agency guidelines and comitology decisions.

- Introduce new regulatory management standards covering scientific evidence used in decision-making and ex post evaluation of regulatory decisions.

- Draw up additional impact assessment (IA) guidelines that are relevant to the management of technological and lifestyle risks.

- Improve the credibility, accountability and transparency of the comitology process.

1. BACKGROUND

Throughout the OECD area, many public risk management objectives are achieved through a complex, multi-stage approach, involving framework primary laws and technical, implementing processes.

Primary risk management laws provide, in general, a framework for carrying out case-by-case implementing decisions[1]. Derived through a political process, the legislative framework sets out in the social goals to be achieved, defines the level of social acceptance of risk, and, ideally, specifies the principal characteristics of the implementing process, including risk assessment and risk management mechanisms.

In turn, the objectives of primary risk management legislation are implemented through "technical regulatory decision-making processes". These are used by governments to make large numbers of complex case-by case decisions efficiently and to adapt rapidly and flexibly to technical progress.

This form of 'technical' risk management decision-making has become one of the most important ways in which social goals are met. It helps protect citizens and the environment from technological risks; it reduces the impact of lifestyle risks; and is an important determinant of prosperity.

This complex, multi-level approach is favoured by legislators at EU-level, and elsewhere in the OECD area, for two reasons:

- **Scale and complexity of the problem** - most modern risk management laws tend to deal with complex and extensive risks, frequently involving threats of damage to human health, the environment and public safety. In many cases, risks emerge from large numbers of individual product, substance, or technology choices made by private sector actors and individuals. Moreover, many decisions have yet to be made: some risks are prospective – they lie in the future. The scale and complexity of such problems cannot be managed easily or efficiently by legislative bodies.

- **Technical progress** – in many cases, laws designed to manage the risks posed by technologies or lifestyles set out general objectives based on reduction or re-allocation of particular types of risk, rather than focusing on specific processes, products, or technologies. Such legislation assumes that technology and science will advance, creating new ways to mitigate risk; revealing more information about the nature of risk; and triggering innovation in new products and processes. As long as the overall nature of the risk being controlled does not change, framework laws allow regulators to adapt rapidly to technical progress, without the need for major political investment in new legislation. When this is done well, it provides a flexible and rapid means of protecting the public interest and maintaining a positive environment for innovation and investment.

[1] At EU-level primary laws correspond to secondary legislation, such as EU Directives or Regulations: the EU treaty is defined as the primary level of law.

2. EU-LEVEL PROCESSES

2.1. COVERAGE

Technical regulatory decision-making at EU-level covers a wide range of risks, industries, processes, substances, and products. Examples include 'positive' lists for food additives, food supplements, food packaging materials, and active substances used in crop protection products; emission limits; pre-market approval processes for human pharmaceuticals, veterinary medicinal products, new chemical substances, and genetically-modified foodstuffs; and hazard classification and labelling of chemical substances.

In many cases, risk assessment processes are defined by primary law, and final risk management decisions take place through the EU's 'comitology' process.

Common safety and environmental standards are essential pre-condition for the effective functioning the EU's internal market. High quality and predictable regulatory risk management processes stimulate innovation, facilitate access to global markets, and, in some cases, create consumer confidence.

Equally, poor quality or unpredictable processes are likely to be an obstacle to prosperity.

2.2. RISK MANAGEMENT AND TECHNICAL DECISION-MAKING PROCESSES

At EU-level, technical regulatory decision-making mechanisms are used to achieve social objectives covering an extensive range of risks, products, processes, substances, technologies and production methods. Despite the heterogeneity of the application of this approach to rule-making, it is possible to characterise it on the basis of two distinct forms of risk management used by the EU:

- **"Ex ante" management of the risks posed by new or improved products, substances, and technologies** – in this case, the emphasis is on assessing and controlling risks before new ideas are utilised or exploited in the market. In many cases, this is achieved through establishing standards, covering issues such as safety, environmental impact, ethics, efficacy, quality, and trade. Standards are applied through a range of different mechanisms, including mandatory pre-market approval processes, as well as voluntary risk assessment.

  In this case, the emphasis is on regulating the process of innovation. Regulatory requirements may affect the time, cost, and uncertainty of product and process development decisions, influencing expected returns on investment in innovation and shaping technological choices.

- **"Ex post" management of the use and usage conditions of existing products, substances, and technologies** – this encompasses controls such as hazard classification and labelling; labelling of food, drink an tobacco products; emission limits on production processes and plants; manufacturing process requirements; restrictions on the price, promotion and distribution of products;

use limitations; product or substance withdrawals; safety reviews; and 'positive' lists of approved substances or products.

These controls focus on existing investments in physical and intangible assets. They may have a direct impact on the revenues, margins, and costs of operations, including the scale of returns that existing investments will generate in the future. Indirectly, through the mechanism of "demand stigmatisation", they may also affect wider demand conditions for specific products, substances or technologies.

2.3. EU-LEVEL TECHNICAL DECISION-MAKING 'MODELS'

Over the last 40 years, the EU has introduced a wide range of different technical regulatory decision-making models. In many cases, these have been established by specific pieces of primary legislation.

Older methods include the involvement of the European Parliament in agreeing changes to "positive lists" (as is the case for some food additives, for example), and the use of technical working groups to assess risks. Based on nominated national experts, technical working groups have been widely used in areas such as chemicals management and restrictions on emissions. In most cases, technical working groups assess risks, with final risk management decisions being taken by the Commission using the comitology process.

Although many of these older 'models' continue to be used, EU-level technical regulatory decision-making is increasingly dominated by **four different, modern approaches**:

- Agency 'model';
- Standards 'model';
- Independent Scientific Committee 'model'; and,
- Decentralised Approach

2.3.1. Agency 'Model'

This is a centralised risk management approach, involving the use of an independent EU-level agency to assess risks and set appropriate test guidelines for companies, with risk management decisions being taken through the comitology process. This 'model' has a clear, institutional split between risk assessment and risk management. Agencies are independent of the Commission.

An advantage of this approach is that it strengthens transparency. Scientific assessments are clearly separated from final, political risk management decisions. Over time, it also helps provides a mechanism for improving scientific quality and increasing public trust. Most importantly, however, the agency 'model' provides rapid access to the entire EU market.

In a variant of this approach, Member States assist the independent agency in carrying out risk assessments. This is used for crop protection products, for example.

Three major agencies have been established: EMEA; EFSA; and ECHA. These will cover a wide range of sectors including human pharmaceuticals; veterinary medicines; foodstuffs and related materials (including novel foods, food supplements); biotechnology; and chemical substances, including inorganic materials such as metals, paper, glass, cement, and paper.

2.3.2. Standards 'Model'

This is also known as the "New Approach". It is a devolved form of risk management, and makes companies responsible for assessing and managing risks. It involves the use of framework laws to establish broad social goals and appropriate safety or efficacy objectives. These are then turned into standards by voluntary EU-level standard-setting bodies. Standards provide a way of demonstrating that products or processes meet the objectives set out in the primary law. Companies regulated by this approach are obliged by law to satisfy themselves that products or processes meet the overall objectives set out in the primary law. Failure to do this leads to government action.

As well as product or process-specific standards, generic standards for assessing and managing risks have also been established by the standards-setting bodies.

The 'standards' model provides companies with a flexible way of meeting social goals and legal requirements. Moreover, standards are developed with assistance from a wide range of stakeholders thus taking account of extensive "real world" experience.

A very wide range of sectors are covered by this 'model', including electrical goods, electronics, 'traditional' medical devices, and vehicle parts.

2.3.3. Independent Scientific Committee 'Model'

This is another centralised risk management decision-making process. It involves the use of independent scientific committees to assess risks. Risk management decisions are taken using the comitology process. Scientific committees are briefed by the Commission.

European Commission's current Non-Food Scientific Committees are SCEP (Committee on Consumer Products), SCHER (Committee on Health and Environmental Risks), and SCENIHR (Committee on Emerging and Newly Identified Health Risks).

This model is used to regulate a small number of sectors, most notably cosmetics. (It is also used to provide policy-makers with independent advice prior to the development of legislative proposals, most notably for new and emerging risks.)

2.3.4. Decentralised Approach

The fourth 'modern' approach to technical regulatory decision-making is based on the "mutual recognition" principle. It involves extensive links between the EU's Member States. Under this approach, an initial Member State assesses the risks posed by a

product or process, and if it meets agreed standards of safety, then it can be placed on the market in that country. Other countries are then required to accept the product or process.

A benefit of this process is that it allows a company to decide which parts of the EU market it wishes to focus on. A further advantage is that risk management decisions are, in theory, only made in one country: other Member States are supposed to respect this decision under the "mutual recognition" principle. This may enable companies to achieve risk assessment in countries with highly predictable regulatory processes. A disadvantage is that the process often suffers from delay, because Member States continue to apply different safety and environmental standards and to interpret common guidelines in different ways. It may also fragment Europe's single market, if companies systematically avoid specific countries because of additional regulatory costs or uncertainties.

Sectors covered by this 'model' include human pharmaceuticals and veterinary medicinal products.

3. ISSUES

Based on evidence from different OECD countries, academic studies and other sources, a number of issues of importance for the evolution of the EU's technical regulatory decision-making processes can be identified. These include:

- New Complex Decision-Making 'Model';
- Process Management Standards and Guidelines;
- Agencies and Guidelines;
- Comitology; and,
- "Politicisation"; and,

3.1. NEW COMPLEX DECISION-MAKING 'MODEL'

Historically, regulatory risk management decisions set out to minimise physical harms (to people or the environment), using scientific evidence to determine the scale and nature of the problem and the most effective solution. At the same time, safety thresholds took account of technological feasibility and cost. Decisions were made, in general, using expert and closed processes.

Although this model of regulatory decision-making was, in many ways, highly effective, it is no longer in widespread use. In response to social and political pressures (including the impact of regulatory failures, such as BSE), regulatory decision-making models have changed, creating new and more complex challenges for regulators. Changes have occurred in most parts of the decision-making model, including:

- **Risk Acceptance** - there is a shift, in some areas of risk management legislation, away from risk acceptance and towards risk avoidance. This reflects the greater role of the precautionary principle in influencing some aspects of risk management policy in the EU, as well as the emergence of new, more complex risks characterised by high levels of uncertainty.

- **Objectives** – as well as limiting scope for physical harm to the population as a whole, some risk management laws now focus on protecting vulnerable groups from physical harm or on maximising the "well being" of citizens or on promoting certain lifestyles. This latter concept goes beyond physical harm and, in some cases, encompasses ideas about the mental state of citizens, including their happiness.

- **Methods** – the tools used to achieve policy goals are also changing. Alongside traditional risk reduction tools such as emission limits or use restrictions, policy-makers have established new methods such as substitution or 'stigmatisation'. In many cases, these new tools seek to alter the operation of product markets by distorting the relative attractiveness of different products or substances for buyers and users.

- **Decision-making factors** – new 'models' of risk management decision-making often embed additional factors that regulators are required to consider when evaluating risk management options. Such factors include ethics, social concerns, and the precautionary principle. They also place much greater emphasis on non-scientific evidence and sometimes treat science as only one of a number of equally important knowledge inputs.

- **Processes** – decision-making processes have also changed. In general, new models of regulatory risk management require decision-makers to be more open and transparent. Some go beyond this and require public participation in parts of the decision-making process.

Although these changes reflect shifts in social attitudes and concerns, many aspects of this new approach remain, however, embryonic. These are new ideas had they have yet to be tested fully. Evidence from a limited number of examples in other countries

suggests that some elements of this model may pose major problems of workability, effectiveness, and legitimacy.

3.2. PROCESS MANAGEMENT STANDARDS AND GUIDELINES

Since the late 1990s, the Commission has introduced a succession of reforms to improve the quality of law-making, and to strengthen governance. These focus on policy-making and the development of new primary legislation. Reforms include the introduction of integrated impact assessment (a combination of a policy-making framework and cost-benefit analysis) and new consultation standards.

There are, however, three major problems:

- **Inadequate Scope** - the scope of these new process management tools is confined to policy and law-making. Regulatory decisions, and other implementing measures, are, in general, excluded.

- **Lack of Relevance** - a further problem is that the new impact assessment tools are generic: they are designed to deal with all forms of policy and law-making. They are not designed to be applied to risk management decisions.

  They fail, for example, to recognise the need for extensive use of science and other evidence to provide policy-makers with a clear understanding of the nature and causes of the threat, especially when dealing with 'lifestyle' risk and when distinguishing between hazard and risk. This is an inadequacy of the "Problem Definition" part of the impact assessment guidelines.

  A further weakness is to be found in the "Options Evaluation" section. In this instance, the guidelines fail to recognise the possibility of 'risk-risk' (creating other unintended risks, when managing perceived risks or hazards) and the need to assess workability, effectiveness, and legitimacy, especially when considering options to manage lifestyle risks. This section also fails to consider adequately the importance of assessing complex costs and benefits associated with risk management decisions, such as demand stigmatisation and substitution. There is, moreover, no requirement to use "cost effectiveness" tools to measure the physical benefits of specific options.

- **Gaps** - if the process management standards are to be used to make high quality regulatory risk management decisions then additional guidelines and standards are needed. These include: science and scientific evidence, including standards for risk assessment; and, ex post evaluation.

3.3. AGENCIES AND GUIDELINES

Since the mid-1990s, independent risk assessment agencies have been increasingly used by the EU as part of the process of making technical risk management decisions in a number of areas. Beginning with the European Medicines Evaluation Agency (EMEA), EU-level risk assessment agencies now include food safety (EFSA) and chemicals.

Independent agencies form part of an institutional separation of risk assessment and risk management at EU-level. Agencies are responsible for using science to assess risks, whilst final risk management decisions are taken by the European Commission using the comitology process. Agencies provide a mechanism for mobilising and focusing EU-wide scientific expertise on assessing certain risks. In part, this aims to improve public trust in the quality and independence of scientific advice used by policy-makers to assess and manage risks. And, because of their independence, agencies aim to improve the transparency and openness of the regulatory decision-making process.

As part of the process of assessing the risks of new and existing products or substances, agencies need to establish **guidelines**. These define test requirements and standards that must be met if companies are to demonstrate that their products or substances meet the objectives of relevant framework laws. Guidelines enable regulators to adapt to technical progress rapidly, whilst also providing companies with a degree of certainty and predictability. In general, companies tend to recognise the benefits of guidelines.

The development of guidelines by risk assessment agencies does, however, raise a number of important issues for EU-level technical risk management decision-making:

- **In many instances, guidelines are a form of risk management**. Because guidelines often deal with testing standards or exposure limits in areas such as public safety or human health, they have to make assumptions about the social acceptance of risk. Such decisions involve value judgements; they are not solely based on science or scientific evidence. The processes for making such decisions remain embryonic and, in some instances, lack transparency.

- **Guidelines are a form of 'soft' law.** They set out desirable requirements that companies should meet if their products or substances are to satisfy the requirements of primary laws. Whilst these requirements are not legally binding, failure to adhere to them may lead to products or substances failing to be approved for use, or being withdrawn from the market. 'Soft' law provides companies and regulators with the benefits of flexibility, speed, and certainty, but it does not provide the protections or other benefits of formal law.

- **Guidelines have a major influence on the economic decisions of companies**. They affect the time and cost needed to develop new products; the cost of maintaining existing products on the market; the operating efficiency of existing investments; and the scale of resources available for investment in innovation. These are major impacts, and can lead to changes in the level of innovation, the availability and use of technology, and product availability. Understanding these complex potential impacts is essential, if regulators are to

make high quality judgements about the extent to which guidelines help meet the overall social goals of primary laws.

- **The process of developing and applying guidelines falls outside the formal scope of the Commission's regulatory process management tools and standards,** despite their importance for managing risks and their potential impact on economic decisions, Individual agencies, such as EMEA, have, however, taken some steps to develop their own bespoke regulatory management tools in this area.

3.4. COMITOLOGY

Comitology emerged in the 1960s when the European Council recognised that it lacked the resources to make all the necessary implementation rules and decided to delegate implementing powers to the Commission. However, the Council did not want to delegate such powers to the Commission without keeping some legislative control. This was done through the creation of committees – composed of experts from each Member State – which work with the Commission on the technicalities necessary for the application of EU law. In most cases, the Commission can only adopt implementing measures if these are approved by the relevant committee and, in the absence of this approval, the proposed measure is referred back to the Council.

This process has recently been amended to permit the Parliament to block certain implementing measures made under co-decision legislation. This will, however, require an absolute majority of MEPs.

In the context of risk management laws, the comitology process is the formal mechanism through which technical risk management decisions are taken.

The comitology process has many strengths, most notably speedy access to the EU's internal market for non-controversial products, substances, and processes. It provides a rapid mechanism for obtaining the political commitment needed to facilitate market access throughout the EU. It does, however, also have a number of major weaknesses:

- **Opacity** – the comitology process is 'closed' and lacks transparency. Citizens have little access to the activities of comitology committees, and the basis on which decisions is taken is often unclear. Accountability is weak, and because processes lack openness, there are fears that outcomes may be subject to "regulatory capture". All of these weaknesses reduce public trust in the effectiveness and legitimacy of risk management institutions at EU-level.

- **Expertise** – the ability of the comitology committees to review fully and rigorously the risk assessment dossiers produced for and by the Commission, depends on the scientific and technical expertise available in each Member State. For a number of emerging, complex technologies, relevant scientific or technical expertise is distributed unevenly throughout the EU and may be unavailable in some Member States. It may even be the case that, in some circumstances, adequate technical and scientific knowledge may not be available in the EU. This situation is occurring because of scientific progress in general, and the increased

emphasis on investment by the private sector in development research, rather than fundamental knowledge.

Without adequate expertise, members of the comitology committee may well be unable to assess adequately the risk assessment dossiers provided to them. This is a public interest issue. Lack of knowledge potentially weakens the capability of regulators to understand and manage risks. Potentially, it also makes regulatory decision-making less predictable, with negative impacts on innovation and investment.

- **Uncertainty** – 'comitology' is a politicised process. It provides a formal and explicit opportunity for the EU's Member States to debate with each other, on the basis of, amongst other things, different values and attitudes, the desirability of specific technical risk management decisions. In this context, scientific and technical factors may be overruled in favour of social concerns or cultural factors. For some categories of technologies or risks, this political process may lead to considerable uncertainty of risk management outcomes. This is made worse because the comitology committees are not required to explain why scientific advice is ignored or to identify additional evidence used to support their opinions.

  Uncertainty in technical regulatory decision-making processes poses major challenges to companies. It raises the time and cost of investing in new products; distorts technology choices; and, in certain circumstances, closes markets. This creates major negative outcomes for citizens if it reduces choice, increases costs, or creates new, unintended risks.

  Additional involvement of the EP in the comitology process may lead to a significant increase in uncertainty.

3.5. "POLITICISATION"

'Politicisation' of technical regulatory decision-making occurs if outcomes or processes are influenced by political factors (such as values or ideologies) rather than the results of science-based risk assessment. At EU-level, it occurs in a number of different ways:

- **'Comitology'** - final risk management decisions at EU-level are often taken through the comitology process. This is a political step. Decisions are made by Member States, and comitology committees are not bound to accept the outcomes of risk assessments. Committees may, if they wish, make decisions on the basis of social values.

  Although this decision-making structure may create the possibility of uncertainty of outcome, it is a legitimate method of managing risks within open, democratic societies. It provides Member States with a final opportunity to review decisions made by the Commission, before risk management measures are implemented. It enables societies to ensure that social values can be taken into account, if necessary.

  In general, this process works well. Committees accept the results of risk assessments and endorse them. This provides companies with rapid access to

the EU's single market. Problems tend, however, to occur with products, substances or technologies that are defined as 'controversial' by one or more Member State. This occurs because of different social values within the EU and can spark political conflict within comitology committees. Outcomes of these debates are unpredictable, leading to regulatory uncertainty for companies. These problems are made worse by the opacity of the comitology process.

Problems may arise in the future if the number of 'controversial' products, technologies, or substances subject to the comitology process increases.

- **Politics and risk assessment** – 'politicisation' can also occur if political factors influence overtly the outcomes of science-based risk assessments. This occurs, for example, if 'precaution' (a political concept) is used systematically to make judgements within the risk assessment phase, rather than being confined to the risk management phase of the decision-making process.

  Evidence from a range of sectors shows how this occurs. In some instances, assessors fail to consider realistic usage conditions or systematically use worst-case exposure scenarios to evaluate potential risks or place undue emphasis on individual studies rather than on the overall weight of scientific evidence. Precaution also occurs when assessors use the concept of "read across" unscientifically. This technique is used when there is a lack of relevant safety or environmental data about particular substances or products. To close these gaps, some assessors use the hazard characteristics of one form or a substance and apply it to other forms for which there is no data.

  If these problems occur, it weakens political accountability, erodes transparency, and creates significant unpredictability. Accountability is lost because officials or scientists, rather than elected governments, have used value judgements or similar factors to influence the outcome of the risk assessment phase of the decision-making process, such that risk acceptance has been determined through administrative rather than political processes.

4. RECOMMENDATIONS

EU-level technical regulatory decision-making processes are extensive and complex. Significant steps have been taken to improve their efficiency and predictability, most notably through the greater use of independent scientific committees, the establishment of agencies, and the extensive use of voluntary standards. Despite these reforms more needs to be done, if technical, implementing decisions are to continue to be of high quality. Possible improvements include:

- **Establish a formal Commission-wide policy** for risk assessment and management decisions made using technical regulatory decision-making processes.

- **Include agency guidelines within a formal risk management policy**, recognising that, in many instances, risk management measures are a form of 'soft law'.

- **Extend the scope of the Commission's regulatory management tools** (most notably impact assessment and consultation) to include implementing measures, such as agency guidelines and selected comitology decisions.

- **Introduce new Commission-wide regulatory management standards covering science and scientific evidence used in decision-making and ex post evaluation of regulatory decisions**.

- **Draw up additional impact assessment (IA) guidelines that are relevant to the management of technological and lifestyle risks** to human health, public safety, and the environment.

- **Improve the credibility, accountability and transparency of the comitology process** by agreeing minimum standards of expertise for participants; by establishing new disclosure rules; and by requiring committees to provide a full and reasoned explanation of their decisions, including the rationale for rejecting scientific evidence.

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This background note was written by Richard Meads, the European Risk Forum's rapporteur, with help from members of the Forum. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.