EUROPEAN RISK FORUM – POLICY NOTE 13

GUIDELINES AND THE GROWTH OF THE REGULATORY STATE AT EU-LEVEL

2009

European Risk Forum

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, cost, benefits, and legitimacy of different policy options (risk management).

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);

- 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

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.

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

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

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

- Develop a Commission policy statement recognising that guidelines play an important role in assessing and managing risks,;
- Extend the scope of the Commission's regulatory management tools (impact assessment and consultation) to include the development of new guidelines;
- Require all EU-level risk assessment agencies to establish common processes and standards for creating new guidelines or amending existing ones;
- Ensure that the need for new or revised guidelines is based on well-established, high quality scientific evidence;
- Undertake systematic ex post evaluations of the impact and effectiveness of new and existing guidelines;
- Accelerate the development and implementation of an agreed set of risk assessment principles and procedures for all EU-level risk assessment bodies

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1. BACKGROUND

At EU-level and throughout the OECD area, many public risk management objectives are achieved using a complex, multi-stage approach. Framework legislation, normally derived through a political process, sets out the social goals to be achieved, identifies the hazards to be controlled, and defines the level of social acceptance of risk. A number of procedures and tools are then used to by governments to implement legal requirements and to deliver the goals set out in primary law[1]. These implementation activities are often categorised as "technical regulatory decision-making processes".

Technical and administrative processes, often involving extensive regulatory and scientific activity, are used by governments to make the large numbers of heterogeneous case-by case decisions needed to manage complex risks to human health, public safety, and the environment over long periods of time. Indeed, 'technical' regulatory risk management decision-making has become one of the most important ways in which social goals are met in most OECD countries. It includes the delegation of regulatory powers to sectoral agencies, the creation of scientific and expert committees, the development of private (voluntary) standards, as well as the production of 'guidelines'.

Guidelines are extensively used by EU-level risk management institutions to assess and, increasingly, manage risks. In many sectors, and for a wide range of risks, they form a substantial part of the overall technical regulatory decision-making process used to implement secondary legislation. Examples include the specific test requirements needed to demonstrate the safety, quality, and efficacy of new drugs for humans or animals set out by EMEA[2]; BREF documents describing acceptable technologies for managing emissions; the RIP programme designed to implement REACH and hence manage risks posed by chemical substances; and safety testing requirements in areas such as novel foods, food additives, crop protection, cosmetics, advanced medical devices, and biotechnology.

The increased use of guidelines as a tool for managing risks highlights a wider regulatory challenge facing the EU's institutions, namely the need to ensure effective governance of the so-called "Regulatory State"[3].

This concept highlights the shift in governance that has occurred in the last thirty years, as regulation, often implemented by semi-independent agencies, rather than direct ownership or control of economic assets, has become the main tool for intervention in the economy. Many risks posed by technologies and lifestyle choices are already managed using this institutional approach, and its scope will grow rapidly over the next decade. Implementation of REACH, the EU's new law for managing risks posed by the use of chemicals will require most of Europe's manufacturing industries to comply with risk management guidelines issued by the EU, for instance.

[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] As an example, the Veterinary Medicine industry in the EU, part of the pharmaceutical sector, must comply with nearly 150 guidelines issued by EMEA, designed to manage risks on an ex ante and ex post basis. In the USA, the Federal Food and Drug Administration has issued over 1,500 guidance documents, covering a wide range of regulated industries.
[3] See for example Majone G. 'The Rise of the Regulatory State in Europe' (West European Politics, Vol. 17, 1994)

2. GUIDELINES AND RISK MANAGEMENT

'Guidelines', issued by risk assessors and managers, form an important part of many technical regulatory decision-making processes. They are non-binding statements by government regulators and agencies that 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.

Guidelines provide regulators with a critical mechanism for structuring the way in which a wide range of risks are assessed and for delivering risk management outcomes. As such, they help regulators reduce, shift, or remove potential harms on a systematic or case-by-case basis. In the risk assessment phase, they are used to define hazards, exposures, risks, and levels of acceptable use or exposure, as well as to describe test requirements, methods, processes, and standards needed to demonstrate safety and quality. Moreover, guidelines often include embedded assumptions about the social acceptance of risk. Many guidelines include judgements that limit or prevent exposures through decisions about safety limits or test methods or methods of interpreting test data (such as requirements to use worst case scenarios), for instance. They also provide evidence of compliance with risk management requirements.

Used well, and supported by appropriate regulatory decision-making policies and institutions, guidelines are a highly effective mechanism for managing risks, creating major benefits for citizens and businesses. Specifically, high quality guidelines:

- Provide regulatory certainty for smaller enterprises, defining clearly what must be done to comply with the law;

- Restrict "administrative discretion" and politicisation amongst regulators, improving the predictability of decision-making;

- Enable regulators to respond flexibly to advances in scientific and technical knowledge by taking timely action to protect the public interest without, in many cases, waiting for new or additional primary legislation; and,

- Strengthen the evidence-based approach to decision-making, enhancing transparency, effectiveness, and public trust.

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': they impose obligations on citizens and businesses without the provision of formal legal and process protections. They set out, in practice, a detailed definition of the legislative requirement. Failure to adhere to guidelines is seen to be 'prima facie' evidence of non-compliance. Finally meeting the requirements set out in guidelines imposes costs and requires changes in behaviour.

3. REGULATORY QUALITY AND USE OF GUIDELINES AT EU-LEVEL

Traditionally, guidelines have been seen as forming part of the risk assessment phase of the decision-making process at EU-level: their role in managing risks, and hence creating obligations, costs and benefits, has not been fully recognised or highlighted. There is some evidence, however, that EU-level regulators have begun to recognise formally the role that guidelines can play in effective and flexible management of risks:

- **Nanotechnology** - EU-level policy-makers have, for example, accepted that the potential risks posed by some new technologies (most notably nanotechnology) can be managed effectively through changes in guidelines rather than through the introduction of new, technology-specific legislation[4].

- **Veterinary medicine** - The European Medicines Agency (EMEA), for instance, has established process standards for the development of new guidelines for human pharmaceuticals and animal health products[5]. They aim to establish a consistent and transparent approach to the development of new or revised guidelines. They require costs and benefits to be assessed, and lay out clear rules for openness and for consultation with affected parties. They also require regulators to identify the problem that a new or revised guideline will resolve.

- **Impact Assessment** – whilst the scope of the European Commission's impact assessment process is confined primarily to Commission initiatives and Community legislation, the recently revised IA guidelines recognise that it may be necessary for officials to carry out assessments of significant implementing measures, most notably comitology decisions[6]. (Development of new or revised guidelines is, however, not yet included in the list.)

Alongside these initiatives, the Commission has taken steps to try and develop a common approach to the development of guidelines by EU-level organisations responsible for risk assessment and management. Improved co-ordination between these bodies has, for example, helped endorse a revised approach to the functioning of EU-level scientific committees.

Despite this increase in awareness amongst EU-level regulators of the role that guidelines play in managing risks, the formulation and implementation of new or revised guidelines remains outside the formal scope of the EU's regulatory process management requirements. New guidelines are not routinely subject to impact assessment nor are they covered by the Commission's consultation standards. In addition, the large stock of existing guidelines at EU-level is not subject to rigorous ex post evaluation of relevance and effectiveness.

[4] European Commission *'Regulatory Aspects of Nanomaterials'* (European Commission Communication SEC (2008) 2036)
[5] These are set out in EMEA *'Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework'* (EMEA/p/24143/2004, revised 2009)
[6] European Commission *'Impact Assessment Guidelines'* (SEC(2009) 92) and European Commission *'Annexes to Impact Assessment Guidelines'* (2009)

4. RECOMMENDATIONS

At EU-level, non-binding guidelines issued by agencies, scientific committees, and regulators 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 recognise fully the role that non legally-binding guidelines play in implementing risk management laws; to ensure that new guidelines are of high quality and are developed using open, transparent processes; and, to assess the impact and effectiveness of existing guidelines. Possible reforms include:

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

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

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

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

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

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

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

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

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This policy brief 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 state or reflect those of the European Risk Forum.