EUROPEAN RISK FORUM – POLICY NOTE 08

AGENCY GUIDELINES AND IMPACT ASSESSMENT – IMPROVING TECHNICAL REGULATORY DECISION-MAKING

MARCH 2008

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, the objectives of many primary risk management rules 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.

Non-binding 'guidelines', issued by risk assessors and managers, form an important part of many technical regulatory decision-making processes. These set out detailed technical, scientific, or regulatory requirements, or provide an interpretation of statutory obligations. They provide officials with a flexible and speedy mechanism with which to respond to technical and scientific progress, as well as providing companies with a degree of certainty within the process of implementation of secondary legislation. Guidelines are widely used by EU-level risk management institutions, most notably the European Commission and its agencies.

Such standards are, however, a form of 'soft law'. For most companies affected by guidelines, they provide, in practice, a detailed definition of the legal requirement. Failure to adhere to guidelines is, all too often, seen to be 'prima facie' evidence of non-compliance. Moreover, guidelines often embed assumptions about the social acceptance of risk. This is a form of risk management.

Poor quality guidance can increase costs, without adequate compensating benefits for citizens. They may also provide agencies or officials with a mechanism for making rules more stringent, without effective oversight or changes in legal requirements.

A recent expansion of the scope of the US government's regulatory decision-making rules recognises the role that 'guidance' plays in modern technical regulatory decision-making processes. The new requirements aim to force guidelines to be more consistent, compatible, and understandable. They also strengthen the capacity of the White House to identify and resist "regulatory creep" by federal agencies.

In contrast, the role of 'guidance' (or guidelines) within EU-level technical regulatory decision-making processes is unclear. 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, to assess the impact and effectiveness of existing guidelines. Possible reforms include:

- Develop a policy statement recognising that guidelines play an important role in assessing and managing risks,;
- Extend the scope of the Commission's regulatory management tools (most notably impact assessment and consultation) to include the development of new guidelines;
- Undertake systematic ex post evaluations of the impact and effectiveness of new and existing guidelines;

1. BACKGROUND

At EU-level and throughout the OECD area, the objectives of many primary risk management rules 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.

Non-binding 'guidelines', issued by risk assessors and managers, form an important part of many technical regulatory decision-making processes. These set out detailed technical, scientific, or regulatory requirements, or provide an interpretation of statutory obligations. They provide officials with a flexible and speedy mechanism with which to respond to technical and scientific progress, as well as providing companies with a degree of certainty within the process of implementation of secondary legislation.

Guidelines are widely used by EU-level risk management institutions, most notably the European Commission and its agencies. 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; 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.

Such standards are, however, a form of 'soft law'. For most companies affected by guidelines, they provide, in practice, a detailed definition of the legal requirement. Failure to adhere to guidelines is, all too often, seen to be 'prima facie' evidence of non-compliance. Moreover, guidelines often embed assumptions about the social acceptance of risk. For example, many guidelines include judgements that limit or prevent exposures through decisions about safety limits or test methods. This is a form of risk management.

Whilst high quality guidelines are recognised by many companies as providing a flexible way of responding to new knowledge, reducing uncertainty, and meeting social goals, poor quality guidance can increase costs, reduce innovation, and erode revenues without adequate compensating benefits for citizens. In practice, they may also provide agencies or officials with a mechanism for making rules more stringent, without effective oversight or changes in legal requirements.

2. 'GUIDANCE' AND REGULATORY OVERSIGHT - REFORMS IN THE USA

Since the end of the Second World War, there has been a substantial increase in the use of federal legislation to manage risks to human health, public safety and the environment in the United States of America. In many cases, legal requirements, established by the US Congress, are implemented on a case-by-case basis by federal agencies through a process of technical regulatory decision-making. Such agencies form part of the executive function of the federal government.

The growth of this so-called "Federal Regulatory State" has triggered the development and implementation of a series of policies, institutions, and mechanisms designed to manage "regulatory quality". These include formal consultation requirements based on the "notice and comment" process; centralised oversight and quality management through the US Office of Management and Budget (OMB), part of the White House; and, explicit standards for regulatory quality.

Standards are set out in a series of Presidential Executive Orders, culminating in Executive Order 12866 ('Regulatory Planning and Review') signed by President Clinton in 1993. Based on earlier orders by President Reagan, this requires regulators to use rational decision-making procedures, to develop a consensual rather than an adversarial approach, to use innovative policy instruments, and to meet a set of regulatory quality standards. The order also formalises the centralised oversight role of the OMB.

The quality standards set out in President Clinton's order require regulators to identify the problem to be addressed and assess its significance, identify and assess alternatives to direct regulation, design regulation in the most cost-effective way, regulate only when benefits are likely to exceed costs, avoid regulations that are inconsistent or duplicate other requirements, and draft regulations that are simple and easy to understand. A statement of "regulatory philosophy" is also included in the order.

These requirements remain in place, and have been recently expanded and up-dated by Executive Order 13422 from President Bush. The principal purpose of this new order is to up-date the earlier requirements and to expand the scope of the US federal regulatory quality standards to include 'guidance' as well as traditional rule-making.

The new Executive Order imposes three significant new requirements on regulatory agencies:

- **Political accountability** – all agencies covered by the order must designate a presidential appointee as the "regulatory policy officer" (RPO). The RPO must, in future, approve all 'significant' regulations before they are included in the agency's annual plan.

- **Regulatory process** – a written rationale for new regulations or guidance must be included in the justification for new rules. Alongside this, an estimate of the overall costs and benefits of all new regulatory proposals should be included in each agency's plan.

- **Guidance** – the new presidential order brings 'guidance' within the scope of the federal government's regulatory philosophy. Moreover, it requires 'significant' guidance to be based on the best available information about the 'need' for government action; to avoid duplication; and to minimise uncertainty. Citizens and the OMB are to be notified prior to the issuance of new 'significant' guidance. Finally, additional analysis, consultation, and justification may, in some instances, be required by OMB.

  Guidance is defined as: *"an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory issue."*

  Only 'significant' guidance is covered by the new presidential order. 'Significant' guidance imposes more than $100 million of annual costs on citizens or businesses, or creates a serious inconsistency with other requirements, or triggers material budgetary costs, or, finally, raises novel legal or policy issues.

This expansion of the scope of the US government's regulatory decision-making rules recognises the role that 'guidance' plays in modern technical regulatory decision-making processes. (For instance, the FDA has more than 1,500 guidance documents currently in use.) Agencies use them to provide an interpretation or policy on particular regulatory or technical issues. For some smaller or less well-resourced businesses, they may also provide a means of defining how to comply with specific regulatory requirements. Used well, 'guidance' can provide a flexible way of responding rapidly to scientific progress, and of reducing regulatory unpredictability.

The new requirements up-date the USA's regulatory process management rules. They aim to force guidelines to be more consistent, compatible, and understandable. They also strengthen the capacity of the OMB to identify and resist "regulatory creep" by federal agencies.

3. EU – GUIDELINES AND TECHNICAL REGULATORY DECISION-MAKING

Unlike the USA, the role of 'guidance' (or guidelines) within EU-level technical regulatory decision-making processes remains unclear:

- There is some evidence that regulators have begun to recognise formally the role that 'guidance' can play in effective and flexible management of risks. Traditionally, 'guidance' has been seen as forming part of the risk assessment phase of the decision-making process: its role in managing risks, and hence creating costs and benefits, has not been recognised or highlighted. Recently, this has begun to change. EU-level policy-makers have, for example, accepted that the risks posed by some new technologies (most notably nanotechnology) can be managed effectively through changes in 'guidance' rather than through the introduction of new legal powers.

- In some cases, regulators have taken action, at the level of specific agencies, to make the process of formulating new guidelines more rational, predictable, and

transparent. The European Medicines Agency, for instance, has established process standards for the development of new guidelines. These require costs and benefits to be assessed, and lay out clear rules for openness and for consultation with affected parties.

Despite this increase in awareness and activity amongst some regulators, the formulation and implementation of new 'guidance' remains outside the formal scope of the EU's regulatory process management requirements. New guidance is not routinely subject to impact assessment, nor is it covered by the Commission's consultation standards.

4. ISSUES

The recent reforms in the USA, and the emerging changes at EU-level, raise three important issues about 'guidance', its role in managing risks, and the use of process management tools to manage regulatory quality:

- The role of non-legally binding technical, scientific, and regulatory advice from officials and institutions as a mechanism for managing complex risks in modern societies has been recognised and legitimised by the decision of the US federal government to expand the scope of its regulatory philosophy and principles to include guidance;

- Guidance provides 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. These are important benefits for citizens and businesses.

- Guidance, along with comitology decisions, forms one of the principal mechanisms through which the EU manages technological and lifestyle risks to the environment, public safety, and human health. As a result, guidance can impose costs on societies that should be matched by commensurate benefits, and should be developed using open rational, processes. This needs to be recognised by policy-makers and taken account of in the EU's regulatory process management rules;

5. RECOMMENDATIONS

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

- **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;

- **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;

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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 state or reflect those of the European Risk Forum.

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