EUROPEAN RISK FORUM – COMMUNICATION 05

DRAFT OECD RECOMMENDATION ON REGULATORY POLICY AND GOVERNANCE

COMMENTS

June 2011

1. 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.

For nearly twenty years, the ERF and its founders have supported the adoption by the EU institutions of modern regulatory process management tools, including consultation, impact assessment, ex post evaluation of regulations, and standards for the collection and use of evidence. On the basis of this extensive experience, and its recent work, the ERF provides comments on the recommendations set out by the OECD in its 'Draft OECD Recommendation on Regulatory Policy and Governance'.

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2. OVERALL COMMENTS

2.1. Revision

The draft recommendations build on and update a series of OECD instruments adopted since 1995. These have played a major role in stimulating the adoption by the EU's institutions of a number of important regulatory process management tools and the creation of new institutions (most notably the Impact Assessment Board) to oversee their implementation. It is clear that this has, in turn, contributed to improvements in the quality of regulatory decision-making at EU-level.

In view of this, this revision is to be welcomed. It is to be hoped that the additional recommendations identified in this latest instrument will trigger further improvements in the way in which the EU institutions and its Member States make regulatory decisions, and in the quality of those decisions.

2.2. Improvements

In overall terms, the recommendations expand and up-date the OECD's existing, excellent standards for regulatory policy and governance. Major changes and improvements set out in the draft include:

- **Ex post analysis** – there is more explicit recognition of the importance of systematic retrospective analysis of regulatory decisions in the revised instrument. Adoption of this process management tool completes the policy cycle and helps regulators identify areas where costs do not justify benefits, as well as highlighting the causes of success or of failure. High quality ex post analysis also helps improve accountability, and provides the means to develop a well-informed understanding of the unintended consequences of regulatory decisions.

- **Reviewing performance** – for the first time, the instrument identifies the need for regulators to assess the overall performance of regulatory programmes. This fits well with the increased focus on retrospective analysis of individual regulatory decisions, forcing decision-makers to examine the extent to which groups of related interventions deliver benefits that exceed costs. Such reviews may also provide an opportunity to examine the 'horizontal' consequences of similar types of regulatory decisions, such as the impact on product availability and innovation of risk management rules targeted at the use of complex technologies in large numbers of heterogeneous applications.

- **Public management of risk** – the instrument recognises the role that regulatory decisions play in the public management of risk, most notably risks to human health, public safety, and the environment posed by technologies and lifestyle choices. It identifies some of the unique characteristics of these decisions, including the need for high quality scientific evidence to support regulatory interventions.

- **Administrative appeals** – the draft instrument highlights the need for regulatory decision-making processes to be subject to rules and procedures, protecting

users and affected entities. In the light of the progressive introduction by the EU institutions of regulatory process management tools, along with the increased use of regulatory instruments at EU-level, this issue of "procedural justice" is becoming increasingly important, if the legitimacy and effectiveness of the regulatory decision-making process is to be sustained. In too many cases, the EU institutions have made regulatory decisions, including those made through comitology, without adhering fully to the standards laid down in their own regulatory processes. At EU-level, the introduction of a binding Administrative Procedures Act (or equivalent) would provide an important complement to judicial review of the decisions of the EU institutions by the ECJ and other equivalent courts.

2.3. Gaps

Whilst the draft recommendations expand significantly the scope of the OECD's standards, a number of important issues are not addressed. These include:

- **Predictability** – high quality regulatory decision-making processes ensure that outcomes are predictable, limiting regulatory uncertainty, administrative discretion, and politicisation. This should be one of the principal objectives of any overall regulatory policy. Without predictability, innovation and investment is distorted, limiting the development of new ways of improving social welfare and triggering risk-risk outcomes. Ideally, predictability of regulatory processes is underpinned by legal protection and "due process" requirements.

- **High quality evidence** – evidence-based policy-making, including regulatory decisions, depends on the collection and use of high quality information and data to support decision-makers. The necessity of ensuring that this occurs should be set out in any overall policy statement designed to ensure regulatory quality.

- **Standards for evidence, its collection, and use** – experience gathered over the last twenty years suggests that it is no longer sufficient simply to require policy-makers to use evidence to support decision-makers, without specifying standards for what constitutes acceptable and relevant evidence, for collecting evidence, for its interpretation, and for the processes that oversee the overall quality of evidence. Such standards are of particular importance for the collection and use of scientific evidence. For instance, in too many cases regulators are influenced by risk perceptions fuelled by hypothesis-forming science when making difficult risk management decisions, rather than basing regulatory judgements on evidence that meets the widely-accepted standards of the "scientific method". Standards for evidence, including the use of peer review of risk assessments, should be an additional recommendation endorsed by the OECD.

- **Compliance** – more emphasis needs to be placed within the draft recommendations on the importance of ensuring compliance with regulations.

- **Guidelines and 'soft law'** – across a wide range of policy domains, particularly those involved in the public management of risks to human health, the

environment, and public safety, the goals of primary legislation are achieved through a mix of formal regulatory instruments and 'soft law' decisions, primarily the adoption of guidelines often by regulatory agencies. Guidelines provide regulators with a way of rapidly adapting to technological and scientific progress without the need for additional primary laws. They are also flexible, allowing regulatory requirements to be tailored to meet the needs of specific problems. In the pharmaceutical sector, for instance, guidelines determine the testing needed for new products to demonstrate safety, quality, and efficacy. Although guidelines are often non-binding, they are essentially a form of 'soft law' and, through their impact on the investment decisions of businesses, they have economic consequences. In many instances they are used implicitly to define the level of social acceptance of risk as well. The role of guidelines as a form of regulatory instrument is increasing, particularly at EU-level. The scope of the OECD's recommendations should be expanded explicitly to include the use of guidelines as a form of regulatory activity.

- **Benefits of regulatory proposals** - good risk management decisions, along with other public policy interventions, occur when benefits justify costs. Evidence 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. The OECD recommendations should give greater emphasis to the importance of regulators, during ex ante assessments, assessing benefits rigorously and, wherever possible, quantifying and monetizing them.

- **Resources** – the recommendations should endorse the need for member countries to support regulatory policies with adequate human and financial resources, and to ensure that officials involved in regulatory decision-making receive continuous training.

3. SPECIFIC RECOMMENDATIONS - COMMENTS

3.1. Explicit Policy on Regulatory Quality

The following amendments to the draft recommendation are suggested:

- Create an additional secondary recommendation stating that regulatory policy should be conceived and implemented as a package of mutually dependent elements, such as forward planning and programming, RIA, public consultation, ex post evaluation, access to documents, and standards for the collection and

use of evidence. Designing these elements together is critical to ensuring a strategic, coherent vision of reform.

- Amend recommendation 1.3 to require regulations to be based on the best available science, to take account of costs and benefits both quantitative and qualitative, and to promote predictability.

- Revise recommendation 1.4 by including a preference for regulations to be the least prescriptive, onerous and burdensome means of achieving agreed social goals.

- Further revise recommendation 1.4 through the widening of the goals of regulatory activity to include the promotion of economic growth and innovation, as well as the protection of public health, welfare, and the environment.

3.2. Users of Regulation

Possible amendments include:

- Create a new, additional secondary recommendation requiring governments to establish high quality standards for the use, by regulators, of information obtained through public consultation. (It is, for example, vitally important to distinguish between scientific evidence obtained through established risk assessment processes and risk perceptions and quasi-science provided through consultations. Users of information should be made aware of the differences in utility and relevance of these two different types of information.)

- Revise recommendation 2.4 to ensure that adequate feedback to those participating in consultations is undertaken by regulators.

- Remove the reference to 'perception' in recommendation 2.5. Instead, performance assessments should be triggered by credible evidence provided by users. (If this is not done, then the implementation of regulatory policies could be triggered by bias, ill-informed comment or "manufactured dissent".)

- Make a major amendment to recommendation 2.7 by adding additional requirements for establishing policies for assessing compliance. Possible text could be: "governments should promote the use of risk-based approaches in the design and enforcement of regulatory compliance strategies to increase the likelihood of achieving compliance goals and to minimise the imposition of costs on businesses and citizens through compliance and enforcement procedures". (This text is taken from recommendation 9.5 which should be amended to remove it.)

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3.3. Regulatory Oversight

The following changes are suggested:

- Strengthen recommendation 3 through two amendments: first, institutions and mechanisms should be close to the centre of government; and, second, they should be permanent.

- Revise recommendation 3.3 by removing the responsibility for planning future regulatory policies from the oversight unit. (In general, this involves political decisions and should remain the responsibility of the Minister for regulatory policy or equivalent.)

3.4. Regulatory Impact Assessment

A number of amendments should be considered, including:

- Amend recommendation 4 to recognise the need to clearly identify policy goals and options, and to ensure that regulatory goals are achieved in a proportionate manner. This recommendation should also require RIA to be used whenever agencies or similar institutions create significant guidelines.

- Create a new secondary recommendation that highlights the need to embed the ex ante assessment process in forward planning of regulations and in a formal public consultation process that commences before regulatory options are identified and continues throughout the entire assessment process.

- Revise recommendation 4.3 to require regulators to explore and outline thoroughly the causes of the problem as part of the "problem definition" phase of the assessment. Moreover, regulatory options should be required to demonstrate a strong relationship with the causes of any problem.

- Change recommendation 4.3 so that regulators are required to consider a "no action" baseline scenario as part of any review of regulatory options. This should ensure that the costs and benefits of any regulatory option are solely due to the proposed change.

- Improve recommendation 4.4 by requiring officials to monetise costs and benefits wherever possible, as well as providing quantified analyses;

- Expand recommendation 4.7 to include the following additional requirements: officials should ensure that the level of analysis is proportionate to the potential impacts of any proposed rule; and, analyses of costs undertaken by officials should consider potential unintended impacts (such as risk-risk outcomes) and complex costs (such as impacts on demand stigmatisation or innovation).

3.5. Reviews of Regulatory Stock

A number of revisions are suggested:

- In the light of new initiatives being launched in a number of OECD member states, it may be more appropriate to re-label this group of recommendations. A better title would be “Ex Post Analysis of Regulation” or “Retrospective Analysis”. (These alternative titles are more dynamic and modern. In contrast, the focus on regulatory stock could become confused with simplification of even de-regulation.)

- Revise recommendation 5 so that any review of existing regulations ensures that they are consistent with each other. A similar change should be made to recommendation 5.2.

- Amend recommendation 5.2 to include the following additional requirements: reviews should ensure that benefits justify costs and that all significant unintended consequences of regulations are identified.

- Expand recommendation 5.3 to require governments to define roles and responsibilities for reviews.

3.6. Reviewing Performance of Regulatory Programmes

Possible amendments include:

- Revise recommendation 6 such that performance reviews include compliance with public consultation practices, as well as with standards for the collection and use of evidence.

- Amend recommendation 6.4 to require information used for reviews to be of high quality.

- Create an additional secondary recommendation that urges governments to promote and support the development of independent institutions able to scrutinise regulatory policies and compliance with regulatory quality standards.

3.7. Organisation of Regulatory Agencies

A number of possible amendments are suggested, including:

- Revise recommendation 7 to require decisions by regulatory agencies to be based on high quality evidence and to meet regulatory quality standards.

- Create a new secondary recommendation which requires agencies to comply with regulatory quality standards (including RIA, consultation, and collection and use of evidence) when drawing up guidelines or other forms of ‘soft law’.

3.8. Administrative Appeals

Recommendation 8 could be improved by ensuring that administrative appeals processes are allowed to review compliance with regulatory quality standards as part of any assessment of "due process", and that the decisions of such processes are legally binding.

3.9. Risk and Regulation

The following amendments are suggested:

- Replace the proposed recommendation 9 with the following:

  "Regulations designed to manage risks to human health, public safety, or the environment should meet additional regulatory quality standards. They should be derived from a systematic, expert and rigorous assessment of risks based on high quality scientific evidence and a realistic estimate of potential harms. Final risk management rules should be predictable, consistent, and proportionate; they should minimise negative unintended consequences; and they should be informed, wherever possible, by quantified estimates of regulatory costs and of expected improvements in health or the environment."

- Remove recommendations 9.2 and 9.5 and add them to recommendation 2 et al.

- Amend recommendation 9.1 so that officials are required to consider "risk-risk" outcomes, as well as effectiveness and workability when assessing different risk management options.

- Revise recommendation 9.6. Guidance for the use of the Precautionary Principle should ensure that it is only applied in a small number of exceptional and clearly defined circumstances. Moreover, its use should be proportionate, temporary (subject to review), informed by an analysis of costs and benefits, derived from a formal risk assessment, predictable, and non-discriminatory.

- Create an additional secondary recommendation that requires officials to establish formal standards for the collection and use of scientific evidence used to inform risk assessment and risk management processes. These standards should define the quality of studies, information, and data to be used in scientific assessments used to inform risk management decisions. Guidance for the interpretation of scientific evidence by risk assessors should also be drawn up, emphasising the importance of basing judgements on the weight-of-evidence approach rather than alternative, precautionary methods.

- Add a further, new secondary recommendation that urges governments to make it mandatory for all measures designed to manage risks to health, safety or the environment to be supported by a full cost effectiveness analysis.

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