EUROPEAN RISK FORUM – COMMUNICATION 04

SECRETARIAT-GENERAL CONSULTATION – DRAFT COMMISSION IMPACT ASSESSMENT GUIDELINES

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2. IMPACT ASSESSMENT

2.1. Importance

Throughout the OECD area, Regulatory Impact Analysis (RIA) is one of the most widely-used processes for improving the quality of regulatory decisions[1]. In a wide range of different legal and regulatory settings, it helps regulators improve the effectiveness of regulatory outcomes, whilst, at the same time, reducing the costs of regulatory decisions. RIA reduces the risk of regulatory failure.

RIA is used to support decisions made by regulators and politicians: it is not a substitute for political action. Nor is it a mechanistic process, basing decisions on simplistic comparisons of quantified costs and benefits. Instead, it encompasses a wide range of qualitative and quantitative methods aimed at systematically and openly assessing the negative and positive impacts of proposed and existing regulation.

RIA forms an essential part of a modern, transparent, accountable, and empirically-based regulatory system.

Regulators employ RIA tools and processes because, if designed well and implemented effectively, they deliver a wide range of benefits for decision-makers, citizens, and businesses. Specifically, high quality RIA processes:

- Enhance the rigour, transparency, and accountability of regulatory decision-making processes, including strengthening consultation;
- Provide a formal mechanism for better structuring of the decision-making process, helping to ensure that the "need" for government action is justified fully and based on a credible understanding of cause and effect;
- Help decision-makers assess alternative policy interventions (including no action by government) explicitly;
- Highlight "true" impacts of regulatory decisions, including qualitative benefits, complex costs[2], and unintended consequences;
- Promote regulatory strategies that maximise net benefits of government action;

2.2. EU Institutions and Impact Assessment

The EU's institutions have taken a series of steps to improve the quality of regulatory decision-making over the last 20 years. These have included greater use of outcomes-based laws (the so-called "New Approach" in directives related to product standards); Treaty Protocols on the principles of subsidiarity and proportionality; new methods for consultation; partial impact assessment tools (such as the Business Impact Assessment); and presidential guidelines for the preparation of legislative proposals by the European Commission.

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[1] Within this note, the use of the term 'regulations' refers to primary law-making decisions as well as implementing or regulatory decisions. At EU-level this corresponds to secondary legislation, such as EU Directives or Regulations, and technical implementing decisions made through processes such as 'comitology'.

[2] Traditional impact assessments only measure the direct costs of complying with new or revised rules. Increasingly, these are of only limited importance. Of much greater importance to citizens are the complex costs created by regulatory activity. Such costs include the response of companies to government intervention, including impacts on location of economic activity, nature and price of products, level of employment, and extent and nature of innovation. Complex costs also occur when regulatory activity triggers complex market mechanisms, such as demand stigmatisation, leading to losses of sales and margins.

3. DRAFT COMMISSION IMPACT ASSESSMENT GUIDELINES - COMMENTS

3.1. Revision

The IA guidelines set procedural rules for impact assessment in the Commission and explain how to conduct analyses. Practical advice is included in both the guidelines and the annexes. The technical annexes provide guidance on specific issues or problems that are likely to emerge during the impact assessment process, and are a non-exhaustive collection of ideas and tools open to further improvement and up-date.

Whilst most of the guidelines and technical annexes are advisory, parts are mandatory. These include the format of the IA report, for instance.

During 2008, the Commission intends to revise the guidelines used by Commission services when they prepare impact assessments to support related policy initiatives. In 2003, the Commission published its first guidelines for IA. These were subsequently up-dated in 2005 and 2006.

This latest revision has been triggered by an external evaluation of the Commission's impact assessment system completed in 2007 and the establishment of the Impact Assessment Board in 2006. It is, moreover, the first time that draft guidelines have been submitted to public consultation, providing an opportunity for expert scrutiny and comment. This is to be welcomed.

3.2. Improvements

In overall terms, the proposed guidelines and annexes represent a major improvement in many areas, and are to be welcomed. Major changes and improvements set out in the draft include:

- **Evidence-based decision-making** – there is a renewed emphasis on the importance of basing legislative and regulatory decisions on evidence. This builds on earlier versions of the guidelines;

- **Resource allocation** – the new guidelines require scarce IA expertise to be focused on policy or legislative proposals with the "most far-reaching impacts", rather than being spread across all actions included in the Commission's annual work programme. Over time and if implemented effectively, this new requirement should enhance the credibility, relevance, and effectiveness of the overall IA process;

- **Institutional responsibilities** – the new Impact Assessment Board (IAB) is clearly and explicitly integrated into the Commission's process for producing and approving IAs. This further strengthens the IAB's oversight role;

- **Proportionate analysis** –new and more explicit guidance, describing the concept of "proportionate analysis" and providing examples of how to apply it during the preparation of different types of IA (including a description of its application to an assessment of the potential impacts of a comitology decision), is provided to Commission officials;

- **Data quality** – the revised guidelines further reinforce the general requirement for Commission officials to use high quality and credible data to inform the development of impact assessments;

- **Policy effectiveness** – the importance of ensuring clear linkages between the causes of problems, their subsequent impacts on the EU (and its citizens), and policy action, is highlighted by the revised guidelines. If this approach is applied by policy makers it should, over time, improve the quality of legislative and regulatory decision-making;

selected comitology decisions. The new guidelines envisage the use of the IA process for some comitology decisions but only on a 'voluntary' basis. Moreover, the draft guidelines do not provide an explanation of how this is to be undertaken at an operational level. Changes may be required in the minimum standards for consultation, for example.

- **Establish clear quality standards for data, its collection, and use**, most notably for scientific evidence supporting public risk management decisions. (The use of information provided by the Commission's SINAPSE programme should be limited, for instance, to data or studies that meet widely-accepted standards of scientific quality. Moreover, the potential limitations of poor quality studies, potentially made available through this process, should be highlighted in the guidelines);

- **Introduce additional mandatory standards for consultation with stakeholders during the IA process.** These should require greater use of consultation at the beginning of the policy-making process, so as to help identify proposals with "far reaching impacts" and to help inform the application of the concept of proportionate analysis;

- **Set out a transparent process that policy-makers should use to determine whether or not proposed policy actions are likely to include the "most far-reaching impacts".** The process should involve mandatory consultation with stakeholders, include the use of including appropriate qualitative and quantitative thresholds, and should be overseen by the IAB;

- **Require Commission officials to undertake, in certain circumstances, an assessment of the costs, benefits, strengths, and weaknesses of a wider range of policy options.** This may be required if, for instance, it is anticipated that the Council or EP may seek to make further substantial amendments to legislative proposals.

3.3.2. PROBLEM DEFINITION

- **Strengthen the requirements to establish clearly the additional costs and benefits of new, EU-level rules.** This should form part of the 'baseline' analysis. It should assess fully the coverage, strengths, and inadequacies of existing EU and national rules. Improvements in the enforcement of existing rules should also be considered, as part of the 'baseline' review.

- **Improve the description of the questions listed under the "problem definition" section of the typical roadmap form set out in the main guidelines.** The questions listed are, in parts, vague, and could usefully be replaced by some of those set out in the relevant supporting appendices.

3.3.3. ASSESSMENT OF IMPACTS

- **Highlight the need for policy-makers to identify the potential responses of businesses, citizens and other affected parties to proposed policy actions.** More use should be made of "impact-response" models, for instance. These emphasise the need for policy-makers to understand changes in behaviour (intended and unintended) triggered by government interventions, leading to a more informed and rigorous analysis of costs and benefits. At present, many analyses of costs and benefits are restricted to assessments of projected compliance costs.

- **Require officials to place greater emphasis on understanding more of the complex impacts of modern regulatory actions on businesses and citizens.** Such impacts

PROBLEM DEFINITION

- **Require all legislative and regulatory proposals designed to manage lifestyle or technological risks to human health, public safety, or the environment to be accompanied by the findings of formal scientific risk assessment**, designed to support analyses of problem definition and regulatory options.

- **Recognise the characteristics of different types of threats (including lifestyle and technological risks)**, define them on the basis of scientific knowledge, and take account of this in assessing problems, identifying risk management options, and assessing the costs and benefits of policy action;

- **Base all scientific risk assessments on the best available scientific and technical information**, and ensure that conclusions about a problem's potential risks to human health, public safety, and the environment assessments take full account of the weight of scientific evidence. Assessments should, moreover, distinguish clearly between 'hazard' and 'risk', identify realistic exposures to hazards; and highlight scientific uncertainties (using well-established typologies of different types of uncertainty);

- **Require risk assessments to be subject to peer review** if they are to be used to support major legislative or regulatory decisions;

OBJECTIVES

- **Require objectives for new or revised EU-level risk management rules to recognise the importance of risk-taking** for economic prosperity and long-term improvements in the quality of life; and, to accept that zero risk is neither achievable nor desirable in modern societies and that legislation cannot achieve this;

POLICY OPTIONS

- **Highlight precaution as one of a number of legitimate and distinctive approaches to risk management decision-making but recognise its weaknesses** and require its use to be cost-effective, based on scientific evidence, proportionate, limited in scope, non-discriminatory, consistent with international agreements, and provisional. The guidelines should, for instance, highlight the limited and specific circumstances in which the precautionary principle should be considered as a potential option for managing risks at EU-level;

ASSESSMENT OF IMPACTS

- **Require officials to make extensive use of quantitative analyses when assessing the costs and benefits of different risk management options.** These should include, wherever appropriate, monetary analyses and the use of modern cost effectiveness analyses. Assessments of potential benefits and costs should, moreover, recognise potential unintended negative consequences, and the loss of existing benefits, of specific policy options.