
# EUROPEAN RISK FORUM – COMMUNICATION 03

## SECRETARIAT-GENERAL CONSULTATION – DRAFT COMMISSION IMPACT ASSESSMENT GUIDELINES

**July 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 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, costs, 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.

# 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

[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

[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.

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.

However, the most important changes have been introduced by the European Commission, the EU institution responsible for initiating new secondary rules and for implementing existing laws, in the period since 2002. In that year, the Commission introduced an integrated impact assessment system (IA), covering economic, social, and environmental factors, and supported by detailed technical guidelines. These changes form part of wider series of initiatives designed to both improve governance and instil a "new regulatory culture" at EU-level.

IA requirements and processes were up-graded further in 2005 and 2006, reflecting lessons learned from the operation of the new system. The revised requirements for the Commission set out the following approach:

- IA is embedded within a formal six-step framework for policy-making (problem identification; definition of objectives; development of options; analysis of impacts of options; comparison of options; and ideas for monitoring and evaluation);

- IAs are mandatory for all new proposals for secondary legislation and for some other major policy initiatives, and they are based on the principles of "proportionate analysis";

- Mandatory procedural rules for the policy-making process are established, including cross-sectoral consultation within the Commission and final publication of the IAs;

- Extensive policy guidelines support the process and structure procedural requirements. These encourage officials to understand and identify indirect impacts of proposed rules; to make use of outside expertise; to consult with external stakeholders and to review alternatives rigorously. A small number of key technical assumptions are also included in the guidelines, along with ideas about possible quantification techniques for costs and benefits, including on administrative burden;

- The quality of IAs is overseen by an Impact Assessment Board (IAB) in combination with other internal scrutiny mechanisms. Set up in 2006, this small group of high-level officials examines draft assessments and issues opinions. It reports to the President of the Commission and works through informal, collegial processes rather than using formal powers, such as "letters of return".

In contrast to the initiatives taken by the Commission, progress within the other EU institutions involved in decision-making, the European Parliament and Council, has been limited.

Since 2002, the Commission has made substantial progress in establishing one of the largest and most comprehensive IA programmes in the world. By the end of 2007, for instance, it had carried out more than 250 assessments over a four-year period. Moreover, many of its initiatives have been highly innovative, notably the establishment of a central oversight body (IAB) within the collegiate culture of the Commission.

## 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;

- **Risk management** – the draft guidance recognises formally the public management of risks as an important area of policy action at EU-level. This a new requirement;

- **Alternatives to traditional regulation** – the new guidelines encourage greater focus on alternatives to traditional forms of regulation. This is of particular relevance to policy actions designed to manage risks to human health, public safety or the environment posed by lifestyle choices, new technologies, and climate change;

- **Measurement of impacts** – the proposed guidelines emphasise the value of providing decision-makers with quantified and monetised estimates of the costs and benefits of policy options, where this is appropriate. In certain circumstances, the guidelines suggest that it may, moreover, be appropriate to monetise the benefits of policy interventions by providing values for mortality and morbidity reductions, including using tools such as the "value of a statistical life". This represents a major change from earlier versions of the IA guidelines. It is an important improvement in the guidelines and provides the basis for modern assessments of the cost effectiveness of policy actions designed to improve human health or public safety.

- **Ex post evaluation** – compared to earlier versions, the new guidelines place greater emphasis on the importance of effective ex post evaluation of the outcomes of regulatory and legislative decisions. This reinforces recent initiatives taken by other parts of the Commission to strengthen the "evaluation culture" at EU-level;

### 3.3. Further Improvements – Specific Comments

The new guidelines are to be welcomed. Despite these improvements, more needs to be done if the EU's institutions are to maximise the effectiveness of the new IA process. This could include possible improvements to the draft IA guidelines in the following areas:

- General Requirements (see paragraph 3.3.1.);
- Problem Definition (3.3.2.);

- Assessment of Impacts (3.3.3.);
- Comparison of Options (3.3.4.)

### 3.3.1. GENERAL REQUIREMENTS

- **Ensure that all guidelines, used to support the Commission's IA process, are available for expert review and public scrutiny.** Whilst the draft guidelines made available for public consultation constitute a rich body of information for officials, other, technical, tailored guidelines are posted on the Commission intranet only. This additional guidance should be subject to external review and public consultation.

- **Revise the scope of application of the IA process by encompassing major technical regulatory decisions**, while limiting the numbers of IAs done on non-legislative initiatives. Technical regulatory decisions subject to IA should include guidelines drawn up by EU agencies; major decisions by EU agencies that embed risk management assumptions; comitology decisions that affect multiple products, substances, or processes, and comitology decisions subject to detailed and regular scrutiny by the EP.

- **Develop additional structured guidance so that the IA process can be applied effectively and rigorously to technical implementation decisions, including 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 include problems of demand stigmatisation, barriers to dissemination of new "general purpose technologies", and the impact on innovation of regulatory options that increase the time, cost, or risk of developing new ideas.

- **Strengthen the requirements for officials to assess the potential benefits of regulatory options rigorously and comprehensively.** Benefits should be expressed quantitatively, wherever this is possible.

- **Expand the explanation of the problem of "unintended consequences" of policy options that is included within the draft guidelines.** As currently set out, the examples of unintended outcomes are limited and incomplete. A more extensive list of examples, supported by a more complete text, may help officials to become more aware of this important issue.

#### 3.3.4. COMPARISON OF OPTIONS

- **Require officials to assess the 'workability' and 'legitimacy' of policy options, as well as their effectiveness and efficiency.** Analyses of 'legitimacy' should consider, for instance, the acceptability of proposed actions to citizens (including highlighting clashes with deeply-held values or attitudes), and the potential for policy choices to increase criminalisation or criminality. Reviews of 'workability' should assess the potential for poorly designed proposals to increase the need "administrative discretion" by officials, for instance.

### 3.4. Further Improvements – Risk Assessment and Management

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Today, it is most readily associated with government actions to protect people at work and to protect citizens and the environment from harm. But as a core function of government, risk management has been a potent and pervasive form of public policy for more than 200 years. In that period it has been used to support a range of varied policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment; protecting industrial workers from the impacts of economic activity; and protecting citizens and the environment from ruinous risks.

Public risk management can be broadly defined as any government action designed to prevent, reduce, or re-allocate risk. It includes actions to manage risks posed by technologies, economic activity, and lifestyle choices.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their risk management responsibilities. These now encompass issues such as product safety, food safety, pharmaceuticals, chemicals, environmental protection, public health, occupational health and safety, and consumer protection.

For the first time, the Commission's IA guidelines recognise public risk management as an important 'horizontal' theme of EU-level policy-making. Whilst this is a welcome improvement, the draft guidelines in this area are incomplete and place too much emphasis on the concept of precaution as a basis for making risk management decisions. If these weaknesses are to be rectified, then further changes to the guidelines are needed.

Specifically, the following improvements could be made to the Commission's draft IA guidelines:

**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.

**COMPARISON OF OPTIONS**

- **Recognise that risk management decisions can, under certain circumstances, create negative unintended consequences**, and require risk managers to take this into account when assessing options (the "risk-risk" problem);

- **Examine the 'workability', 'effectiveness' and 'legitimacy' of new risk management tools and mechanisms, including substance-based substitution, precaution, and direct restrictions on lifestyle activities.** The guidelines should include, for instance, a comprehensive description of the problems associated with using the Precautionary Principle to manage risks.

- **Consider issues of social acceptance of risk openly and rigorously during the process of comparing different risk management options**, using scientific evidence to distinguish between threats of harm and perceptions of risk. Guidelines should require officials to provide an assessment of likely risk acceptance and to highlight relevant evidence used to support such analyses;

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**This communication was written by Dirk Hudig, Chairman of the European Risk Forum, and Richard Meads, the European Risk Forum's rapporteur. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or of its members.**