EUROPEAN RISK FORUM – POLICY NOTE 01

REGULATORY IMPACT ANALYSIS (RIA)

2007

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

Regulatory Impact Analysis (RIA) is one of the most widely-used processes for improving the quality of regulatory decisions. 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 regulations. RIA forms an essential part of a modern, transparent, accountable, and empirically-based regulatory system.

The EU's institutions have taken a series of steps to improve the quality of regulatory decision-making over the last 20 years. 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. IA requirements and processes were up-graded further in 2005 and 2006, reflecting lessons learned from the operation of the new system.

Despite these advances, more needs to be done, if the EU's institutions are to maximise the effectiveness of the new impact assessment process. Specifically:

- Revise the scope of application of the IA process by encompassing major technical regulatory decisions, such as comitology and guidelines;
- Establish clear quality standards for data, its collection, and use;
- Make the IA process legally binding;
- Persuade the European Parliament and Council to agree to have IAs carried out on all "substantive amendments" after the First Reading of legislative proposals;
- Recognise that new regulatory tools for managing risks (especially precaution) may create substantial negative unintended consequences;
- Make greater use of modern "cost effectiveness" tools to assess options for managing risks;
- Revise mandatory procedural requirements to ensure that IAs are carried out at the beginning of the policy-making process;
- Develop additional and specific guidelines for risk management decisions.

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1. DEFINITION AND BENEFITS

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.

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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;

[1] Within this briefing paper, 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

[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.

2. SUCCESS FACTORS

Since the mid-1990s, the use of RIA by governments in the EU and in other parts of the OECD area has increased vastly in scale and scope. Using evidence gained from this experience, and accepting that the precise role and objectives of specific programmes may differ between countries, it is possible to identify the "success factors" for effective use of RIA. Specifically:

- The requirement for RIA to be carried out should be legally-based, supported by high-level political commitment, and embedded in a wider regulatory policy framework designed to improve regulatory decision-making;

- RIA should be carried out widely, covering primary law-making and technical, implementation decisions, although its use should be restricted to decisions that have significant negative or positive impacts;

- A well-resourced central unit, established close to the centre of government, should oversee the RIA process, establish common methodologies (including technical assumptions), define data quality standards, provide expert support, and enforce compliance;

- RIA should form part of an overall decision-making framework, and commence at the beginning of the process, rather than being added-on at the end;

- Process standards, methodologies, data quality standards, and technical assumptions should be set out in detailed, mandatory guidelines;

- Additional mandatory guidelines should support decision-makers focused on specific areas of government activity, most notably public risk management;

- Analyses should be complete and of high quality, covering the "need" for government action, alternative regulatory strategies, complex costs, benefits, and unintended consequences (most notably "risk-risk"[3]);

- Consultation with stakeholders and citizens should take place regularly throughout the RIA process, commencing at the earliest possible opportunity;

[3] "Risk-risk" is a term used to describe some of the unintended consequences of government action, especially decisions about the best way to manage real or perceived risks to human health, public safety, and the environment. Typically, a "risk-risk" situation occurs when government actions taken to manage one risk (often a perceived risk or a hazard) create additional or new substantive risks elsewhere.

3. 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.

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.

4. RECOMMENDATIONS

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 will have 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. This is to be welcomed.

Despite these advances, more needs to be done, if the EU's institutions are to maximise the effectiveness of the new impact assessment process. This could include a number of possible improvements:

- **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.

- **Establish clear quality standards for data, its collection, and use**, most notably for scientific evidence supporting public risk management decisions;

- **Make the IA process, and supporting procedural requirements and technical guidance, legally binding**;

- **Persuade the European Parliament and Council to agree to have IAs carried out on all "substantive amendments" after the First Reading of legislative proposals**, basing the requirement on objective, measurable, and transparent criteria. ;

- **Recognise within the policy-making process that new regulatory tools for managing risks (especially precaution and substance-level substitution) may create substantial negative unintended consequences**, if used inappropriately and without considering factors such as workability, effectiveness, and legitimacy;

- **Make greater use of modern "cost effectiveness" tools** (such as cost per life saved) to assess options for managing risks;

- **Revise mandatory procedural requirements to ensure that IAs are carried out at the beginning of the policy-making process**, before proposals are drafted and prior to the assessment of options;

- **Require officials to review complex regulatory impacts rigorously**, including evidence of benefits; the likelihood of "risk-risk" and other unintended consequences; and the creation, through regulatory decisions, of indirect costs, such as demand stigmatisation;

- **Develop additional and specific guidelines for risk management decisions**. These should require the definition of the problem to be based on a rigorous scientific risk assessment; distinguish between "hazard" and "risk"; highlight scientific uncertainties; provide a characterisation of the risk to be managed; highlight the need to consider "risk-risk" and other unintended consequences; and, ensure that risk assessment and risk management outcomes are kept separate;

- **Speed up the process of strengthening the powers and increasing the resources of the IAB**, such that it adopts formal powers of veto over inadequate IAs, including "letters of return", and becomes responsible for developing revised procedural requirements, process standards and technical guidelines.

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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.

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