



## **EUROPEAN RISK FORUM – POLICY NOTE 19**

### **EUROPEAN COURT OF AUDITORS - AUDIT OF IMPACT ASSESSMENTS IN THE EU INSTITUTIONS**

**2011**

## 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 practitioners 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.

## EXECUTIVE SUMMARY

Regulatory Impact Analysis (RIA) is one of the most widely-used processes for improving the quality of regulatory decisions. 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.

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. These changes form part of wider series of initiatives designed to both improve governance and instil a "new regulatory culture" at EU-level. Indeed, the Commission has made substantial progress in establishing one of the largest and most comprehensive impact assessment (IA) programmes in the world.

The European Court of Auditors identified in late 2007 the EU's 'Better Regulation' programme and impact assessments as a relevant audit subject. Specifically, the audit focused on "Impact Assessments in the EU institutions: Do they support decision-making?" At its meeting of 19 May 2010, the Court of Auditors adopted the final report.

The audit provides an extensive analysis of some of the most important strengths and weaknesses of the Commission's impact assessment system. Based on these findings and other research carried out by The European Risk Forum, it is possible to identify a series of reforms that, if implemented together, could contribute significantly to improvements in the quality, utility, and effectiveness of impact assessment at EU-level. Reforms include:

- Require the Court of Auditors to audit the IA system every three years;
- Establish data quality standards for the use of scientific evidence in IAs;
- Revise the Commission's technical guidance for assessing the costs and benefits of risk management decisions;
- Develop new technical guidance for the assessment of complex regulatory costs;
- Amend existing technical guidance to ensure a more rigorous review of the benefits of government intervention;
- Consult widely on all draft IAs;
- Develop and adopt binding rules of procedure requiring the Council and EP to use IA to examine all substantive amendments to Commission proposals;
- Establish an independent capacity to review annually the quality of IAs produced and compliance with agreed processes.

## 1. BACKGROUND

### 1.1. Regulatory Impact Analysis

Throughout the OECD area, Regulatory Impact Analysis (RIA) is one of the most widely-used processes for improving the quality of regulatory decisions<sup>1</sup>. 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<sup>2</sup>, and unintended consequences;
- Promote regulatory strategies that maximise net benefits of government action;

### 1.2. EU Institutions and Impact Assessment

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<sup>1</sup> 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’.

<sup>2</sup> 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. Indeed, the Commission has made substantial progress in establishing one of the largest and most comprehensive IA programmes in the world.

IA requirements and processes were up-graded further in 2005, 2006 and 2009, 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 items included in the Commission's Legislative and Work Programme and for some other major policy initiatives (notably the ones related to the implementing powers of the institutions), and they are based on the principles of "proportionate analysis";
- Mandatory procedural rules for the policy-making process are established, including the production of early-stage "roadmaps", 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<sup>3</sup>.

### 1.3. European Court of Auditors Report

The European Court of Auditors identified in late 2007 the EU's 'Better Regulation' programme and impact assessments as a relevant audit subject. Specifically, the audit focused on "Impact Assessments in the EU institutions: Do they support decision-making?"

Initial studies were carried out in mid-2008 which determined the precise scope of the audit. The audit fieldwork was carried in between October 2008 and July 2009. At its meeting of 19 May 2010, the Court of Auditors adopted the final report.

## 2. AUDIT METHODOLOGY

The audit comprised five strands of work:

- A comparison of the Commission's IA system with systems elsewhere on the basis of publicly available documentation, academic literature, comparative studies, and a programme of country visits;
- A quantitative analysis of the extent to which Commission initiatives in the period up to the end of 2008 had been subject to IA, and the extent to which the European Parliament and Council used the Commission's IAs. A range of sources were used including a database of almost 5,000 Commission initiatives and publicly available documentation of the EP and Council;
- A 'scorecard' analysis of all IA reports produced by five Commission directorates (Energy and Transport; Regional Policy; Employment, Social Affairs, and Equal Opportunities; Research; and Information Society and Media) between 2003 and 2008 to verify whether the Commission had carried out its assessments in accordance with its own internal procedures and methodological guidance. This corresponds to 115 reports, or nearly 25% of all reports produced by the Commission between 2003 and 2008;
- Depth interviews with more than 190 people involved in performing, reviewing, and using the Commission's IAs both within and outside the Commission; and,
- Two surveys among members of Council working parties and attendees at a Directors and Experts of Better Regulation meeting.

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<sup>3</sup> Whilst Parliament and the Council have, to date, made limited use of IAs, some procedural improvements have been made. These include 'Inter-institutional Agreement on a Common Approach to IA, (2005), EP Conference of Committee Chairmen 'IA Handbook' (2008), and Council of the EU General Secretariat 'Handling IAs in Council – indicative guidance for working party chairs' (2007)

### 3. AUDIT FINDINGS

#### 3.1. Key Strengths

The audit identified a number of strengths of the EU's impact assessment system. These include:

- Since 2003, there has been a significant increase in the number of IAs carried out by the European Commission. Indeed, IA has become an established dimension of the process of policy development at EU-level.
- Progressive improvements have been made in the functioning and effectiveness of the IA system since its introduction in 2003. The most important changes have been the steady improvement in the quality of technical guidance and the establishment of the Impact Assessment Board as a central oversight institution.
- In recent years, many IA reports have become broader in terms of the number of alternative policy options analysed. This enhances their potential utility for policy formulation.
- IA reports provide a valuable source of information for the College of Commissioners, and are actively used in decision-making.
- Users of IA reports in the European Parliament and Council believe that they have had a positive effect on the quality of EU law-making.
- Interest groups, including business organisations, NGOs, and other stakeholders, take IA reports into account when they debate policy development with decision-makers.
- The establishment of the IAB, as an internal quality review body, has put pressure on directorates to produce high quality reports and, because IAB opinions are published, transparency of the system has also been improved.

#### 3.2. Key Failings

Alongside these important strengths, the auditors identified a number of major failings of the EU's impact assessment process, including:

- When making decisions about targeting IA reports, the Commission does not use quantifiable indicators to establish thresholds above which IAs need to be carried out;
- Too many IAs fail to provide a clear illustration of the “intervention logic” underlying the intervention. In other words, they fail to demonstrate clearly how the objectives and expected outcomes of the proposed intervention can be achieved with the intended delivery mechanism;
- The analysis and presentation of impacts can be improved: more needs to be done, for instance, to ensure that all impacts are quantified and monetised where

possible and appropriate. Alongside this, comparisons between alternative options are difficult to make because of insufficient quantification of impacts, and an asymmetry in the depth of analysis between different options;

- A lack of availability of data limits the extent to which impacts can be quantified and monetised;
- Across a wide range of IA reports insufficient attention is paid to assessing the potential costs, difficulties, and unintended consequences of policy implementation;
- Ex post evaluation of legislative initiatives and regulatory decisions is not carried out systematically;
- The IAB lacks the mandate to require directorates to undertake and IA;
- Draft IA reports are not subject to public scrutiny; and,
- Amendments to initial CEC proposals made by the Council or EP are not subject to additional assessments of potential impacts, highlighting one of the weaknesses of the existing inter-institutional agreements

### **3.3. Improvements**

To remedy these failings, the Court of Auditors identified a series of improvements. These include:

- The Commission should provide a reasoned justification when an IA is not performed;
- The draft version of an IA should be published for information and comment by the Commission;
- The Commission should make sure that the IAB's review of the quality of an IA report always takes place on a timely basis;
- Quantification and monetisation of impacts should be improved by the Commission, facilitating a better understanding of alternative options and of the overall consequences of an intervention for the EU;
- A strategy needs to be developed by the Commission for improving data quality;
- IA reports drawn up by Commission officials need to place more emphasis on understanding the implementation phase of policy-making;
- The Commission should undertake systematic ex post evaluation of legislative and regulatory initiatives; and,



- The EP and Council need to revise the inter-institutional agreements on Better Regulation and on IA, taking account of the findings of the report by the Court of Auditor.

#### 4. CONCLUSIONS

The report by the Court of Auditors, if its findings are implemented fully, should help improve the functioning, utility, and effectiveness of the Commission's IA system. It highlights significant achievements, whilst at the same time identifying major failings. A number of areas for improvement, including specific recommendations, are set out in the report. These need to be adopted by the EU's institutions.

Indeed, the audit demonstrates the value of establishing an additional, independent oversight mechanism within the institutional architecture of the EU's IA process. In the light of this, the Court of Auditors should carry out a major, general audit of the EU's IA system, on regular basis, probably every two or three years. Additional oversight, complementing the role of the IAB, strengthens the accountability and legitimacy of the process.

The report does, however, have weaknesses. First, because of the audit mandate, it fails to include within its scope legislative and policy initiatives taken by DG SANCO, DG Enterprise and DG Environment: the most important directorates for risk management, one of the most important roles of the EU institutions. A second problem is the coverage of the recommendations. No actions are identified to strengthen the mandate of the IAB or to improve the "intervention logic" in IA reports or to ensure that substantive amendments to initial Commission proposals by the EP and Council are subject to impact assessment. All of these weaknesses were identified by the auditors, and all limit significantly the effectiveness of the IA process. The value of the report would have been strengthened if specific improvements had been targeted at these major problems.

Future audits of the IA system by the Court of Auditors should build on the excellent work described in the 2010 report. Alongside this, the auditors should also examine:

- The value of establishing legally-binding requirements, ensuring that IAs are carried out for all significant legislative and regulatory interventions;
- The use and effectiveness of impact assessments during the process of making implementing decisions, including technical and other regulatory decisions;
- The use of science in legislative and regulatory decision-making, including the use of risk assessments to justify risk management decisions, peer review of risk assessments, and the adequacy of standards for scientific evidence;
- The nature and adequacy of technical guidance for the impact assessment of interventions that aim to manage technological or lifestyle risks to human health, public safety, or the environment; and
- The nature and sufficiency of analysis by officials of complex regulatory impacts, such as the impact of technical decisions on demand or margins (through the

operation of stigmatisation mechanisms) or the impact of regulatory requirements of the cost or time of innovation, when undertaking impact assessments.

## 5. RECOMMENDATIONS

The audit provides an extensive analysis of some of the most important strengths and weaknesses of the Commission's impact assessment system. Based on these findings and other research carried out by The European Risk Forum, it is possible to identify a series of reforms that, if implemented together, could contribute significantly to improvements in the quality, utility, and effectiveness of impact assessment at EU-level. Reforms include:

- **Require the Court of Auditors to audit the IA system as a whole every three years**, improving the methodology to examine risk management policies and expanding the issues examined;
- **Establish data quality standards for the use of scientific evidence in IAs**, requiring studies, information, and data to be based on widely-accepted sound and objective scientific practices ("the scientific method") including peer reviewed science;
- **Revise the Commission's technical guidance for assessing the costs and benefits of risk management decisions**, stressing the importance of risk acceptance, basing intervention on the findings of a peer reviewed risk assessment, highlighting the difference between hazard and risk, and recognising the limitations of different regulatory options;
- **Develop new technical guidance for the assessment of complex regulatory costs**, helping officials understand the impact of technical regulatory decisions, as well as secondary legislation, on innovation processes, the diffusion of new technologies, and levels of sales and margins;
- **Amend existing technical guidance to ensure a more rigorous review of the benefits of government intervention**, highlighting the overall value of policy actions ensuring that complex benefits are understood (such as benefit-risk trade-offs), and improving legitimacy;
- **Publish and consult widely on all draft IAs**, requiring processes to meet the Commission's established process standards for consultation;
- **Develop and adopt binding rules of procedure requiring the Council and EP to us IA to examine all substantive amendments to Commission proposals**, ensuring that legislators understand fully the benefits and costs of legislative proposals;
- **Establish an independent capacity to review annually the quality of IAs produced and compliance with agreed processes**, building on existing expertise in a Think Tank and strengthening transparency and accountability.

**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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