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REGULATORY IMPACT ANALYSIS: IMPROVING THE QUALITY OF EU REGULATORY ACTIVITY



FOREWORD

The Council of Ministers has declared that the European Union should be the most competitive, knowledge-based economy by 2010. It has, in addition, ambitious public health, social and environmental objectives. This requires a regulatory framework that, at one and the same time, supports the long-term competitiveness of European business, while facilitating the development of the European social model.

Regulatory Impact Analysis (RIA) can help legislators to achieve these, often-conflicting objectives and to reduce the democratic deficit between the European Union and its citizens.

This Occasional Paper identifies emerging trends and best practices in RIA systems in leading industrialised countries. It then compares and contrasts the status of RIA at the EU level with those best practices.

The paper finally makes recommendations for a new improved RIA system in the European Union, including a step-by-step Action Plan that focuses on the key

changes that the EU institutions must take, in the short term, to begin the implementation of the new process.

Considerable effort will be needed to implement the new process and to change the culture among policy-makers throughout all the European institutions; but I am sure that the effort will be worthwhile.

I am delighted that the Risk Forum of *The European Policy Centre* decided to undertake this work and that the European Commission provided financial support; and I commend the results to you.

Stanley Crossick
Chairman

The European Policy Centre

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However, responsibility for the final report (especially the errors and omissions) is mine alone.

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EXECUTIVE SUMMARY

Regulatory Impact Analysis (RIA) is an analytical and systematic approach to regulatory problems, encompassing a range of tools and techniques aimed at assessing the effects of regulation. It also provides a structured way of communicating results to decision-makers and to the public at large.

Modern RIA systems are a means to an end, not an end in themselves. They neither replace the political process, nor limit the basis of legislative decision-making to quantitative economic factors; but they can help legislators to reduce the risks of regulatory failure and the risks of unintended consequences following the introduction of new regulations.

While the focus of the legislative programme of the European Union was on the 'harmonisation' of the legislation that existed at Member State level, it could be argued that there was no need for a formal RIA process. National legislation had already been justified and "The Cecchini Report"¹ had provided an ex-ante impact analysis of the Single Market as a whole.

However, the case for a formalised RIA process at the level of the European Union has been strengthened in recent years as the EU has moved into new, cross cutting legislative areas. It has also launched a number of initiatives to improve the quality of legislation.

Moreover, the European Parliament has been given greater legislative powers and civil society has become more active in the legislative process.

The European Commission currently uses a number of Impact Assessment systems. These have, when used well, helped to improve regulatory quality. However, in most cases, they are ineffective in informing the process of legislative development, because many Directorates use the Impact Assessment systems as bureaucratic procedures rather than as decision-support tools, and because the existing processes fail to meet the standards set by global best practices. In particular, there is little consistency in the analyses undertaken by the different Directorates of the Commission, and there is little attempt to complete a systematic analysis of costs and benefits.

Moreover, each of the Impact Assessment systems is only a partial process. Each seeks to provide an assessment of the impact of proposed legislation on only one sector of the community. There are, in addition, few links between the various Impact Assessment systems, which have been developed over time to reflect the interests of individual stakeholder groups.

To overcome these weaknesses and establish an effective, integrated Regulatory Impact Assessment (RIA) process, fundamental reforms are needed. They must encompass all aspects of the Impact Assessment process and involve all of the principal Community-level institutions.

In the first place, the legal basis for RIA at the level of the European Union should be simplified and the new RIA process based on a Council Resolution along the following lines:

"All major regulatory initiatives should be accompanied, at all stages, by a statement of Regulatory Impact Analysis."

"All major regulations should be re-assessed, every five years, to ensure that the original policy objectives are being achieved in a proportionate and effective way."

The RIA process should be based on four guiding principles:

- It should be developed as a sub-set of the regulatory reform process, which should, in turn, be part of the wider review of governance.
- It should cover all elements of European society.
- It should be fully transparent.
- The analysis should be "high quality".

In the long term:

- There should be a single Regulatory Management Policy. This should commit all EU institutions to achieving common regulatory quality goals, to following agreed administrative procedures, and to undertaking RIAs in a systematic fashion.
- The Commission should, in principle, complete an RIA in respect of any legislative or regulatory activity by the Commission, the Council, and the European Parliament.
- RIA guidelines should describe the process and the methods as well as the principal roles and responsibilities of each of the EU institutions.
- Each RIA should include a detailed analysis of the 'need' for regulation, the alternatives examined and the overall impact of regulation.
- The guidelines should establish mandatory standards for consultation of citizens (including business and other elements of civil society) during the RIA process and for the communication of the results to all stakeholders, including the results of the consultation process.
- A Regulatory Assessment Office (RAO), established within the Secretary-General's Office in the European Commission, should establish quality standards and common analytical methodologies for the RIA process. It should also advise the Secretary-General on the quality of individual RIAs undertaken by Directorates.
- A Regulatory Audit Bureau (RAB), established within the Court of Auditors, should undertake a review of the implementation of the RIA guidelines, each year. The RAB should also undertake post-project audits of differences between 'actual' and 'predicted' impacts for a sample of the legislative proposals that include RIAs. It should present an Annual Report, to all the EU institutions, of the results of all the work done during the year.
- The European Parliament should provide the new RAO and the RAB with enough resources to enable them to perform their tasks effectively. The European Parliament should also ensure that individual Directorates-General have sufficient resources to enable them to prepare RIAs that meet the guidelines.

In addition, there are a small number of actions that, if implemented fully in the next 2-3 years, will move the process of change, irreversibly, towards achieving the ultimate vision:

- A common Regulatory Management Strategy for the European Community should be agreed by all Community-level institutions.
- The legal basis for the whole of the RIA process should be simplified: it should be based on a Council Decision.
- The RAO and the RAB should be established.
- The European Commission should introduce a new Consultation and Communication Process.
- Preliminary Guidelines for a new RIA process for the European Community should be established.

It is estimated that it will cost some €5-10 million per annum to implement the necessary actions in the short-term and €25-30 million per annum to achieve the long-term vision.



Regulatory Impact Analysis Improving the Quality of

1. INTRODUCTION

1.1. PROJECT BACKGROUND

Increasing government intervention in society has characterised all leading industrial countries in recent years. This trend reflects rising expectations amongst citizens about the role of governments in promoting wider social goals such as consumer protection, the environment and health and safety.

Regulations create many benefits for citizens and companies. They help to improve public health and safety, and they provide social and environmental benefits for citizens. They also provide legal certainty for consumers and companies in the process of buying and selling products and services. However, there is growing evidence that they also have negative effectsⁱⁱ.

There are few definitive estimates of the scale of these negative effects, but studies indicate that they are significant and growing rapidly. Work in the USAⁱⁱⁱ, for example, concluded that the costs of regulations had grown to \$670 billion by the mid 1990s, which represented nearly 9% of US GDP. Another US report indicates that the cost of social regulations has doubled in the last ten years^{iv}. At company level, recent work by the OECD^v suggests that administrative compliance costs alone average 4% of turnover for SMEs.

Whilst the costs of regulation are felt most directly by companies, regulations can, in the long term, also create costs for society at large. They do this because, in many cases, they reduce freedom of consumer choice, and increase costs to consumers. They also undermine the competitiveness of companies (by reducing entrepreneurship and innovation and increasing costs), restrict economic growth, and inhibit the creation of jobs^{vi}. Moreover, there is evidence that, in some cases, regulations fail to achieve their goals and that, in other cases, significant unintended, negative consequences arise from regulatory activity by substituting one adverse effect with another (the "risk/risk paradox")^{vii}.

In response, governments in many countries are increasingly initiating regulatory reform programmes^{viii}. Initially conceived as 'de-regulation' programmes, many countries have now developed more sophisticated programmes that seek to improve regulatory quality, i.e. to enhance regulatory effectiveness whilst reducing regulatory costs. In practice, this means that

governments increasingly seek to ensure that the costs of each regulation are justified by its benefits, and that the particular form of regulation chosen yields the greatest possible excess of benefits over costs^{ix}.

To achieve this, many governments are developing new processes, structures, and tools to help them to develop new regulations and to review and reform existing ones. Regulatory Impact Analysis (RIA) is one of the most widely used of these tools. It helps regulators to overtly and systematically analyse the impacts of a regulation, and to consider how best to maximise net social benefits. Used alongside other tools, such as law drafting standards, RIA can contribute significantly to the goal of improved regulatory quality^x.

Indeed, most leading industrialised countries now use some form of RIA as part of the overall process of making regulatory decisions. A recent survey of OECD governments, for example, shows that RIA is required for (all or some) new regulations in over three-quarters of the countries surveyed^{xi}.

However, the process of implementation remains embryonic in many countries. In part this reflects the practical difficulties of implementing modern RIA systems.

1.2. PROJECT OBJECTIVES

The principal aim of the project is to make recommendations for a new, improved RIA system at the level of the European Union, including a simple, step-by-step Action Plan that focuses on the key changes needed to implement the new approach.

The project has two additional objectives:

- To promote awareness amongst opinion-formers and policy-makers, in the European Union, of the importance of using modern RIA systems to improve the quality of government decision-making; and
- To encourage the adoption of RIA as an integral part of the regulatory process in the European Union.

The project also seeks to provide input to the debates on the administrative reform of the Commission and on the design of the regulatory system of the EU, as part of the wider debate on governance in the EU.

EU Regulatory Activity

2. REGULATORY IMPACT ANALYSIS

2.1. DEFINITION

Regulatory Impact Analysis (RIA) is an integrated decision support process used by governments, in many leading industrialised countries, to help improve the quality of regulation. It contributes to the creation of an open, transparent, and empirically based regulatory system. The OECD^{xii} describes it in the following terms:

"RIA encompasses a range of methods aimed at systematically assessing the negative and the positive impacts of proposed and existing regulation."

Too often, however, RIA is confused with specific analytical tools or mechanistic decision-making based on simplistic quantification. RIA is not the same as benefit-cost analysis nor is it a substitute for decision-making by policy-makers or elected officials.

RIA is a tool to ensure that decisions are better informed by clarifying the costs and the benefits; to make government processes more open, transparent, and accountable; and to avoid unnecessary costs - within a framework that recognises that there are no "risk free" options.

Conceptually, RIA is based on six pillars:

- **Justification** – the clear identification of a specific social, economic, or environmental problem and a convincing justification of the value and likely effectiveness of government intervention.
- **Consultation** – extensive and transparent consultation with all stakeholders to widen public debate about government intervention, to identify the costs and benefits of regulatory proposals and to minimise the risk of "regulatory capture".
- **Analysis** – a systematic, empirical analysis of costs, benefits, and alternatives that take account of the "real world" impacts of regulatory strategies on stakeholders, public health and safety, and the environment.
- **Maximising overall net benefits** – a focus on achieving regulatory solutions that maximise the overall net welfare of all citizens.
- **Consistency** – the use of common, standard, practical

operating procedures that ensure consistency of analysis throughout all parts of government.

- **Accountability** – clear, structured communication to decision-makers of the consequences of choosing specific regulatory goals or strategies.

2.2. BENEFITS

Recent studies^{xiii} have identified nine principal benefits from the use of RIA. RIA can help decision-makers to:

- **Identify alternatives to regulation:** The RIA process can help to identify situations in which the use of non-regulatory tools is a more appropriate course of action than traditional "command and control" regulation. It can also identify situations in which no action by government will yield the greatest benefit to society.
- **Understand the "true" costs and benefits of regulations:** The RIA process can help legislators and regulators to understand the full extent of the economic, environmental and social costs and benefits of regulations. It can help to identify "unexpected" consequences of regulations, including "risk/risk" paradoxes (where reductions in one risk lead to an increase in another).
- **Maximise the benefits of regulations:** The RIA process can help regulators to identify those specific interventions that produce real benefits and to structure regulations around the most effective solutions to produce results.
- **Avoid "Regulatory Failure":** RIA can help governments to avoid the introduction of regulations that fail to achieve their original objectives or that have negative impacts that significantly exceed the benefits.
- **Improve the design of regulations:** RIA can identify different regulatory design options where small changes in the design of a regulation can lead to significant differences in net benefits or to greater coherence between different policies. RIAs can also identify potential problems, which enable decision-makers to redesign or even abandon policy proposals.
- **Improve the consultation process:** RIA can help to achieve greater transparency in the consultation



process by actively engaging business, consumers and other stakeholders.

- **Increase the accountability of regulators:** RIA can help to make more explicit the basis on which decisions are taken, and the policy trade-offs involved. RIA can also make it easier for regulators to resist pressures from special interest groups, as it encourages public debate of the net benefits, and exposes the distribution of likely impacts amongst groups in society.
- **Achieve a culture shift within government:** RIA can help to introduce new ways of thinking in government founded on greater questioning of the need for government intervention; improved discussion of the alternatives to traditional regulation; greater consideration of the importance of regulatory design; improved awareness of the benefits of stakeholder consultation; greater awareness of the unintended costs and wider impacts arising from regulations; and improved awareness of the policy 'trade-offs' implicit in decision-making.
- **Reduce the democratic deficit:** RIA can help to reduce the democratic deficit and enhance the legitimacy of the institutions in the eyes of the public, by helping to increase transparency and improving the dialogue between the institutions and the citizens.

2.3. EMERGING TRENDS

The majority of developed countries are now committed to the use of RIA^{xiv} and most have sought, in recent years, to increase the scope of their RIA programmes and the rigour of their analytical requirements^{xv}. Specifically, there has been an increase in:

- The number of countries that *always* require an RIA to be carried out before new regulation is adopted.

- The requirement for quantification, particularly of the benefits of new regulation.
- The number of RIA programmes that explicitly require regulators to demonstrate that the benefits of new regulation justify the costs.
- The number of RIA programmes that require documents to be publicly released for consultation.

2.4. USING RIA – THE KEY ISSUES

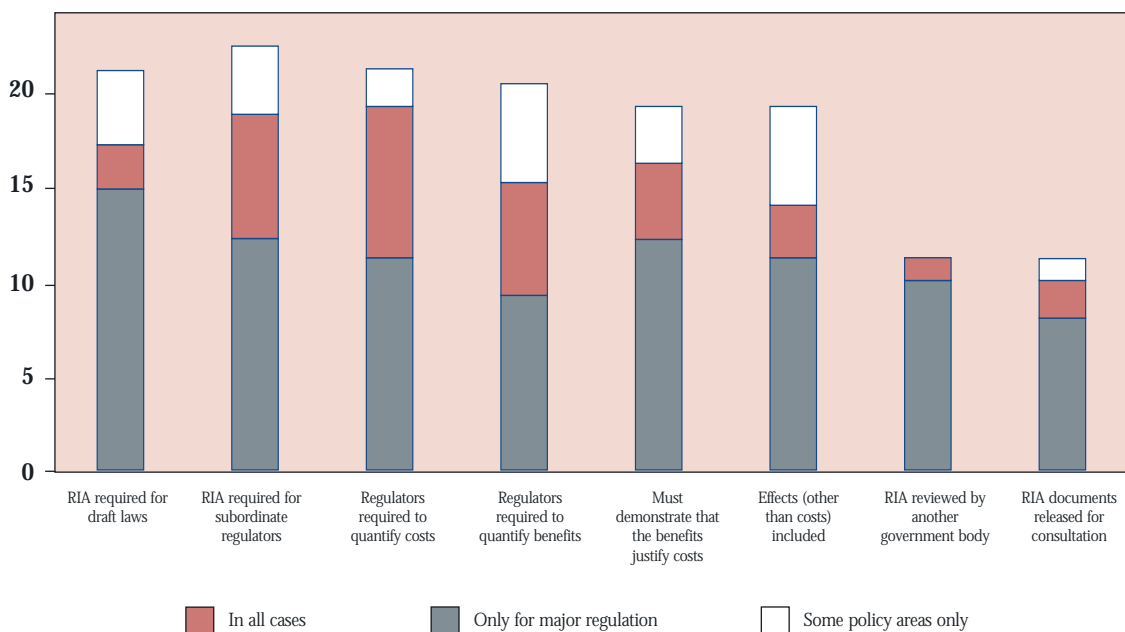
There are two main issues associated with the practical application of the RIA process. The first is **the design of RIA programmes**. The most effective RIA programmes:

- Impose a legal requirement on legislators and regulators to undertake an RIA (including an assessment of costs and benefits) on all major pieces of legislation and regulation.
- Invite all stakeholders to contribute data.
- Require another government department or an independent body to review the results of the RIA.
- Release RIA documents for consultation.

However^{xvi}, some countries do not require regulators to quantify costs or benefits, or to demonstrate that benefits justify the costs. In most countries, a separate government body does not review RIAs, and most governments do not release RIA documents for consultation. (Figure 1)

Another main issue concerns **the way in which RIAs are conducted in some countries**. The most effective RIAs are characterised by good quality and complete analysis (particularly with regard to consideration of the

Figure 1. Aspects of Regulatory Impact Analysis Policies in 24 OECD Countries



benefits and the indirect costs arising from regulation); the assessment of alternative options; full consultation; and the complete integration of RIA into the decision-making process^{xvii}.

However, recent work in the USA^{xviii} reveals that, even when the government sets out high standards for the conduct of RIAs, regulators often fail to comply with them. Evaluation of 48 recent RIAs conducted in the USA between mid 1996 and mid 1999 in the area of health, safety and environment concludes that typically they do not provide enough information to make decisions that will maximise efficiency or effectiveness. For example, less than a third quantified net benefits and only a third quantified the costs and benefits of alternative options.

There are many reasons why there are difficulties in programme design and implementation:

- **Technical Difficulties:** To ensure that the results of RIAs are generally accepted, the analysis should be rigorous.

However, there are many technical problems associated with RIA. Analytical methods are not well developed (e.g. the evaluation of the impact of regulations on innovation or on SMEs). There are disagreements about important technical issues (e.g. social discount rates), and there are often difficulties in evaluating costs and estimating benefits. There are difficulties in collecting appropriate data, and methodologies are complex. There are also difficulties in valuing "qualitative" factors, and, on occasions there are multiple and inconsistent policy objectives.

- **Legal Issues:** To ensure that the RIAs are used effectively, there should be a secure legal basis.

There are, however, legal difficulties in some countries. For example, legislation may limit the options open to regulators.

- **Consultation and Communication:** For RIA to be effective, stakeholders must be involved in data gathering and analysis. Moreover, the results of the RIA must be communicated to decision-makers in a timely and understandable manner.

There are, in some cases, problems in ensuring that new consultation and communication processes are established when new RIA requirements are put in place.

- **Time Requirements:** Good RIAs require policy-makers to allocate time in the decision-making process to gathering data, undertaking analyses, and discussing analytical outcomes with stakeholders.

Many regulators consider that Regulatory Impact Analysis delays decision-making and inhibits the ability of policy-makers to respond to urgent problems or the demands of citizens.

- **Skills and Resources:** Good quality RIAs require adequate skills and resources.

Many regulators find it difficult to carry out high quality RIAs because they do not have the skills or because they lack resources.

- **Cultural Resistance:** An effective RIA system requires extensive institutional and cultural change within government^{xix}.

This is difficult to achieve, particularly as there is often significant opposition from important groups of stakeholders. Regulators sometimes resist such changes because they undermine their status as 'expert' decision-makers and reduce their ability to formulate public policy independently. Politicians are sometimes resistant because RIA appears to reduce the scope for 'single issue' actions. They also fear that analytical requirements will slow down the decision-making process and lead to 'policy paralysis'. Special interest groups who benefit from other, less empirical, decision-making processes also tend to resist the changes necessary to implement an effective RIA system.

2.5. CRITICAL SUCCESS FACTORS

In spite of these difficulties, the benefits of using Regulatory Impact Analysis are considerable, and we have been able to identify a number of Critical Success Factors ("Best Practices"), which under-pin effective RIA processes in different countries^{xx}.

Regulatory Management Policies and Processes

- a. Effective RIA processes form an integral part of wider regulatory reform programmes, designed to improve regulatory quality, including law drafting standards and the assessment of alternatives to regulation^{xxi}.
- b. Clear, mandatory guidelines for developing high quality regulation are developed, including a requirement that RIAs should be conducted as early as possible in the process of developing regulation^{xxii}.

The Overall RIA Programme

- c. There is a political commitment to RIA from the highest levels within government.
- d. The requirement to carry out RIA has legislative backing.
- e. Effective systems ensure that RIAs are applied, selectively and progressively, to:
 - Existing as well as new regulations;
 - Independent regulatory agencies as well as traditional ministries;
 - Secondary as well as primary legislation; and
 - All levels of government (supra-national, national, regional and local).



Roles and Responsibilities

- f. Regulators are responsible for carrying out RIAs^{xxiii}.
- g. A Central Unit is established, close to the centre of government, with strong powers to ensure control quality and compliance. This Unit also produces guidelines and provides expert resources, support and advice to regulators^{xxiv}.
- h. There is ministerial accountability for compliance with RIA requirements, and for the quality of RIAs produced.

Resources

- i. Regulators are given the financial resources and the physical capacity to carry out high quality RIAs.
- j. Regulators are given training in how to carry out high quality RIAs, how to make use of the results, how to involve the public and affected parties effectively, and how to communicate the outcomes.

Analytical Methodologies^{xxv}

- k. Mandatory guidelines are issued to ensure consistency in analytical methodologies. These include a common list of technical assumptions to be used in all RIAs, irrespective of which organisation is carrying them out^{xxvi}.
- l. Analytical methodologies permit flexibility but ensure that all significant positive and negative effects are taken into account. These include effects on stakeholders, such as effects on public health and safety, and on the environment. They also include estimates of administrative compliance costs (for all stakeholders), the wider impacts on business (e.g. on innovation and on productivity), and the distributional effects (e.g. the impact on specific groups).
- m. The principle of benefit-cost analysis is established. This ensures that the net benefits to society of any particular regulation or regulatory proposal are overtly examined, taking into account both quantitative and qualitative evidence^{xxvii}.
- n. Scientifically based Risk Assessments are undertaken to establish a clear justification for any regulatory activity that seeks to manage technological risks to human health, safety or the environment.
- o. There are clear data collection strategies that specify standards of acceptability and suggest methods of collecting high quality data within time and cost constraints^{xxiii}.

Implementation

- p. RIAs are only carried out where the impacts of regulation are likely to be most significant. Clear and transparent "decision rules" are, however, established

to determine precisely when RIAs should be undertaken. The justification for not undertaking an RIA on any particular regulation is communicated widely, and subject to challenge if appropriate.

- q. Effective RIAs involve the public extensively through a formal, mandatory, multi-stage consultation process^{xxx}. This includes:
 - requests for information and comment prior to the start of an RIA;
 - the opportunity to comment on draft RIAs;
 - the publication of all submissions made during the consultation process and responses to them; and,
 - the publication of all final RIAs.
- r. There is widespread communication of the results of RIAs within government and to the stakeholders and the wider public.
- s. Ex-post analyses are undertaken on a sample of RIAs, to compare expected and actual impacts. Feedback loops are established to ensure that the results of these analyses are taken into account in future RIAs and in the design of future analytical methodologies.
- t. Independent analysts are encouraged to assess and review RIAs carried out by governments^{xxx}.
- u. The RIA process allows for challenges on the grounds that the process or the data is incomplete or defective.

No single country employs the complete range of best practices, but all countries that have effective RIA systems use those practices that help them to achieve their policy objectives within their own political, cultural and legal environments.

Hence, these best practices provide directional pointers to the policies that the European Union should adopt to achieve the necessary improvements in regulatory quality, through an effective Regulatory Impact Analysis system.

3. RIA AT EU LEVEL

3.1. IMPROVING REGULATORY QUALITY

Since the 1980s, there have been a number of initiatives to improve regulatory quality at EU level^{xxxix}. These include:

- New, less prescriptive forms of regulation, such as: the "New Approach" for establishing product safety standards; Framework Directives; and the use of "Home Country" supervision and Internal Market "passports" in key service sectors.
- Legal quality requirements through inter-institutional agreements on issues such as drafting quality, and codification/consolidation.
- Internal European Commission guidelines that seek to ensure that legislative texts are consistent and of proper quality.
- More structured and extensive consultation procedures, including greater use of White Papers, Green Papers and public hearings.
- The Business Impact Assessment (BIA) process for new legislation.
- The Molitor Report, which examined opportunities for regulatory simplification in six major areas.
- The Regulatory Policy Guidelines of 1996, issued by the President of the European Commission, which seek to ensure that all legislation proposed by Commission is subject to assessment.
- A declaration annexed to the Maastricht Treaty, in which the European Commission undertakes to take account, in its legislative proposals, of the costs and benefits to all parties concerned.
- A legally binding Protocol to the Amsterdam Treaty on the application by the European institutions of the principles of subsidiarity and proportionality to law-making. This includes a formal requirement for the Commission to "consult widely before proposing legislation and, where appropriate, publish consultation documents".
- The SLIM programme which seeks to simplify and improve existing regulations.
- The BEST programme which aims to improve the business environment, including the administrative and regulatory framework.
- Regulation 1049/2001 *Regarding Public Access to European Parliament, Council and Commission Directives*.

Work continues at EU level to improve regulatory quality:

- The European Council included a 'Better Regulation' resolution in its Lisbon Conclusions, in March 2000.
- The Member States set up a high-level body, the Mandelkern Group, at the end of 2000, to identify ways in which the regulatory quality of new and existing EU legislation might be improved. It submitted an Initial Report to the Stockholm summit in March 2001, and is due to submit a final report later this year.
- The European Commission presented an interim report to the Stockholm Council on improving and simplifying the regulatory environment, and it intends to present an action plan to the Laeken European Council.
- The White Paper on "European Governance" has also contributed to this debate.

3.2. THE POLICY AND LEGAL BASES

3.2.1. Regulatory Management Policy

The EU's Regulatory Management Policy is not set out in any clear or simple way. It has emerged over time and pursues a range of legal quality objectives alongside initiatives to improve the awareness of the impact of legislative proposals on wider policy goals.

Within the European Commission, these general ideas and commitments are pulled together in the Regulatory Policy Guidelines. Issued in 1996 by the President of the Commission these apply to all new legislative proposals. They aim to ensure that all legislative texts are consistent and of proper quality; that the drafting process is open, planned, and co-ordinated; and that monitoring and evaluation are thorough.

Responsibility for implementation, monitoring and development of these guidelines rests with the Secretary-General's office. Its tasks include: reviewing all proposals for new legislation to ensure that there is a legal basis for action and that the proposals satisfy the principles of subsidiarity and proportionality; maintaining the Regulatory Policy Guidelines; and drawing up the annual *'Better Lawmaking Report'* for the European Council.

The Legal Service also supports the regulatory management process. It provides advice on proposed legal instruments and checks the "legal quality" of draft legislation.

The importance of good drafting has been increasingly recognised by all parties to the law-making process in recent years culminating in the Inter-institutional Agreement between Parliament, Council, and



Commission on common guidelines for the quality of drafting of Community legislation.

3.2.2. The Legal Basis for Regulatory Impact Analysis

There have been many political statements, by Europe's leaders, in support of the need to undertake Impact Assessments as part of the legislative process. Despite this, there is no simple legal basis for undertaking RIAs at European Union level. Nor is there any legal requirement to undertake comprehensive RIAs.

- Some legal support for Regulatory Impact Analysis can, however, be found in Article 157 of the EC Treaty that focuses on measures to improve the **business environment**. The Council has, on this basis, adopted a number of Decisions concerning the evaluation of the impact of legislative proposals on business.
- Article 6 of the Treaty requires that the definition and implementation of all Community policies must take account of **environmental protection**, with a view to promoting sustainable development, while Article 174 provides that the Community must take account of the potential benefits and costs of action (or lack of action) when preparing its policies on the environment.
- Article 127 requires the Community to take account of the objective of a high level of **employment**.
- Articles 152 and 153 require the Community to achieve high levels of **human health protection** and **consumer protection**.
- Further support comes from Declaration 18 to the Maastricht Treaty, where the Commission undertakes to take account of the **costs and benefits** of its legislative proposals on all concerned parties.

3.3. THE CURRENT SITUATION

3.3.1. Commission-wide Requirements

Under the Regulatory Policy Guidelines of 1996, the Explanatory Memorandum, accompanying every legislative proposal must include answers to a list of questions. Specifically they must:

- Specify the objective and the justification of the measure being pursued.
- Have a clearly identified legal basis.
- Comply with the principles of subsidiarity and proportionality.
- Aim at legislative and administrative simplification.
- Be simple, concise, and clearly worded.

- Be consistent with the Commission's priorities and actions.
- Be based on rationalized and modernized assessments "which provide a genuine evaluation of the common interest".
- Be subject to assessment throughout the decision-making process and the period of implementation.
- Be the result of broader external consultations.

However, the Regulatory Policy Guidelines are general and do not specify the methods or technical assumptions to use when evaluating the impact of any proposal. Moreover, the Commission Secretary-General has no explicit power to refuse to accept proposals that fail to satisfy the basic standards set out in the guidelines.

Hence, each Directorate determines how this mandatory requirement is to be satisfied.

There are three exceptions to this general rule. These are:

- **Budgetary Evaluation:** This sets out the financial implications for the European Union institutions of a proposed measure. Along with an assessment of potential fraud risks, a budgetary evaluation must accompany every legislative proposal.

As part of the process of change set out in the White Paper on Internal Reform, the Commission has established a new process (the Strategic Planning and Programming Cycle – SPP) for the evaluation of policy proposals that are non-mandatory and involve the use of EU financial resources. All such proposals must now be justified in terms of their impact on the policy priorities of the current Commission. A new, central unit has been established in the Secretary-General's Office to oversee the process and to establish common methodologies, technical assumptions and process standards.

This assessment process helps decision-makers to understand the impact of their actions on public resources. It has less value in exposing the wider costs and benefits of regulatory action to policy-makers.

- **Environmental Impact:** an Environmental Impact Assessment should be undertaken if the environmental consequences of a proposed measure are significant.

DG Environment has recently published a new, internal code of conduct to clarify the responsibilities of all Directorates in this area.

This should help the Commission to take account of environmental protection in a more consistent fashion, when developing legislative proposals. However, this new impact assessment process is not

designed to provide a systematic analysis of all the principal benefits and costs of new regulatory proposals.

- **Business Impact** – a formal Business Impact Assessment (BIA) must be carried out for all legislative proposals with a significant impact on business.

Business Impact Assessment

Although BIA is only a partial form of Regulatory Impact Analysis, it is the most widely used Commission-wide method of assessing the impacts of proposed regulations.

The aims of the BIA process are:

- To ensure that the Commission does not add unnecessarily to the burdens placed on business by legislation.
- To encourage the Commission to consult and take account of the views of business.
- To inform decision-makers (such as the Commission, the Council, and the European Parliament) of the likely impact of a proposal on business.

The coverage of all BIAs follows a common format:

- Description of Proposal.
- Impact of the Proposal on Business (sectors and regions affected; activities to be undertaken by business to comply with the Proposal, and compliance costs; economic effects on employment, investment and the competitive position of business; and, any special measures for SMEs).
- Consultation on the Proposal (organisations consulted and the main views expressed).

Each individual Directorate that is responsible for drawing up a new legislative proposal is also responsible for completing the necessary BIA.

DG Enterprise is responsible for supporting and coordinating the BIA process. It is currently re-examining the BIA system in a Pilot Project, which will run to February 2002. Its aim is to review and to strengthen the BIA tools and working methods, by reviewing a sample of legislative proposals.

3.3.2. Individual Directorates

Individual Directorates use a range of methods to assess other impacts of proposed legislation. These tend to be tailored to meet the specific requirements of the Directorate and its policies. In general, all of these techniques are designed to provide a partial analysis of the impact of new legislation.

Directorates differ in the extent to which they have developed and implemented formal structures or processes to ensure that assessments are carried out consistently and systematically.

Within **DG SANCO (Health and Consumer Protection)**, guidelines have been issued for undertaking the ex-ante impact assessment of policy proposals on consumer interests. These use qualitative techniques to assess the potential impacts of each proposed policy action on topics such as consumer safety, physical access, affordability of goods and services, and information availability.

DG Employment has a process for evaluating the impact of expenditure under the "Structural Funds" on employment. These guidelines recommend a three-stage, bottom-up process for measuring Structural Fund employment effects. This is complemented by approaches using econometric and statistical techniques.

DG Environment uses economic analyses to support the development of policy in selected areas. Where this occurs, it is usual for such analyses to be carried out by external consultants and for the results to be made public. Although there is flexibility to determine technical assumptions, data quality standards and analytical methodologies on a case-by-case basis, some common guidelines have been developed for assessing costs and benefits.

3.4. A COMPARISON WITH "CRITICAL SUCCESS FACTORS"

Judged on the basis of the quality of information provided to decision-makers through the RIA system in the EU (particularly the Explanatory Memoranda and the Business Impact Assessments that accompany legislative proposals), the overall standard of ex-ante impact analysis produced by the European Commission is patchy. A small number of analyses provide useful information to help decision-makers understand the costs and benefits of legislative proposals. Most, however, only provide limited, descriptive information, and, in a number of cases, there is a failure to provide any evidence that impact analyses have been undertaken.

Our evidence from a sample of Explanatory Memoranda and Business Impact Assessments produced between 1996 and 2001^{xxxii}, suggests that:

- There is little consistency in the nature and scope of Impact Analysis carried out by the different Directorates of the European Commission.
- Systematic analysis of costs and benefits is rarely carried out. Detailed costs, for example, were only identified in less than 20% of the Explanatory Memoranda and Business Impact Assessments reviewed. Moreover, in more than 60% of cases, it was claimed that there would be no costs to the business community of legislative proposals designed specifically to change business behaviour.



- A description of the potential benefits is included in most Explanatory Memoranda. However, this is frequently fragmented across different sections of the document, and, in most cases, is confined to a generalised description of the desirability of the legislative proposal. Evidence to support and justify the potential benefits is rarely provided.

3.4.1. Regulatory Management Policy

The strongest part of the Commission's regulatory management policy is the requirement, set out in the Regulatory Policy Guidelines, for all legislative proposals to be based on Impact Assessments that "provide a genuine evaluation of the common interest". Another strength of the existing guidelines is that they require the Commission to consult widely when preparing legislative proposals. In theory, these provide a basis on which other, more rigorous Regulatory Impact Analysis processes can be built. However, this has not yet happened in practice, in a consistent fashion, across the Commission as a whole.

Other features of the existing Commission-wide approach satisfy few of the success factors for Regulatory Management Policy. They fail to include:

- A single, consolidated, legally binding statement of Regulatory Management Policy.
- A single set of administrative procedures and tools for undertaking regulatory impact analyses.
- Clear, mandatory guidelines that specify how and when analyses must be carried out.

3.4.2. Structures and Procedures

Although the Secretary-General's Office has the power to review Explanatory Memoranda, the existing Commission-wide approach does not meet the standards set by the Critical Success Factors (CSFs) because:

- The existing Impact Assessment systems are not integrated.
- The requirement for Impact Assessment is limited in scope to legislative proposals. It does not include other activities by the Commission that have regulatory effects on citizens, such as guidelines issued by agencies and decisions reached using the "comitology" process.
- There are no detailed quality standards, against which the Secretary-General's Office can evaluate the quality of Impact Analyses undertaken by individual Directorates.
- The Secretary-General's Office lacks the power to refuse to accept legislative proposals that fail to satisfy the basic standards for impact analysis set out in the Regulatory Policy Guidelines.

- The Secretary-General's Office does not have the resources needed to undertake the "oversight" role.

3.4.3. Roles and Responsibilities

A strength of the existing system is that the individual Directorate responsible for drawing up a legislative proposal is also responsible for undertaking the Impact Assessment. Major weaknesses are that there is no central unit with the explicit power to establish common methodologies, define data quality standards, provide expert support and enforce compliance. Moreover, there are no sanctions for failing to provide an impact assessment.

But, perhaps the greatest problem is a cultural one. Impact Assessment processes conflict with the tradition of the European Commission that it is the responsibility of 'expert' officials to make impartial recommendations to decision-makers, in the best long-term interests of society. Hence, many officials believe that the Business Impact Assessment system and other Impact Assessment systems are unnecessary at the level of the European Union.

3.4.4. Resources

The existing Impact Assessment process at EU level does not meet the Critical Success Factors in terms of the resources available to undertake high-quality impact assessments. There is:

- Little investment in training of staff in the process.
- No central cadre of skilled staff available to support individual Directorates and to spread expertise through inter-service job transfers.

3.4.5. Analytical Methodologies

The existing Impact Assessment process at EU level fails to meet the CSFs for analytical methodologies because:

- The existing guidelines are only advisory.
- The coverage of the assessment is too limited, because it fails to require an analysis of all significant impacts.
- There is no requirement to collect information from a range of sources.
- There is no requirement to publish all information received or to explain why one set of data is preferred to another.
- There are no common technical assumptions, such as discount rates and valuation methods for reduced mortality risks and improved public health.
- There are no data quality standards.
- No guidance is provided on the best way of valuing the compliance costs of any new legislative proposal.

- There is no mandatory requirement to quantify benefits and costs, whenever possible.

3.4.6. Implementation

There are major failings in the way in which the existing system is implemented at EU level, such that, in general, implementation does not satisfy the CSFs. Problems include:

- The lack of transparent and objective "decision rules" for deciding whether or not to undertake an impact assessment.
- The failure to publish supporting analyses for impact assessments.
- The failure to undertake systematic 'ex-post' analyses of the actual impact of regulations.

But the principal failing in the existing system, in terms of implementation, is that there is no specific requirement to consult stakeholders during the process of developing an impact assessment. Although there is a legally binding requirement for the Commission to consult during the preparation of a legislative proposal, the form and effectiveness of consultation depends, to a large extent, on the attitudes and experience of the specific officials responsible for managing the legislative proposal (and producing the impact assessment).

Business Test Panels

To improve consultation during the Business Impact Assessment process, the Internal Market DG has set up a pilot project to examine the use of Business Test Panels. Using existing national test panels (based on a group of businesses from a range of sectors), Internal Market DG has assessed the potential compliance costs of a number of directives and reviewed alternative ways of achieving legislative goals. In a few cases, the test panels have identified useful improvements in regulatory design.

There are a number of weaknesses in the current Business Test Panel programme.

- The panels are based on *all* business sectors rather than those affected by the legislation. This dilutes the impact of responses from businesses strongly affected by legislation, and reduces the scope to undertake more detailed, diagnostic-type analyses about the failings of legislative proposals.
- Panels are solely used to consider direct compliance costs of proposed legislation. There is no attempt to obtain views from companies about the wider, 'knock-on' effects of legislative proposals on key business processes and strategic decisions, such as the potential impact of legislative proposals on the underlying competitiveness of industry.

3.5. GOOD EXAMPLES OF RIA AT EU LEVEL

In spite of these systemic failings, a number of Explanatory Memoranda and BIAs demonstrate that useful information can be conveyed to decision-makers through the impact assessment process. Notable examples of good practice include:

- **Directive on Late Payments:** This includes information about benefits and costs, provides a wide range of supporting data, and includes a clear statement of the likely impact of the proposal on SMEs. The BIA was also updated to take account of amendments agreed with the European Parliament.
- **Directive on Equal Treatment:** The BIA explains the different points of view of the various stakeholders on some elements of the proposal. It also responds to a number of the concerns.
- **Directive on Waste Electrical and Electronic Equipment:** This includes quantification of compliance costs for business and an assessment of the wider economic impact of the proposal on prices, output, and employment.
- **Regulation on the Community Patent:** The consultation process included a public hearing of interested parties, incorporating consultation on the potential costs and benefits of the Regulation.
- **Directive on Measuring Instruments:** The Impact Analysis draws on the results of questionnaires sent to a wide range of organisations.
- **Regulation implementing Articles 81 and 82 of the Treaty (Competition Policy):** This provides a detailed analysis of the direct and indirect of the effects of the proposal on SMEs.
- **Directive relating to Limit Values (for sulphur dioxide, oxides of nitrogen, particulate matter, and lead in ambient air):** This includes data on costs and benefits, and, hence, provides clear evidence of the overall net benefit to Europeans from the proposal.
- **Regulation on Food Law and the European Food Agency:** All comments received, as part of the (general) consultation, are available on the Internet. This includes comments on the likely impact on business.

Our review focused on the scope of the Explanatory Memoranda and the BIAs. It did not attempt to review the "quality" of the information and the conclusions drawn from the data. Some stakeholders consider that some of the information used is poor quality and that some of the conclusions are of questionable validity.



3.6. OPINIONS ABOUT RIA

Stakeholders have strong views about the existing process and about the options for a new, improved RIA process.

3.6.1. European Commission

Most officials of the European Commission acknowledge that there are weaknesses in the current system of Impact Assessments, but consider that the tools available have helped to improve the quality of new legislation. Specifically, they consider that good Impact Assessments:

- Inform policy-makers about the impact of regulation on stakeholders, particularly European business.
- Stimulate the assessment of alternatives to traditional forms of regulation.
- Promote awareness of the cost effectiveness of different legislative options.
- Help the European Commission to explain to the European Council and the European Parliament, the reasons for choosing one legislative option rather than another.
- Improve the quality of negotiations with the European Parliament during the co-decision process.
- Help justify regulatory decisions to citizens and businesses.

Moreover, many officials consider that the Impact Assessment process provides greatest value to decision-shapers and decision-makers, when the benefit-cost principle is used to help policy-makers identify the most cost-effective way of achieving their overall policy objectives.

3.6.2. External Stakeholders

All types of stakeholders consider that the current Impact Assessment processes are ineffective in informing the policy development and legislative processes at EU level. They consider that there is a major gap between the frequent expressions of intent to improve regulatory quality made by politicians on the one hand, and the reality of legislative development on the other.

Many stakeholders consider that:

- Impact Assessments are too often treated by officials as administrative requirements to be completed at the end of the policy development process. As a result, many Impact Assessments included in the Explanatory Memoranda tend to be formalistic, partial, and not systematic.
- There are inconsistencies between Impact Assessments because each Directorate has

considerable discretion in determining when an assessment is needed, how to carry it out, and when to do it.

- Impact Assessments have been 'captured' by special interest groups. For example, some stakeholders claim that business interests have captured the Business Impact Assessment process, because BIAs focus on the cost to companies of new legislation and are controlled within the European Commission by DG Enterprise. Businesses claim that other types of Impact Assessment have been captured by NGOs, with their emphasis on "qualitative" benefits not "quantitative" costs.
- The conclusions set out in Impact Assessments are not always credible, because the Commission does not have to give reasons for accepting some data and rejecting other data, and because it does not have to validate its conclusions with stakeholders or independent third parties.
- There is little evidence that those responsible for undertaking Impact Assessments learn from previous assessments.
- There is no requirement to up-date Impact Assessments to take account of amendments put forward by the European Council or the European Parliament and amendments agreed as part of the co-decision process.

But the major weakness, acknowledged by all stakeholders is that the scale and quality of consultation is poor, and all stakeholders support a move towards a more transparent RIA process, with improved consultation and communication.

There are, however, differences in the views of different groups of stakeholders about a number of aspects of the future development of the Regulatory Impact Analysis process in the European Union:

- Many business organisations support the need for a legally binding, mandatory RIA process. This is not supported by most NGOs.
- Most business organisations support the need for a formal, fully integrated RIA process. Most NGOs accept the principle of an integrated RIA, but many are concerned about its practical application, because they fear that it will place an excessive emphasis on the "quantification" of costs and benefits.
- Most business organisations support a requirement to undertake a formal Cost Benefit Analysis (CBA), as part of each RIA. NGOs argue against the use of simplistic benefit-cost tests, based on purely quantitative data. However, most NGOs support the benefit-cost test as a basis for choosing between alternative ways of achieving the same objective.

Achieving change in any large organisation is difficult. The particular structural problems of the European

4. RECOMMENDATIONS

Community's legislative processes and the weaknesses of the existing regulatory management systems make the process of adopting a new Regulatory Impact Analysis system even more difficult.

In recognition of this, our recommendations are in four parts:

- A simplified legal basis for the establishment of an effective future system of RIA at the level of the European Union.
- A statement of guiding principles.
- A long-term vision of the future system of RIA at Community level, which may take 8-10 years to achieve.
- A small number of actions that, if implemented fully in the next 2-3 years, will move the process of change, irreversibly, towards achieving the ultimate 'vision'.

The recommendations are, for the most part, consistent with the request made by the Council of Ministers in Lisbon and with the Interim Reports made to the Stockholm summit by the Mandelkern Group and the Commission. They also seek to take account of existing institutional arrangements within the European Union.

4.1. THE LEGAL BASIS

The new RIA process should be based on a Council Decision along the lines that:

"All major regulatory initiatives should be accompanied by a statement of Regulatory Impact Analysis."

"All major regulations should be re-assessed, every five years, to ensure that the original policy objectives are being achieved in an effective way."

4.2. GUIDING PRINCIPLES

The RIA process should be based on four key 'guiding principles':

Context

The RIA process in the EU should be developed as a subset of the regulatory reform process.

- There should be a political consensus to make systematic use of a new RIA process, that 'locks-in' all of the principal institutions and recognises the different roles that each plays in the legislative process.
- The RIA process should be capable of being tailored to reflect the special circumstances of each individual legislative proposal.

- There should be a clear separation of responsibilities for the individual elements of the RIA, between the different parts of the European Union institutions.

Content

The RIA process in the EU should cover all aspects of European society.

- The process should cover social and environmental dimensions, as well as economic and financial ones, and should take account of the interests of all stakeholders – consumers, employees and society at large, as well as business.

Transparency

The RIA process in the EU should be fully transparent.

- All stakeholders should have access to all information that is relevant to the RIA process.
- All stakeholders should be consulted in a systematic and timely fashion. This should include the collection and dissemination of information about alternatives, assumptions, reasoning, conclusions and policy proposals. It should also include consultation on draft RIAs.
- The basis for decisions should be clear to all stakeholders.

Quality

The RIA process in the EU should be "high quality".

- Regulatory Impact Analysis should be an integrated part of the EU decision-making process - within all the EU institutions and in all Member States.
- The process should be underpinned by a well-defined, multi-stage structure, with a set of decision-rules to 'trigger' the use of RIA in individual cases.
- Each RIA should include comments on alternatives to regulation, and alternative forms of regulation.
- The tools and techniques on which the RIA process is based should be specified clearly, and a common set of assumptions should be used in all RIAs.
- The RIA should encompass qualitative and quantitative analyses of the costs and benefits of regulatory proposals.
- Input data should be of a high quality and should be captured from a variety of sources, including third parties, such as the stakeholders.
- The process should benefit by learning from the lessons learned from past RIAs.



4.3. THE LONG-TERM VISION

To improve the quality of the Regulatory Impact Analysis process in the EU in the long-term, action is needed in seven main areas.

Regulatory Management Policies and Processes

Rec. 1: There should be a single Regulatory Management Policy that commits all EU institutions to achieving common regulatory quality goals, to following agreed administrative procedures, and to undertaking RIAs in a systematic fashion.

Rec.2: The precise details of the Regulatory Impact Analysis process in the European Union should be set out in a series of mandatory guidelines that apply to all of the principal Community-level institutions.

These guidelines should include the aims and the advantages of RIA, along with a description of the process by which the Community will undertake RIAs. This should be a multi-stage process with full consultation at all stages.

A "Pre-Assessment" RIA should be used to assist in assessing policy options. An "Intermediate", and hence more complete, RIA should be submitted whenever a legislative proposal is put forward for inclusion in the Commission's Annual Work Programme. The "Final" RIA should be produced when the legislative proposal is finalised. The Commission should up-date the RIA when amendments are proposed.

The Scope of the RIA Process

Rec. 3: The Commission should, in principle, complete an RIA in respect of any legislative or regulatory activity by the Commission, the Council, and the European Parliament.

The scope of the RIA process should include regulatory programmes and the SLIM process. The RIA system should also cover advice or rules from agencies, technical advisors, or scientific advisors that have a general (regulatory) effect on private citizens, voluntary organisations, public bodies, or businesses. It should, in addition, cover new, non-traditional areas such as "soft law" and codes of conduct.

Rec. 4: Each Member State should complete an RIA when it transposes an EU Directive into national law.

This is particularly important when they make additions to the Directive.

Rec. 5: Each Member State should submit an RIA when it notifies the Commission of its intention (under Directive 98/34) to introduce national, technical legislation in areas not yet covered by the provisions of the Single Market.

Member States should address, specifically, any adverse effects of the proposed measure on the functioning of the Internal Market.

Roles and Responsibilities

Rec. 6: The RIA guidelines should describe the principal roles and responsibilities of each of the EU institutions.

Directorates that develop legislative proposals should be responsible for carrying out RIAs and for up-dating them to take account of amendments agreed within the Council or the European Parliament. Staff responsible for these activities should be properly trained.

The guidelines should permit Directorates to tailor the RIA to the specific circumstances of each new piece of legislation.

Rec. 7: A 'Regulatory Assessment Office' should be established within the Secretary-General's office in the European Commission.

Responsibilities should include: the establishment of binding process quality standards; the establishment of common analytical methodologies; and the provision of expert support and advice, to individual Directorates, in the preparation of RIAs. The Office should be responsible for adjudicating on requests from Member States, the European Parliament and stakeholders for the production of an RIA. It should also be responsible for advising the Secretary-General on the validity of individual RIAs. (The Secretary-General should be responsible for deciding whether to accept the RIA, as conforming to the guidelines.)

The Office should establish a series of Commission-wide training courses. These should include "technical" training for the officials who are responsible for carrying out the RIAs in individual Directorates, and for decision-makers, including members of the European Council and MEPs.

The Office should also be responsible for leading the network of experts who carry out the RIAs in individual Directorates, for facilitating the transfer of expert staff between Directorates and for improving inter-service co-operation.

Rec. 8: A 'Regulatory Audit Bureau' should be established, within the Court of Auditors, to oversee the operation of the RIA process by all of the principal Community-level institutions.

The Bureau should undertake audits of a sample of the RIAs produced by individual Directorates, to ensure that they meet the guidelines agreed by the Community and to learn the lessons from implementation (ex-ante analysis). The Bureau should, in addition, undertake comparisons of projected and actual regulatory impacts, over time ('ex-post' analysis).

Analytical Methodologies

Rec. 9: Each RIA should include a detailed analysis of the 'need' for regulation, the alternatives examined and the overall impact of the regulation.

Each RIA should include analyses of potential major impacts of the regulation on public health and safety, the environment, consumers, business and society at large. In short, the new RIA system should integrate and expand upon the existing, formal and informal impact assessment systems, such as the Business Impact Assessment system, the Environmental Impact Assessment system and the Trade Assessment system.

Rec. 10: *The new guidelines should describe the analytical methodologies, including the range of tools and techniques, available to those responsible for carrying out RIAs. The guidelines should, however, be sufficiently flexible to facilitate selective application depending on the circumstances of each individual situation.*

The guidelines should ensure that each RIA identifies the economic impacts of regulatory proposals on consumers, employees, businesses, the environment and society at large, including distributional effects. RIAs should, for example, include a scientific risk assessment whenever regulatory proposals seek to manage potential risks to public health, safety or the environment.

Rec. 11: *The guidelines should require each Directorate to undertake a systematic review of costs and benefits in all cases.*

However, the level of detail will vary with the particular circumstances of any proposal and the stage in the development of the process.

For example, a minimum requirement, for the Pre-Assessment Stage of all proposals could be a qualitative statement of the major costs and benefits of the proposal, including the costs and benefits of the principal alternative policy options.

On the other hand, a fully integrated Cost Benefit Analysis (CBA) of the chosen alternative should be required only for the Final Report stage of major^{xxxiii} policy proposals, covering the effects on all stakeholders, with all costs and benefits quantified as far as possible. The Final Report should also include a Risk Assessment if the proposal seeks to manage potential risks to public health and safety or the environment. But it is likely that some costs and many benefits can only be expressed in qualitative terms. Such qualitative assessments are an essential element of any effective CBA.

The **costs** in a fully integrated CBA may cover:

- *Direct fiscal costs to government:* The cost of administering the regulatory system itself, including the costs of development, compliance and adjudication.
- *Compliance costs to business and consumers:* Increases in compliance costs, such as the administrative costs for business and for citizens.
- *Dynamic costs to economic performance:* The "indirect costs" to the economy where regulations reduce

competition, innovation and investment. They also include the costs to the consumer as a result of reductions in choice and quality of products and services.

The **benefits**, in a fully integrated CBA, should be quantified wherever possible; but, where this is not possible, qualitative descriptions should be provided. Areas, which should be covered, in such analyses include:

- *Direct fiscal benefits to governments:* Reductions in the cost of administering the regulatory system itself.
- *Compliance benefits to business and consumers:* Reductions in compliance costs, such as the administrative costs for business and for citizens.
- *Dynamic benefits to economic performance:* The "indirect benefits" to the economy where regulations increase competition, innovation and investment. They also include the benefits to consumers as a result of improvements in choice and quality of products and services.
- *Benefits to society:* The benefits from improved public health and safety or from a better quality environment.

Rec. 12: *The guidelines should specify a core set of key technical assumptions, and establish quality standards for data collection.*

The assumptions should include discount rates and a basis for valuing improvements in public health and the environment.

The guidelines should require Eurostat to collect more disaggregated data and require individual Directorates to collect relevant data from third party sources, including stakeholders. They should also require each Directorate to obtain an assessment, from independent experts, of any major analytical study, which may be used to inform the decision-making process.

However, difficulty in obtaining high quality data should not be used to delay the analysis. Alternative approaches to obtaining data should be developed, on a case-by-case basis.

Consultation and Communication

Rec. 13: *The guidelines should establish minimum standards for consultation of civil society (including business and citizens) and for the communication of the results to stakeholders.*

The guidelines should include requirements to consult all interested stakeholders: in respect of the early disclosure of a possible intention to regulate; and during the RIA process itself. (This should include a requirement to consult stakeholders on the content of draft RIAs.) Well-focused, multi-stakeholder "Test Panels" should be used, where possible.



Lists should be published of all the individuals and organisations that have been consulted, at each stage of the RIA process.

The results of individual RIAs should be presented in a simple easy-to-understand format, tailored to the needs of the policy-makers.

The Commission should publish 'Intermediate' and the 'Final' RIAs, along with supporting analyses, key submissions by stakeholders and Commission responses.

Monitoring and Reporting

Rec. 14: The Regulatory Audit Bureau should undertake a review of the implementation of the RIA guidelines, each year. It should also present an Annual Report, to all the EU institutions, of the results of all the reviews undertaken during the year.

This review should cover the effective use of the guidelines at all stages of the RIA process. Such reviews are important because they will identify opportunities for improving the guidelines in future (and, hence, opportunities for improving the decision-making process).

Rec. 15: The RAB should, three years after the date of implementation of any regulation, undertake a post-project analysis of the differences between predicted and actual regulatory impacts for all legislative proposals that include a 'Final' RIA. This should include a reference to experience in member states, post-implementation. The results of these audits should be included in the Annual Report.

The results of post-project audits are important because they will help to improve subsequent decisions by improving the quality of future ex-ante analysis, as well as identifying weaknesses in specific guidelines.

The European Commission should ensure that the RIA process is "continuously improved". This should be based on feedback from the Member States and from other stakeholders as well as the experience gained by all the European institutions.

Resources

Rec. 16: The European Parliament should provide the new Regulatory Assessment Office and the Regulatory Audit Bureau with enough resources to enable them to perform their tasks effectively. The European Parliament should also ensure that individual Directorates-General have sufficient resources to enable them to prepare RIAs that meet the guidelines.

Rec. 17: The European Parliament should provide appropriate stakeholders (e.g. NGOs) with the necessary additional resources to enable them to respond constructively to requests for consultation.

It is estimated that the total budgetary requirement, in the longer term, will be of the order of €25-30 million.

4.4. THE SHORT-TERM ACTION PLAN

To begin the process of change, a number of major reforms must be undertaken during the next 2-3 year period. Specifically:

- **A Common Regulatory Management Strategy for the European Community** should be agreed by the Community-level institutions and the Member States.
- **The legal basis** for the whole of the RIA process should be simplified: it should be based on a Council Decision.
- **A Regulatory Assessment Office** should be established in the Commission Secretary-General's Office. Expert staff should be recruited, and appropriate financial resources should be made available.
- **A Regulatory Audit Bureau** should be established in the Court of Auditors. Expert staff should be recruited, and appropriate financial resources should be made available.
- **A new Consultation Process** should be introduced. This should be a formal, structured process for the consultation of all relevant citizens and organisations.
- **Preliminary Guidelines** for a new Regulatory Impact Assessment Process for the European Community should be established. These should:
 - Integrate all current RIA-type processes within a single, new RIA framework.
 - Change the procedural rules of the European Parliament and the European Council to ensure that an up-dated version of the RIA is produced, before any amendments, that may have a substantial impact on European economy, are debated.
 - Require individual Directorates to obtain approval from the Secretary-General for all Intermediate RIAs, before any legislative proposal is included in the Commission's Annual Work Programme.
 - Develop a specification for the production of Intermediate RIAs.
 - Require the Commission to undertake pilot projects on the principal analytical methodologies.

It is estimated that it will cost some €5-10 million to implement the Action Plan in the short-term.

END NOTES

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- ^x Jacobs S. et al *Regulatory Quality and Public Sector Reform* (in OECD *The OECD Report on Regulatory Reform – Volume II: Thematic Studies* 1997)
- ^{xi} OECD *Government Capacities to Produce High Quality Regulations in OECD Countries: Analysis and Interpretation* (Forthcoming 2001)
- ^{xii} OECD *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation, OCDE/GD (95) 95* (1995)
- ^{xiii} See, for example, Apogee Research *Regulatory Reform through Regulatory Impact Analysis: The Canadian Experience* (1997), UK Government Better Regulation Unit *Regulatory Compliance Cost Assessment: UK Experience* (1997), J.F. Morrall *An assessment of the US regulatory impact analysis Program* (1996), S.Holmes and S. Argy *Reviewing existing regulations: Australia’s national legislative review* (1996), OECD *Regulatory Reform in the Netherlands* (1999), OECD *Regulatory Reform in Denmark* (1999), and OECD *Regulatory Reform in the United States* (1999)
- ^{xiv} OECD *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation, OCDE/GD (95) 95* (1995)
- ^{xv} See, for example, OECD *Regulatory Reform in Italy* (2001)
- ^{xvi} OECD: *Government Capacities to Produce High Quality Regulations in OECD Countries: Analysis and Interpretation* (Forthcoming, 2001)
- ^{xvii} Deighton-Smith R. *Regulatory Impact Analysis: Best Practices in OECD Countries* (in OECD *Regulatory Impact Analysis: Best Practices in OECD Countries* (1997)
- ^{xviii} R.Hahn, J Burnett, Y Chan, E Mader, and P Moyle *Assessing the Quality of Regulatory Impact Analyses* (2000), R Hahn *Regulatory Reform: Assessing the Government’s Numbers* (1999), and Hahn R. and Litan R. *An Analysis of the Third Government Report on the Benefits and Costs of Federal Regulations* (2000)
- ^{xix} See, for example, Radaelli C. *Steering the Community Regulatory System: The Challenges Ahead* (Public Administration, vol. 77, 1999)
- ^{xx} See also OECD *Regulatory Impact Analysis: Best Practices in OECD Countries* (1997)
- ^{xxi} See, for example, Jacobs S. et al *Regulatory Quality and Public Sector Reform* (in OECD *The OECD Report on Regulatory Reform – Volume II: Thematic Studies* 1997)
- ^{xxii} See, for example, Federal Government of Canada Privy Council Office *Government of Canada Regulatory Policy* (1999) and Apogee Research *Regulatory Reform through Regulatory Impact Analysis: the Canadian Experience* (for the Treasury Board of Canada, 1996)
- ^{xxiii} See, for example, OECD *Regulatory Reform in The Netherlands* (1999)
- ^{xxiv} See, for example, OECD *Regulatory Reform in the United States of America* (1999)
- ^{xxv} See also Arrow K, et al *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation – A Statement of Principles* (1996)



xxvi See, for example, United Kingdom Government Cabinet Office 'Good Policy Making: A Guide to Regulatory Impact Assessment' (2000)

xxvii See also Deighton-Smith R. 'Regulatory Impact Assessment in New South Wales: An Appraisal against OECD Best Practice Recommendations' (a report for the government of New South Wales, Australia, 2000)

xxiii See, for example, Broder I. And Morrall J. 'Collecting and Using Data for Regulatory Decision-making' (in OECD 'Regulatory Impact Analysis: Best Practices in OECD Countries' (1997) and OECD 'Review of Regulatory Reform in Denmark' (2000)

xxix See, for example, OECD 'Review of Regulatory Reform in the USA' (1999)

xxx See also, Lutter R. 'The Role of Economic Analysis in Regulatory Reform' (Regulation Vol. 22, 2000)

xxxi See also Pelkmans J. Labory S. and Majone G. 'Better EU Regulatory Quality: Assessing Current Initiatives and New Proposals' (in 'Regulatory Reform and Competitiveness in Europe - Volume I, Horizontal Issues' ed. Galli G. and Pelkmans J., 2000)

xxxi See also European Commission 'Improving the Quality of Legislation for Business - The European Commission's Business Impact Assessment System' (1997)

xxxiii The Guidelines should include a definition of "major". In the USA, for example, major regulations are defined as those imposing annual costs in excess of \$100 million; those likely to impose major increases in costs for a specific region or sector; and those likely to have significant adverse effects on competition, employment, investment, productivity or innovation. Using this definition, less than 1% of all regulations published each year, in the USA, qualify for a Final RIA (including a full cost-benefit analysis).



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