



## **EPC WORKING PAPER N° 10**

Achieving a New Regulatory Culture in the European Union:  
An Action Plan

**April 2004**

In strategic partnership with the King Baudouin Foundation

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Bruce Ballantine  
Dirk Hudig

**BETTER  
REGULATION**



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*EPC* Working Papers cover the extended discussion of contemporary European integration themes. They are normally written by in-house analysts, although outside experts may also be invited to produce papers. Working Papers are policy oriented and contain an executive summary and key recommendations. The papers represent the views of the authors and not necessarily those of the *EPC*.

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## Achieving a New Regulatory Culture in the European Union: An Action Plan

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## Foreword

The *European Policy Centre* has promoted the debate on Better Regulation in the European Union since 1995. At that time, the only EU commitment was a (political) Declaration by the European Commission attached to the Treaty of Maastricht. Subsequently, the Centre made a number of submissions to the Inter-Governmental Conference which led to the Treaty of Amsterdam, in support of a legally binding provision that cost-benefit analyses should be undertaken for all new EU legislation. This was included in the Subsidiarity and Proportionality Protocol attached to the 1997 Treaty.

Since then, considerable progress has been made, and the section on Better Regulation included in the Presidency Conclusions of the Spring 2004 European Council is just the latest in a series of political statements on the need to improve the quality of the EU regulatory process.

The *European Policy Centre* welcomes these developments; encourages all institutions and stakeholders to maintain the momentum needed for further improvement; and commits itself to support further initiatives on Better Regulation at EU level.

I am delighted that the EPC has decided to publish this comprehensive and timely Action Plan to launch its new “Integrated Work Programme on Better Regulation”. The principal objectives of the Programme are to improve the governance of Better Regulation in the EU and to promote regulatory convergence at an international level, particularly between the EU and the US.

The Working Paper also complements other activities of the EPC designed to support the work of the new Commission, the Council and the European Parliament, by highlighting the changes needed to create a regulatory framework that will enable the Union to realise its potential as the most competitive, knowledge-based economy in the world.

**Stanley Crossick**  
**Director and Founding Chairman**  
***The European Policy Centre***

## Acknowledgments

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We would, in addition, like to thank many senior officials in the Commission (particularly in the Secretariat-General and DG Enterprise), the Council and the Parliament for their input - at meetings arranged by the *European Policy Centre* and in separate discussions.

But, this Action Plan is principally the result of the work undertaken, in recent years, within the framework of the Better Regulation Programme and the Risk Forum of the *European Policy Centre*. It builds on two influential publications: the Occasional Paper, *Regulatory Impact Analysis: Improving the Quality of EU Regulatory Activity* (published in 2001), and the Working Paper, *Improving the Quality of Risk Management in the EU: Risk Communication* (published in 2003).

We would, therefore like to thank the members of the Risk Forum and the members of the Steering Groups of the individual projects for their commitment, support and suggestions during this period.

However, we are responsible for the contents of the report, especially any errors and omissions.

**Lorenzo Allio**  
**Bruce Ballantine**  
**Dirk Hudig**  
***The European Policy Centre***

## List of Abbreviations

COM	European Commission Communication
DEBR	<i>ad hoc</i> Group of Directors and Experts on Better Regulation
DG(s)	Directorate(s)-General
ECOFIN	Economic and Financial Affairs Council
EP	European Parliament
ex.IA(s)	extended Impact Assessment(s)
IA(s)	Impact Assessment(s)
IIA	Inter-Institutional Agreement
MEP(s)	Member(s) of the European Parliament
RAB	Regulatory Audit Bureau
RAO	Regulatory Assessment Office
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SME(s)	Small and Medium-sized Enterprise(s)
TEP	Transatlantic Economic Partnership

## Executive Summary

Regulation is a basis for social, environmental and health protection. It is also a determinant of economic growth.

In recent years, the European Council has regularly confirmed its commitment to improve the quality of EU legislation. A number of initiatives on Better Regulation have been undertaken, including a comprehensive European Commission *Action Plan on Better Law-making* and, most recently, an *Inter-Institutional Agreement on Better Law-making*.

However, despite the considerable progress made in recent years, continued efforts to reform the system are needed. In particular, there is a need for:

- A clear vision of the reform process as a whole.
- Strong leadership to promote the reforms.
- Clear (quantitative) targets and time scales.
- Adequate resources and skills for undertaking Impact Assessments.

In order to reinforce the work of the European Commission, the Council and Parliament, and provide insights and ideas for future EU Presidencies, the *European Policy Centre* has developed an Action Plan, which seeks to develop a new 'regulatory culture' throughout the entire decision-making process of the EU.

The Action Plan identifies three main areas for action and suggests a number of specific improvements.

### Driving a New Regulatory Culture in the European Commission

To instil a new regulatory culture among the officials, advisors and regulators working in and for the European Commission, the Action Plan recommends:

- The appointment of a Commission Vice-President with responsibility for Better Regulation.
- The publication of a formal and binding policy statement for Better Regulation.
- The provision of an adequate level of well-trained resources to support the implementation of Better Regulation programmes.
- An enhanced role for the SME Envoy.

## Developing and Consolidating the Organisational 'Architecture' Underpinning Better Regulation

To achieve an effective and consistent implementation of the *Inter-Institutional Agreement on Better Law-making*, the Action Plan recommends:

- The creation of a 'Regulatory Assessment Office', within the European Commission, responsible *inter alia* for establishing binding regulatory quality standards (including quantitative targets), developing common methodologies, and supporting individual Directorates-General in the preparation of impact assessments.
- The establishment of an independent 'Regulatory Audit Bureau', within the Court of Auditors, responsible for overseeing the operation of the Better Regulation process in all the principal EU institutions.

Both the Regulatory Assessment Office and the Regulatory Audit Bureau should be provided with adequate resources to enable them to perform their tasks effectively.

## Engaging All of the EU Institutions in the Drive to Improve Regulatory Quality

To extend the new regulatory culture throughout all the institutions involved in the EU decision-making, the Action Plan recommends that:

- The principal roles and responsibilities of each of the EU institutions should be established in mandatory guidelines.
- MEPs and members of the Council should be provided with a set of comprehensive guidelines on regulatory quality requirements.
- The Council and the Parliament should play a more significant role in the pre-legislative phase.
- The Council and the Parliament should regularly call public hearings.
- The Council and the Parliament should upgrade their structure and create internal organisations responsible for improving inter-institutional co-ordination and carrying out impact assessments on any major amendments they table.

## Specific Improvements

The Action Plan also identifies a number of improvements that are required in specific areas to further improve the quality of legislation. These include:

- A formal and mandatory consultation process applied by all institutions at all stages of the decision-making process, and supported by adequate resources.
- A more thorough, comprehensive and transparent Impact Assessment system, whereby preliminary analyses are mandatory for each Commission proposal and subsequent extended Impact Assessments are limited in number.
- A clearer, more consistent risk communication policy.
- A review of the implementation procedures, whereby comitology committees are made more transparent and accountable and the transposition and enforcement of EU legislation by Member States is accelerated and improved.

If implemented fully, the Action Plan will help to deliver better and simpler regulations. It will also reduce the quantity of regulation. Hence, it will reduce the negative impacts of regulation on the ability of businesses based in the EU to innovate; to improve productivity; and to respond to change. It will as a result, create more and better jobs and more wealth, while providing a high level of environmental and social protection for the citizens of the EU.

## 1. Need for Action

The European Union (EU) has made encouraging progress in recent years in pursuit of its comprehensive Better Regulation agenda, which is designed to reconcile the conflicting demands of its citizens for better protection against environmental and social risks, for more and better jobs, and for improved living standards.

The European Commission has committed itself to taking both the initiative and leadership in the reforms. It has developed a comprehensive set of measures to undertake reform based on sound principles. It has stimulated the political debate on regulatory reforms and raised the awareness of stakeholders in the issue. The Council and the Parliament have also contributed to the improvements. But further action is still needed to improve the quality of regulatory decisions at EU level.

As economic performance in the EU continues to stutter, and the reforms expected from the Lisbon Agenda fail to materialise, there is a growing awareness of the impact that the regulatory framework has on economic growth because it influences the levels of innovation and entrepreneurship: two of the principal long-term drivers of increased wealth and employment.

On top of this, administrative burden and the impact of compliance costs continue to have a disproportionate effect on small and medium-sized enterprises (SMEs), reducing flexibility; undermining financial viability; and diverting management time.

Moreover, the nature of regulatory activity at EU level is changing. There is a continuing shift away from the harmonisation of existing 'economic' regulations in Member States to build the Single Market and towards the creation of new social and environmental regulations to protect citizens from technological risks, consistent with the new European model. These newer forms of regulation tend to be more 'value-driven'; and costs and benefits are, as a result, more difficult to identify. This creates new challenges for regulators and makes it more difficult to achieve high levels of regulatory quality.

Furthermore, these new forms of regulation have the potential to damage the ability of businesses to innovate, improve productivity and adapt to change. The proposed New Chemicals Policy (REACH) is a good example both of the potential benefits of social and environmental legislation at EU level and its potential, negative impact on wealth creation.

Enlargement of the EU may exacerbate structural weaknesses in the mechanisms used by the EU to make regulatory decisions. Comitology processes are, for example, likely to be less effective in an EU of 25 members than in an EU of 15.

Finally, there is a growing evidence that many Member States increase regulatory costs and reduce benefits by sub-optimally implementing EU legislation: a process known as 'gold plating'.

In response to these trends, the EPC has developed an Action Plan, which seeks to reinforce the work of the European Commission, the Council and the European Parliament, and provide insights and ideas for future EU Presidencies. The Centre hopes that it will provide further impetus to the process of regulatory reform, which is especially timely because of the accession of 10 new Member States, the forthcoming elections to the European Parliament and the subsequent appointment of a new Commission.

## 2. EPC Action Plan - Aim and Objectives

The overall aim of this Action Plan is to promote a new 'regulatory culture' throughout the entire decision-making process of the EU, by changing the attitudes that underpin the regulatory process.

To achieve this, the plan has a number of objectives:

- To provide regulators, decision-makers and opinion-formers with an overview of the initiatives undertaken and envisaged by the Commission in the framework of its *Better Law-making Action Plan*.
- To increase awareness by other stakeholders of the importance of Better Regulation.
- To identify the steps that other EU organisations (in particular the European Parliament and the Council) should take to ensure a consistent and efficient implementation of Better Regulation practices.

## 3. Recent Better Regulation Initiatives in the EU

There have, in recent years, been a number of initiatives to improve the quality of EU legislation. The most important include:

- References to Better Regulation in European Council Conclusions and the Mandelkern Report.
- The creation of an SME Envoy in the European Commission.
- The publication of the European Commission *Action Plan on Better Law-making*.
- The preparation of a *Draft Treaty Establishing a Constitution for Europe*.
- The negotiation of an *Inter-Institutional Agreement on Better Law-making*.

### 3.1. European Council Conclusions and the Mandelkern Report

The European Council decided in Lisbon in March 2000 to establish “a strategy for further coordinated action to simplify the regulatory environment, including the performance of public administration” and to rationalize the transposition of Community legislation,<sup>1</sup> and the Göteborg Summit in 2001 confirmed the overall commitment to a Sustainable Development Strategy.<sup>2</sup> Moreover, Better Regulation was an integral part of the European Commission *White Paper on European Governance*.<sup>3</sup>

An inter-governmental expert group was consequently set up under the chairmanship of Dieudonné Mandelkern to identify ways in which the regulatory quality of new and existing EU legislation and collaboration between Member States could be improved. The recommendations of the Mandelkern Group,<sup>4</sup> endorsed by the Laeken European Council in December 2001, covered key areas for action. The report had a significant impact on the subsequent work by the Commission.

In 2001 in Uppsala, the Directors - General responsible for Public Administration approved a *Medium-Term Programme for the Cooperation in Public Administrations*. In the Meeting of Ministers responsible for Public Administration in La Rioja in May 2002 the programme was updated and it received political backing under the Italian Presidency.<sup>5</sup>

European leaders have made additional political statements about the need for high levels of regulatory quality, especially from the Seville Summit in 2002<sup>6</sup> and, most recently, at the Spring Summit in March 2004.<sup>7</sup> The Irish, Dutch, Luxembourg and British Presidencies announced, in January 2004, a *Joint Initiative on Regulatory Reform*.<sup>8</sup>

*EU-US Guidelines on Regulatory Co-operation and Transparency*<sup>9</sup> were agreed in April 2002 to stimulate greater international regulatory convergence. Improved regulatory co-operation is also one of the key elements in the Transatlantic Economic Partnership (TEP).<sup>10</sup> The EU launched a *Joint Action Plan Canada-EU Regulatory Dialogue and Co-operation*<sup>11</sup> with the Canadian Government in Spring 2003. Moreover, the Commission supports bilateral dialogue on regulatory co-operation with a number of countries, including Japan and China. Discussions are also taking place on a multi-lateral basis, in particular within the OECD. Finally, regulatory co-operation is considered a priority in most of the business round tables and dialogues.<sup>12</sup>

## 3.2. SME Envoy of the European Commission

### BOX 3.1

#### The main functions of the SME Envoy are:

- To consult more systematically, so that the interests and concerns of SMEs are better reflected in consultation and business assessment procedures.
- To act as a bridge between the SMEs and Commission services.
- To facilitate access by SMEs to EU programmes and funding.

The European Commission established the office of an *SME Envoy of the Commission*<sup>13</sup> in December 2001 as a response to the Lisbon Strategy and the *European Charter for Small Enterprises*.<sup>14</sup>

The Envoy, who is integrated in the Directorate-General (DG) for Enterprise and Information Society, is part of the broader commitment of the Commission to improve governance, through a more systematic dialogue between the European institutions and businesses.

## 3.3. Commission Action Plan on Better Law-making

### BOX 3.2

#### Key communications related to the Commission Action Plan on Better Law-making

- General principles and minimum standards for consultation (COM(2002)704 final).
- The collection and use expertise (COM(2002) 713 final).
- Impact assessment (COM(2002) 276 final), including internal *Guidelines*.
- Simplifying and improving the regulatory environment (COM(2002) 278 final).
- The proposal for a new comitology decision (COM(2002) 719 final).
- The operating framework for the European Regulatory Agencies (COM(2002) 718 final).
- A framework for target-based tripartite contracts (COM(2002) 709 final).
- Better monitoring of the application of community law (COM(2002) 725 final).

In June 2002, the European Commission published its comprehensive *Action Plan on Better Law-making* (COM(2002) 275 final). Its aim is to develop a new common “legislative culture” in Europe by improving current procedures; widening the breadth of policy tools employed; and simplifying existing legislation.

The Commission subsequently published eight communications on specific actions that will be implemented within the framework of the existing treaties (Box 3.2).

Since 2001, the Commission has been engaged in a process of reducing and simplifying the *acquis communautaire* (currently, almost 100,000 pages). In its Communication *Updating and simplifying the Community acquis* (COM(2003) 71 final), the Commission provided a framework for the consolidation and codification of the *acquis*, with the specific goal of reducing the volume of the existing text by at least 25 % by January 2005.<sup>15</sup>

Moreover, guidelines require that documents should be drafted in a clearer way and more should be published. Following the Inter-Institutional Agreement on *Common Guidelines for the quality of drafting of Community legislation*,<sup>16</sup> a *Joint Practical Guide*<sup>17</sup> has been issued and the Commission’s Legal Service is also entitled to make drafting suggestions at an early stage of the legislative process. The Commission has organised training in legal drafting and joint seminars with Member States.

In addition, web-sites of the Commission, the Parliament and the Council outline the measures taken to enhance the transparency of the institutions and widen the access to EU documents published in this policy area.<sup>18</sup> The Commission published a progress report (COM(2004) 45 final) in January 2004.<sup>19</sup>

Finally, there have been major changes in the way in which the Commission carries out assessments of the impact of legislative proposals. The new approach developed by the Commission probably constitutes the biggest single innovation in the entire Better Regulation framework. It integrates the various Impact Assessment (IA) practices used by different parts of the Commission into a single template and ensures that a balanced analysis of the economic, environmental and social factors is included in IAs. To assist regulators, the Commission issued internal *Guidelines on Impact Assessment* (accompanied by two technical *Handbooks*).<sup>20</sup>

However, in its annual *Report on Better Law-making 2003* (COM(2003) 770 final) the Commission acknowledges that further improvements are needed:

- Feedback mechanisms to stakeholders must be improved during the consultation procedure.
- The rate of completion of extended Impact Assessments (ex.IAs) must be increased.
- The quality of ex.IAs must be improved in terms of environmental and social impacts; the analysis of subsidiarity and proportionality; the con-

sideration of policy options; and the quantification of the impacts.

- Ex.IAs must be made more accessible to the public.
- Progress on codification and the elimination of out-dated legislation must be accelerated.<sup>21</sup>
- The transposition rate of EU legislation by Member States must be increased.<sup>22</sup>
- A clear and consistent framework for regulatory agencies needs to be developed; and
- Evidence on the effectiveness of the proposed target-based tripartite contracts and agreements needs to be collected.

Evidence from recent reviews of the first IAs published under the new system confirms the Commission's analysis (Boxes 3.3.1 and 3.3.2).

#### **BOX 3.3.1**

##### **Case Study: The implementation of the new Impact Assessment system - 1**

2003 was the first year in which the new Impact Assessment (IA) process operated, so it is too early to draw too many conclusions. But, results of the *European Policy Centre's* review of IAs undertaken by the Commission since January 2003 suggest that:

- The Commission has made a good start in introducing the process.
- DGs/services have published preliminary IAs for only 30% of all proposals (and only 65% of proposals that had a high political priority).
- The Commission have attempted to produce too many ex.IAs, with too few resources.

Moreover, most of the preliminary IAs published fall short of the standards required in a number of areas. In particular they fail:

- To provide sufficient information on reasons for the choice of legal basis.
- To list alternatives, including the 'no-policy change' option.
- To provide adequate commentaries on likely impacts.
- To quantify the impacts.
- To identify 'data gaps'.
- To explain the need for ex.IA.

### **BOX 3.3.2**

#### **Case Study: The implementation of the new Impact Assessment system - 2**

The European Policy Forum has produced a “scorecard” based on the first 20 ex.IAs.<sup>23</sup> The principal conclusions are:

- In general, the Commission has made an excellent start in introducing Regulatory Impact Assessments (ex.IAs) on a systematic basis, with major benefits for transparency and lesson learning.
- The rationale for the selection of the ex.IAs was generally clear and each of the proposals chosen was of economic significance.
- Internal Commission procedures for the preparation of ex.IAs seems to be working.
- The most encouraging measure of progress is that, in half the cases, the ex.IA process seems to have led to a re-design of the original proposal.

However, the EPF concluded that a number of lessons could be learned from the first 20 ex.IAs:

- There is no information available to assess whether the proposals chosen were the most significant in the EU work programme.
- Quantification does not seem to have been pursued as far as it might have been in some cases.
- Only one half of the ex.IAs where risk is a factor include a comparison of one set of risks against another.
- The Commission consulted too many stakeholders, in many cases.
- The poor quality of market analysis appears to be a general problem.

### 3.4. Draft Treaty Establishing a Constitution for Europe

#### **BOX 3.4**

#### **Key references to Better Regulation in the Draft Constitutional Treaty**

The *Draft Treaty Establishing a Constitution for Europe* proposes:

- To streamline and reduce the number of legislative procedures.
- To clarify the hierarchy and reduce the number of the instruments.
- To reform the monitoring process on the application of subsidiarity.
- To consolidate the principles of participatory democracy, transparency and openness.
- To increase the political commitment to undertake IA.
- To improve the mechanisms to ensure compliance with EU law.

Although most of the envisaged measures do not require changes to the existing treaties, the *Draft Treaty Establishing a Constitution for Europe* presented in July 2003 contains a series of provisions that would, if implemented, help to improve the quality of the EU regulatory process.

First, the Convention on the Future of Europe proposes the clarification of the allocation of competences between the Union and the Member States and a considerable reduction in the number of instruments (from 15 to six). Legal acts would be subject to a clear hierarchy and there would be less confusion about their names and the respective definitions. The Convention also underlined the need for substantial simplification of the procedures. If accepted, the EU decision-making process would be better structured, simpler and more flexible.

Second, the Draft Constitutional Treaty suggests that the role of the social partners should be formally recognised at EU level. It proposes to formalise the principles of participatory democracy, by which the EU institutions are required to give citizens and representative associations an opportunity to comment on all areas of EU competence. It proposes that transparency and openness by institutions should be specifically addressed. If accepted, this would promote good governance and ensure better consultation and greater participation by civil society.

Third, the Protocol on the Application of the Principles of Subsidiarity and Proportionality outlines the introduction of a new monitoring system for the application of the subsidiarity principle. If agreed, this would strengthen the role of national parliaments without excessively slowing down the decision-making process.

Moreover, the Protocol proposes the formal inclusion of the requirements for wide pre-legislative consultation and IA - but these could have been more explicit and precise.

Finally, the Draft Constitutional Treaty proposes the introduction of a simplified procedure to ensure compliance with EU rules, including a faster and more effective procedure for applying sanctions.

### 3.5. Inter-Institutional Agreement on Better Law-making

#### **BOX 3.5**

#### **Highlights of the Inter-Institutional Agreement on Better Law-making**

The IIA:

- Calls for better coordination in the programming of legislation and the mutual sharing of information at all stages of the decision-making process.
- Calls for enhancing transparency (information, publication, broadcasting).
- Invites the Council and the Commission to attend EP plenary sessions and committee meetings.
- Frames the use of co- and self-regulation.
- Increases the use of consistent IA practices.
- Introduces a binding deadline for the transposition of directives.
- Calls for a simplification of the EU legislation and a reduction in its volume.
- Envisages the provision of more resources and additional staff.

Regulatory reform depends on strong and continued political commitment. While the Commission bears special responsibility for the preparatory, policy management and implementing stage, the European Parliament and the Council are responsible for deliberating, amending and adopting proposals in an efficient way.

Since mid-2003, the focus of the Commission has shifted from the formulation of principles and tools to the implementation of the new procedures and practices in collaboration with the other institutions. All the EU institutions and Member States have become more involved in Better Regulation issues and have developed their own positions and policies.

The *Inter-Institutional Agreement (IIA) on Better Law-making*,<sup>23</sup> which came into force in December 2003, is the first concrete result. The agreement is in line with the Commission's *Better Law-making Action Plan* and includes a number of positive provisions (Box 3.5).

However, the IIA fails to provide sufficient impetus to the Better Regulation process in a number of important aspects:

- Provisions covering pre-legislative consultation remain vague and general. The IIA, for example, does not explicitly mention the *Guidelines on general principles and minimum standards for consultation*. As a result, these are not legally binding.
- The IIA stresses the importance of IAs but fails to mandate quality standards. It does not require minimum standards for Explanatory Memoranda. Moreover, no specific mention is made of the need to use the 'best available science' when developing legislation involving risk-related issues. It also fails to require the Parliament and the Council to "*have impact assessments carried out prior to the adoption of any substantive amendment.*"
- The IIA provides a common definition of co- and self-regulation. It acknowledges that alternative methods of regulation may constitute efficient regulatory tools and specifies the conditions under which the alternatives may be applied.

The final text reflects - but does not fully satisfy - the concerns of the EP about the eventual misuse of these alternative regulatory methods. On the other hand, the conditions set in the IIA reduce both the scope and the flexibility of the co- and self-regulation approaches and may deter interested parties from initiating new voluntary agreements.

- Finally, the IIA acknowledges the necessity to provide the institutions with the necessary means, but it is vague about the level of resources needed and it makes no specific reference to training programmes.

The impact of the IIA will depend as much on the political willingness of the institutions to implement its provisions and monitor progress, as on its procedural feasibility. A High-Level Technical Group on Inter-Institutional Cooperation, which is responsible for this task, must ensure that a number of short-term provisions are implemented. These include agreement on the criteria and procedures for carrying out IAs on substantial amendments; and modifications in the working methods of the EP and the Council, with particular emphasis on the procedures for the adoption of simplification proposals.

## 4. Action Plan - Key Areas for Action

In order to further improve the EU regulatory processes, the *European Policy Centre's* Action Plan identifies three key areas for action:

- Driving a new regulatory culture in the European Commission.
- Developing and consolidating the organisational 'architecture' within which better regulatory processes are applied.
- Engaging all of the EU institutions in the drive to improve regulatory quality.

The Action Plan also identifies a number of the specific changes that are required to further improve the quality of legislation.

### 4.1. A New Regulatory Culture in the European Commission

The first key area for action is to change the basic approach to regulation among the officials, advisors and regulators working in and for the European Commission by:

- Appointing a Commission Vice-President with responsibility for Better Regulation.
- Publishing a formal and binding policy statement for Better Regulation.
- Providing an adequate level of well-trained resources to support the implementation of Better Regulation programmes.
- Enhanced the role of the SME Envoy.

**A Commission Vice-President with responsibility for Better Regulation:** A necessary pre-condition for improvement in regulatory quality is the establishment of clear accountability for regulatory reform at the highest political level within the Commission. This would ensure that:

- Better Regulation remains high on the political agenda of the Commission.
- The horizontal character of Better Regulation is preserved.
- Efforts to implement reforms are better co-ordinated.
- The effectiveness of the process is enhanced.
- Inter-institutional relations are promoted at the highest level.

The establishment of the new Commission of 25 members provides an opportunity to introduce such high-level change. Specific organisational recommendations are subject to the re-structuring of the college and the Commission services but the

Action Plan recommends entrusting the portfolio of Better Regulation to one of the Vice-Presidents. This Vice-President should have overall political responsibility for regulatory reform, but no direct responsibility for any operational DG or service.

Furthermore, regulatory reform must be one of the priorities of the new Commission President.

**A new formal and binding policy statement:** The work of the different DGs and services of the Commission has traditionally been highly compartmentalised. New DGs have emerged at different stages in the development of the Commission and have historically developed along different administrative patterns. The introduction of a new, common regulatory culture would assist in reducing these disparities, particularly as there will be a large number of new Commissioners in the new college.

In order to facilitate the development of a new regulatory climate, a unique, formal and binding policy statement underpinning Better Regulation should be issued. This statement should indicate the plans and strategies pursued by the Commission as a whole and formulate guidelines for the use of the Better Regulation tools.

**Adequate well-trained resources to support the implementation of Better Regulation programmes:** An adequate level of well-trained resources is another necessary pre-condition for improving regulatory quality. In particular,

- Individual DGs and services should be provided with adequate budgets to enable them to prepare IAs that meet the guidelines.
- The Commission has already organised training and information sessions but these need to be re-structured and extended. Some sessions should give greater emphasis on fostering internal co-ordination among officials from different DGs and services. Other sessions should target individual DGs and address specific, sectoral needs.
- Similar training programmes should be held for officials in the Council and the Parliament, for officials from Member States and MEPs.

**An enhanced role for the SME Envoy:** The SME Envoy should play a stronger advocacy role for SMEs within the Commission. In the preparatory phase, the SME Envoy should:

- Identify proposals specifically affecting SMEs.
- Facilitate the consultation of SMEs on these proposals.
- Make specific recommendations to the Lead DG(s) with the aim of responding to the concerns of SMEs.

The SME Envoy should also be responsible for finding solutions to complaints by SMEs about specific IAs and for advising the European Ombudsman on cases raised by SMEs. The SME Envoy should send an annual report to the Commission President and the European Parliament.

The Office of the SME Envoy should remain within DG Enterprise but he/she should enjoy greater visibility and autonomy. (He/she should be a Director-General directly reporting to the Commissioner).

To be effective, the SME Envoy should be provided with adequate resources.

## 4.2. Developing the Organisation

The second key area for action consists of developing and consolidating the organisational framework within which Better Regulation practices are applied. Good technical instruments and tools are unlikely to be effective unless they are applied in a consistent way within a structured institutional setting. Hence, specific organisations should be created to ensure the optimal implementation of the measures envisaged by the IIA.<sup>25</sup>

Two principal organisational changes are needed:

- The creation of a 'Regulatory Assessment Office' within the Commission.
- The establishment of a 'Regulatory Audit Bureau' within the Court of Auditors.

**The Regulatory Assessment Office:** While the primary responsibility for carrying out IAs should remain with the Lead DGs and the services that develop legislative proposals, a 'Regulatory Assessment Office' (RAO) should be established. This should be a separate regulatory unit within the central oversight group of the European Commission, e.g. in the Secretariat-General's office.

The responsibilities of the RAO should include:

- The establishment of binding quality standards.
- The establishment of common analytical methodologies.
- The provision of expert support and advice, to individual DGs.

Additionally, the RAO should be responsible for:

- Adjudicating on requests from Member States, the European Parliament and stakeholders for the production of an IA.
- Advising the Secretary-General on the validity of individual IAs. (The Secretary-General should be responsible for deciding whether to accept the IA, as conforming to the guidelines.)

- Establishing a series of Commission-wide training courses. These should include ‘technical’ training for the officials who are responsible for carrying out the IAs in individual DGs, and training on ‘the management of regulatory decisions’ for decision-makers, including members of the European Council and MEPs.
- Leading the network of experts who carry out the IAs in individual DGs, in order to transfer lessons between DGs, to facilitate the transfer of expert staff between DGs and to improve inter-service co-operation.

The RAO may need to employ specialist external advisors on an *ad hoc* basis. To make the best use of third party resources, it may be necessary to reform the personnel statute of the Commission.

The RAO should report directly to the Secretary-General, under the political leadership of the Vice-President for Better Regulation.

The RAO should be provided with an adequate budget to enable it to perform its tasks effectively.

**The Regulatory Audit Bureau:** A new ‘Regulatory Audit Bureau’ (RAB) should be established within the Court of Auditors, to oversee the operation of the IA process by all of the principal EU institutions.

The RAB should:

- Undertake audits of a sample of the IAs produced by individual DGs, to ensure that they meet the guidelines agreed by the EU and to learn the lessons from implementation (*ex-ante* analysis).
- Undertake comparisons of projected and actual regulatory impacts, over time (*ex-post* analysis).

In performing its monitoring and reporting tasks, the RAB should:

- Undertake a review of the implementation of the IA guidelines, each year.
- Present an Annual Report, to all the EU institutions.

The RAB should be provided with an adequate budget to enable it to perform its tasks effectively.

### 4.3. Engaging All EU Institutions

The third key area for action focuses on the need to make the new regulatory culture more pervasive in all the institutions involved in the EU decision-making.

**Roles and responsibilities:** The principal roles and responsibilities of each of the EU institutions should be described in mandatory guidelines.

The *IIA on Better Law-making* calls upon the Council and the European Parliament to accept greater responsibility for promoting Better Regulation. Both institutions should not only provide political input to the debate but also integrate new regulatory processes in their own organisations.

First, they should ensure that all EU decision-makers are aware of the benefits of high quality regulation. The Regulatory Assessment Office of the Commission, in collaboration with the Secretariats-General of the Parliament and the Council, should issue a set of comprehensive guidelines on regulatory quality requirements to MEPs and members of the Council.

Second, the Council and the Parliament should play a more significant role in the pre-legislative phase. In particular, they should play a more active role in developing the Annual Work Programme and in the consultation process. Moreover, both branches of the legislature should make greater use of public hearings. These should be mandatory for major issues and follow standardised procedures guaranteeing transparency and equity.

Third, the Council and the Parliament should upgrade their organisational structures and create internal bodies responsible for facilitating the Better Regulation process, including the preparation of IAs for major amendments.

**The European Parliament:** Parliament has already started work on a number of organisational initiatives:

- It has re-convened the High Level Technical Group on Inter-Institutional Co-operation that negotiated the IA to facilitate improvements in regulatory quality both on the technical and the political fronts.
- It is reforming DG 1 and 2 to enhance Parliament's role in programming legislative activity.
- It is likely to launching, in the wake of the *Doorn Report*,<sup>26</sup> internal discussions on the procedures needed to ensure that IAs on major amendments are carried out, including considering of the possibility of re-focussing the remit of the new "EP Policy Department" (formerly DG for Research) on IA to provide an in-house capability for undertaking such assessments.

These should be implemented promptly.

The role of the Parliament's Scientific and Technological Options Assessment unit (STOA) should also be reviewed and made more operational. STOA should be the central unit in the Parliament responsible for overseeing and communicating scientific advice to MEPs.

**The Council of the European Union:** The next Four Presidencies are committed to pursuing the Better Regulation agenda and the implementation of the IIA. They are proposing to enhance the roles of the Competitiveness Council and ECOFIN. But efforts should also be made to strengthen the co-ordinating role of the Secretariat-General of the Council.

The Secretariat-General of the Council should be responsible for:

- Improving the 'horizontal' co-ordination and consultation between the different Council organisations.
- Promoting the simplification of the procedures needed to adopt and publish legislative acts.
- Increasing transparency and improving the access to Council documents.

The Council Secretariat-General should also be responsible for supporting the tasks assigned to a new 'horizontal' Council Working Group on Better Regulation, which should be given responsibility for:

- Developing mechanisms for ensuring inter-institutional co-operation in the programming phase.
- Developing, jointly with the Commission and the Parliament, common methodologies to carry out IAs on major amendments.
- Serving as a centralised audit unit within the Council responsible for overseeing the quality of the assessments done on major amendments by the Council.

The Secretariat-General should be provided with adequate resources to achieve these objectives.

In addition, Council should seek to ensure a coherent and consistent approach to the work of Member States on Better Regulation. Co-operation between the European Ministers responsible for Public Administration should be enhanced and the ad hoc Group of Directors and Experts on Better Regulation (DEBR) should be formalised.<sup>27</sup>

The Competitiveness Council and ECOFIN should promote and support actions by the European Commission aimed at improving the monitoring of the application of EU legislation.<sup>28</sup>

Finally, Member States should be required to transpose and enforce EU legislation effectively and in a timely fashion.

## 4.4. Areas for Improvement

The Action Plan also identifies a number of changes that are required in specific areas to further improve the quality of legislation.

### Consultation

- **Overall rationale:** The consultation process should be formal and mandatory, and encompass the separate stages of the decision-making process. General principles and minimum standards for consultation should apply to the Council and the Parliament (and other EU institutions) as well as the Commission; and to the preparation of advice and rules from agencies and technical advisers and ‘soft laws’ as well as Directives and Regulations.
- **Participation:** The Commission should target those stakeholders most affected by the proposals. Time limits for participation should be set to 12 weeks for initial responses to written consultations. Time limits on subsequent consultations could be shorter (say 2-4 weeks).
- **Communication and Publication:** The Commission should link the ‘consultation’ process more closely with the ‘communication’ process. The Commission should publish, in multiple formats, lists of all the individuals and organisations that have been consulted, the results of the consultations and the responses of the Commission. Each Explanatory Memorandum should highlight the reasons why significant responses have been rejected. The memorandum should also include a measure of the extent to which responses were given in time.
- **Resources:** An adequate budget should be provided to the Commission to enable it to consult effectively.

Appropriate stakeholders (e.g. NGOs) should be provided with the necessary additional resources to enable them to respond constructively to consultation requests.

### Impact Assessment

The Commission should be obliged to complete preliminary IAs when proposals are submitted to the Secretariat-General for consideration and to publish them when the Work Programme is published. But the use of ex.IAs should be restricted to a small number of major political priorities.

Lead DGs should be responsible for carrying out IAs. Each should make a member of staff responsible for promoting and monitoring compliance with the good practices contained in the *Guidelines on Impact Assessment* issued by the Commission.

However, there should be checks and balances:

- Other Commission services and Member States should have an opportunity to input to draft IAs.
- Other stakeholders should have an opportunity to comment before IAs are finalised.
- The RAO should comment on all IAs produced by all DGs/services and publish lessons learned to all DGs/services.

The Commission should provide stakeholders and the public with a single access point for all IAs. This access point should be published on the website of the Secretariat-General in the Commission and should also be used to provide feedback to respondents.

The European Parliament and the Council should not consider Commission proposals if they are not accompanied by an IA that has been accepted by the RAO. They should also be responsible for up-dating IAs to take account of any major amendments they propose.

### **Risk Communication<sup>29</sup>**

- **Overall Policy Environment:** The 1996 *Regulatory Policy Guidelines* should be expanded to require that all Explanatory Memoranda include structured and balanced information about hazards and risks, where the legislative proposal covers the management of technological risks to public safety, human health, or the environment.
- **The Overall Policy Environment:** The 1997 *Risk Analysis Framework* should be revised to provide a framework for making predictable decisions about the assessment, management and communication of risks at EU level. The framework should form part of the 'Better Law-making Programme of the European Union'.

Coverage should be expanded to encompass all Scientific Advisory Committees and officials that provide policy, legislative or regulatory advice to decision-makers. At the same time, the content of the framework should be revised to strengthen the requirement for scientists to distinguish between hazards and risks in their advice to decision-makers.

The coverage of the *Guidelines on Impact Assessment* of the EU should be expanded to encompass risk-related issues.

- **Risk Communication Policy:** The EU institutions should establish a formal and binding policy statement for effective risk communication in policy-making; in the creation and review of legislation; and in the implementation of regulations.

The risk communication policy should be applied to all phases of the

‘regulatory cycle’ (policy development; policy decision-making; operational regulatory decision-making; crisis management; and policy review), all EU institutions including agencies (advisory; risk assessment; and risk management) and all formal and *ad hoc* scientific committees that provide advice to EU policy-makers.

- **Policy Formulation and Legislative Decision-making:** Mandatory guidelines should be developed to describe the scope and nature of information about risks (including their assessment and measurement) that must be communicated to decision-makers.

Mandatory quality standards for the provision of scientific advice to decision-makers should be developed.

- **Roles and Responsibilities:** The ‘Regulatory Audit Bureau’ should be responsible for monitoring and evaluating the implementation and effectiveness of the risk communication policy.

Academic institutes should be encouraged to undertake systematic *ex-post* analyses of the nature and effectiveness of the communication of information about hazards and risk between risk assessors, officials (policy-makers) and decision-makers at EU level, and its impact on risk management decisions.

- **Resources:** All Commission officials responsible for preparing legislative proposals, scientific advisers involved in risk analysis on behalf of the EU or its agencies and officials involved in supporting the Parliament and the Council in the decision-making phase should receive regular training in how to comply with the requirements of the new risk communication policy.

Similar training should be offered to MEPs, Commissioners, and Member State representatives involved in the comitology process.

## Implementation

- **Separation of powers:** The ambiguities about the distinction between legislative instruments and executive measures should be clarified. This will help to better define the legislative and the implementing competences.

The existing legal regime governing comitology committees, (scientific) advisory committees, and (regulatory) agencies should be clarified. Legislators should, however, be free to decide on the nature of the regulatory agencies within the provisions of the Treaty that constitute the specific legal basis for the policy to be regulated.

- **Subsidiarity:** The Commission should be the primary institution responsible for ascertaining subsidiarity both in the legislative and the implementing phases.

- **Simplification:** The comitology procedures should be further streamlined and their number reduced. The regulatory procedure should be replaced by the “*delegated act*” procedure foreseen in the *Draft Treaty Establishing a Constitution for Europe*. Comitology committees should merely have advisory functions.

- **Political accountability and transparency:** Greater political accountability and transparency should be introduced with regard to the selection and appointment of experts and the functioning of committees.

The involvement of national experts and civil servants in executive committees should, for certain subjects and in specific cases, be supplemented by an adequate consultation system.

All documents not subject to protection of data restrictions should be published in a timely fashion.

- **Judicial accountability:** The existing legal regime governing comitology committees, (scientific) advisory committees, and (regulatory) agencies should be clarified.

The ECJ case law on its jurisdiction on committees (and other delegated bodies) should be re-stated within the Treaty.

The juridical nature of committees and their use should be developed, codified and, if necessary, made judicially enforceable.

## 5. Conclusions and Recommendations

Since the early 1990s, a large number of reforms have been initiated by the Commission to enhance regulatory effectiveness in the EU. These have led to important improvements in the quality of the legislative process at the level of the EU.

However, the overall quality of EU regulatory activity remains sub-optimal for a number of reasons:

- There is no clear, well articulated vision of the regulatory reform process as a whole.
- There is no simple legal basis, and no legal requirement to undertake comprehensive IAs at EU level.
- There is no single, consolidated, legally binding statement of ‘Regulatory Management Policy’.
- There are few (quantitative) targets and time scales for achieving improvements in the regulatory process.
- There are no clear, mandatory guidelines that specify how and when assessments should be carried out; no single set of administrative procedures and

tools for undertaking them; and no sanctions for failing to provide them.

- Businesses are concerned that the IA process does not give sufficient emphasis to the impact of regulatory changes on competitiveness, particularly among SMEs.
- NGOs are concerned that the new IA process does not give sufficient weight to environmental and social factors.
- There is no requirement for the Commission to undertake systematic *ex post* analyses of the actual impact of regulations.
- The Commission Secretariat-General has no power to reject legislative proposals that do not satisfy basic standards for impact assessments.
- The institutions have not yet adequately addressed the issue of the resources and skills required for the effective planning and implementation of regulatory reforms, including IAs.
- The initiative lacks external credibility because many stakeholders do not consider that the process is sufficiently independent.

However, the greatest problem is that these initiatives have failed to instil a sound 'regulatory culture' because they conflict with the tradition of the Commission that it is the responsibility of 'expert' officials to make impartial recommendations to decision-makers, in the best long-term interest of society.

This Action Plan identifies three main aspects on which additional effort should be focused:

- The promotion of a new regulatory culture within the Commission.
- The development of Better Regulation practices within the other institutions.
- The internal re-organisation of the regulatory process in all the EU institutions.

The Action Plan also identifies a number of improvements that are required in specific areas to further improve the quality of legislation.

## Endnotes

- 1 Presidency Conclusions, Lisbon European Council, 23/24 March 2000, Point 17.
- 2 Presidency Conclusions, Göteborg European Council, 15/16 June 2001.
- 3 European Commission, *White Paper on European Governance*, COM(2001) 428 final; and [http://www.europa.eu.int/comm/governance/governance\\_eu/index\\_en.htm](http://www.europa.eu.int/comm/governance/governance_eu/index_en.htm).
- 4 Mandelkern Group on Better Regulation, *Final Report*, November 2001.
- 5 [http://www.funzionepubblica.it/docs\\_pdf/MTP%20final%20ing.pdf](http://www.funzionepubblica.it/docs_pdf/MTP%20final%20ing.pdf).
- 6 Presidency Conclusions, Seville European Council, 21/22 June 2002, Point 9.
- 7 Presidency Conclusions, Brussels European Council, 25/26 March 2004, Point 23.
- 8 *Joint Initiative of Regulatory Reform*, an Initiative of the Irish, Dutch, Luxembourg and UK Presidencies of the European Union, 26 January 2004.
- 9 [http://europa.eu.int/comm/enterprise/enterprise\\_policy/gov\\_relations/internatl\\_regul\\_coop\\_eu\\_us/regul\\_coop\\_guide.htm](http://europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/internatl_regul_coop_eu_us/regul_coop_guide.htm).
- 10 <http://europa.eu.int/en/agenda/eu-us/pub/pr/annex2.html>.
- 11 [http://www.europa.eu.int/comm/enterprise/enterprise\\_policy/gov\\_relations/canada/joint\\_action\\_plan.htm](http://www.europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/canada/joint_action_plan.htm)
- 12 For an overview of the international regulatory cooperation, see [http://www.europa.eu.int/comm/enterprise/enterprise\\_policy/index.htm](http://www.europa.eu.int/comm/enterprise/enterprise_policy/index.htm).
- 13 [http://www.europa.eu.int/comm/enterprise/entrepreneurship/sme\\_envoy/index.htm](http://www.europa.eu.int/comm/enterprise/entrepreneurship/sme_envoy/index.htm).
- 14 Adopted by the Council of the European Union on 13 June 2000 and endorsed by the Feira European Council on 19/20 June 2000.
- 15 European Commission, Communication on Simplifying and Improving the Regulatory Environment, COM(2001)726 final, p.5.
- 16 OJ C 73, 17 March 1999, p.1.
- 17 [http://europa.eu.int/eur-lex/en/about/techleg/guide/index\\_en.htm](http://europa.eu.int/eur-lex/en/about/techleg/guide/index_en.htm).
- 18 For instance, [http://www.europa.eu.int/comm/secretariat\\_general/sgc/acc\\_doc/index\\_en.htm](http://www.europa.eu.int/comm/secretariat_general/sgc/acc_doc/index_en.htm).
- 19 Statistics show that the number of requests for access to documents has doubled since the introduction in December 2001 of EU Regulation 1049/2001.
- 20 [http://www.europa.eu.int/comm/sustainable/docs/ia\\_guidelines\\_en.pdf](http://www.europa.eu.int/comm/sustainable/docs/ia_guidelines_en.pdf).
- 21 For a detailed assessment on updating and simplifying, see COM(2003)623 final; SEC(2003)1085, 24 October 2003; and Annex 5 to COM(2003) 770 final.
- 22 European Commission, *Report on the Implementation of the Internal Market Strategy (2003-2006)*, COM(2004) 22 final.
- 23 Frank Vibert, *The EU's New System of Regulatory Impact Assessment - A Scoreboard*, The European Policy Forum, March 2004.
- 24 OJ C 321, 31 December 2003, p.1.
- 25 For a more detailed analysis, see Bruce Ballantine, *Regulatory Impact Analysis: Improving the Quality of EU Regulatory Activity*, EPC Occasional Paper, September 2001.
- 26 European Parliament, *Report on Assessment of the Impact of Community Legislation and the Consultation Procedures*, 23 March 2004.
- 27 Along the lines of the *Mid-Term Programme 2004-2005* mentioned in Footnote 5 above. The first DEBR *Report to the Ministers Responsible for Public Administrations in the EU Member States on the Progress of the Implementation of the Mandelkern Report's Action Plan on Better Regulation* (Athens, May 2003) was presented to the Greek Presidency in June 2003.
- 28 An overview of the actions undertaken by the Commission is given in the European Commission, *Report*

on *Better Law-making 2003*, COM(2003) 770 final, p.9; and in its *Report on the Implementation of the Internal Market Strategy (2003-2006)*, COM(2004) 22 final.

29 For a more detailed analysis, see Bruce Ballantine, *Improving the Quality of Risk Management in the European Union: Risk Communication*, EPC Working Paper 5, June 2003.

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