



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.12.2003  
COM(2003)770 final

**REPORT FROM THE COMMISSION**

**“BETTER LAWMAKING 2003”**

**pursuant to Article 9 of the Protocol  
on the application of the principles of subsidiarity and proportionality**

**(11th REPORT)**

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## 1. INTRODUCTION

Improving legislative processes and output is a permanent challenge for the Union. It calls for mutually supporting actions. One is to ensure **compliance with the principles of subsidiarity and proportionality**. Another is to work on the **quality and accessibility of Union legislation**.

Since December 1992, the Commission is required to report annually to the European Council on the application of subsidiarity and proportionality, as defined in Article 5 of the EC Treaty<sup>1</sup>. More recently, the Union has been devoting increasing attention to better regulation in a wider sense, in particular the quality and accessibility of the Union legislation.

The present eleventh report<sup>2</sup> on “Better Lawmaking” reflects these developments and puts special emphasis on the important “better regulation” efforts that have been made in the Union in 2003<sup>3</sup>.

The report is divided into two parts. The first part is dedicated to the general framework for better regulation. It reviews the implementation in 2003 of the Commission’s Action Plan “simplifying and improving the regulatory environment”<sup>4</sup>. It also reviews progress achieved by the institutions, in particular the adoption by the European Parliament, the Council and the Commission of an Inter-Institutional Agreement (IIA) on Better Lawmaking.

The second part of the report focuses on the application of the principles of subsidiarity and proportionality. It offers an overview of the legal and institutional framework and provides an assessment of how the Commission applies these principles in executing its right of initiative, and how the European Parliament and the Council apply them when amending proposals.

This presentation in two separate parts does not mean that compliance with the principles of subsidiarity and proportionality and implementation of better regulation are unrelated. On the contrary, they are intimately linked as the measures introduced to improve regulation should make for better compliance with the principles of subsidiarity and proportionality, and vice versa. This structure was only chosen because it allows for a systematic review of the very substantial efforts now underway in the Union to improve the quality and accessibility of legislation.

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<sup>1</sup> The request of the Edinburgh European Council of December 1992 was subsequently incorporated into the inter-institutional agreement on procedures for implementing the principle of subsidiarity of 1993 and into the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty of Amsterdam (1997).

<sup>2</sup> The references of the previous reports are listed in the footnote of Annex 1.

<sup>3</sup> It should be noted that the report was finalised in time for presentation to the meeting of the European Council to be held in December 2003. The report is therefore based on the evidence available by early November 2003.

<sup>4</sup> Hereafter referred to as the Action Plan. COM(2002)278 of 5 June 2002.

## 2. BETTER REGULATION

### 2.1. The general context

The institutions of the Union have repeatedly acknowledged the importance of improving the regulatory environment<sup>5</sup>. It is to the benefit of EU citizens to live in a more effective, efficient and transparent system. It also creates favourable conditions for economic competitiveness, growth, employment and sustainable development.

The Commission's 2002 Action Plan and the subsequent communications detailing it constitute the most comprehensive and ambitious efforts yet in pursuit of these objectives.

However, no strategy for better regulation can fully succeed without the strong and continued political commitment of all the institutions of the Union and the Member States. The Commission has a special responsibility at three levels: preparation, follow-up and implementation of the legislation. The European Parliament and the Council have an equally important responsibility when deliberating, amending and adopting proposals. Ideally, agreements on new legislation should not be achieved at the cost of unduly complex solutions that lower the legislative quality. The Member States have an important role to play insofar as they are responsible for applying and, in the case of directives, transposing Community legislation at national level.

Improving the regulatory environment to obtain concrete benefits for citizens is therefore the **joint responsibility of the European Parliament, the Council, the Commission and the Member States**, regardless of whether the concrete actions can be undertaken by each of these actors individually or need to be implemented jointly.

When launching its Action Plan, the Commission therefore not only outlined action that it intended to take on its own responsibility but also called on the other institutions and the Member States to contribute to achieving the objectives, either individually or in conjunction with the Commission. In particular, for those actions that require co-ordinated or joint implementation by the institutions, the Commission proposed establishing an inter-institutional agreement.<sup>6</sup>

The following sections review the main developments in 2003. The presentation is structured according to the key players (Commission, institutions, Member States). The section covering the Commission's activities is the longest. This reflects the fact that, at this point in time, it is mainly the Commission that has committed itself on concrete actions and objectives. The other institutions and Member States are progressively becoming involved in better regulation issues and developing their own positions and policies, which will increasingly have to be juxtaposed with those of the Commission.

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<sup>5</sup> Latest by the Brussels European Council of October 2003 (Conclusions of the presidency, European Council of 16-17 October 2003, point 20 on Better regulation).

<sup>6</sup> See section 2.3.

## 2.2. Actions taken by the Commission

Inspired by the reactions to the Commission's White paper on European Governance<sup>7</sup> and the resolution adopted by the European Parliament in the wake of the Kaufmann report<sup>8</sup>, while bearing in mind the recommendations of the intergovernmental "Mandelkern Group"<sup>9</sup>, the Commission proposed in June 2002 a comprehensive framework for 'better lawmaking' and an action plan for 'simplifying and improving the regulatory environment'<sup>10</sup>.

During 2002 and in early 2003, the Commission developed this action plan through 8 targeted Communications, while defining in parallel with the European Parliament and the Council an overall strategy on better lawmaking. The formulation of detailed Commission policies and the interinstitutional negotiation have now been successfully completed. Since mid-2003, the Commission's focus has consequently shifted fully towards implementing the new procedures and practices.

The Commission's initiatives fall broadly into two categories: measures aimed at *better preparation* of Community legislation and *closer monitoring of the adoption of Union legislative acts*, on one hand, and measures aimed at *better implementation* of Community policies, on the other.

The key measures related to better preparation include (1) minimum standards of consultation; (2) new guidelines on the collection and use of expertise; (3) impact assessment; (4) more attention to the choice of instruments; (5) use of a review clause in legislative acts; and (6) use of the possibility to withdraw proposals when they are obsolete or when amendments introduced by the Parliament and/or the Council denature the proposals.

Better implementation is mainly pursued through (1) improving the quality of policy implementation through better adapted instruments; (2) up-dating and simplifying existing legislation; and (3) stepping up checks on the transposition of Community law.

Given the scope of the present report, only the key actions and developments are reviewed – and even then in summary form. Accompanying actions, such as the upgrade of the explanatory memorandum that accompanies each Commission proposal<sup>11</sup> or improved co-ordination mechanisms, are not covered.

### a) New standards for public consultation

In **2003**, the Commission produced **5 Green Papers and 142 Communications**. It also published **73 reports** and organised **60 Internet consultations** through "Your

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<sup>7</sup> COM(2001)727, 25 July 2001.

<sup>8</sup> Report on the Commission White Paper on European Governance, A5-0399/2001, adopted by the European Parliament on 29 November 2001 (OJ C 153E, 27 June 2002, pp.314-322.

<sup>9</sup> Adopted in November 2001. See <http://ue.eu.int/pressData/en/misc/DOC.68853.pdf>

<sup>10</sup> COM(2002)275 of 5 June 2002 and COM(2002)278 of 5 June 2002.

<sup>11</sup> The explanatory memorandum is the way the Commission presents and explains its proposal. New drafting rules have been prepared in the light of the new undertakings made in the Commission's Action Plan and in the Inter-institutional Agreement on better lawmaking. They should be approved by the Commission before the end of 2003.

Voice In Europe”, the Commission’ single access point for consultation<sup>12</sup>. These figures show how serious the Commission is about providing full information about its activities and policy reflection and about consulting<sup>13</sup>.

To better identify the need for an action, expectations and types of action to be taken, the Commission has introduced **minimum standards for its public consultation**<sup>14</sup>. Based on a review completed by 3 November 2003, the Commission observes that minimum standards regarding publication on the single access point, time limits for responses and report on the results have been properly applied in almost all cases. Special effort, however, still needs to be made to improve feedback to contributors. In a limited number of cases, delay in the adoption of a proposal was attributed to the application of the standards.

#### **b) The new impact assessment procedure**

In 2002, the Commission adopted a new method of assessment for all major Commission initiatives, that takes into account not only the economic impact, but also the social and environmental impact of the proposal concerned<sup>15</sup>. It consists of two main steps: a Preliminary Impact Assessment and, for a selected number of significant proposals, a more in-depth analysis called **Extended Impact Assessment (Ex-IA)**.

Quantitatively speaking, the Commission’s estimate is that approximately 50 % of the Ex-IA initially planned will be completed by the end of December 2003<sup>16</sup>. This relatively low implementation rate seems to be part of a general problem linked to optimistic planning of the Commission Work Programme for 2003, lack of resources and political difficulties. In a limited number of cases, however, Commission services reported that Ex-IAs contributed to delay the adoption of proposals. An extended impact assessment is a demanding exercise and services have had to adapt to the new procedure.

Qualitatively speaking, the direct and indirect consequences of the introduction of the new procedure were largely positive: it facilitated inter-service co-ordination, prompted the Commission and its services to “think outside the box” and contributed significantly to identifying more balanced solutions.

On the basis of this trial year, it appears that the Commission needs to address a number of teething problems. First, environmental and social impacts of proposals need to be fully developed. Second, Ex-IAs should include more thorough discussion of the principles of subsidiarity and proportionality, in particular of the respective merits of different regulatory approaches. Third, analyses tend to focus on one policy option. Policy alternatives should be examined more thoroughly. Fourth, there is so far limited quantification, let alone monetisation, of the impacts. This is obviously one of the most difficult part of the exercise. Fifth, effort should be made to rendering Ex-IAs more accessible to the general public.

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<sup>12</sup> See [http://europa.eu.int/yourvoice/consultations/index\\_en.htm](http://europa.eu.int/yourvoice/consultations/index_en.htm).

<sup>13</sup> For a detailed assessment on public consultation in 2003 and the new consultation procedure, see Annex 2.

<sup>14</sup> COM(2002)704, 11 December 2002.

<sup>15</sup> COM(2002)276, 5 June 2002.

<sup>16</sup> For a detailed assessment on Ex-IA, see Annex 3.

In order to address these quantitative and qualitative shortcomings, the Secretariat General together with other horizontal Commission Directorates-General will push forward a range of new initiatives detailed in Annex 3.

**c) New guidelines on the collection and use of expertise**

Following the commitment made in the White Paper on European Governance and the Commission's Science and Society Action Plan, the Commission adopted in December 2002 a Communication defining principles and guidelines that encapsulate **good practices regarding expertise**<sup>17</sup>. Promoting quality, openness and effectiveness, these practices apply whenever Commission departments collect and use advice from external experts.

Implementation of the new guidelines has started at various levels. First, the need for maximum openness has been taken into account in the definition of the new "standard explanatory memorandum" and the framework for "extended impact assessment". In addition, initiatives aimed at widening and systematising the collection of expertise in specific domains have been taken. In particular, the Commission has made significant progress regarding "Scientific Support for Policies", one of the priorities of the sixth Framework Programme for R&D (2002-6). The SINAPSE e-network (Scientific INformAtion for Policy Support in Europe) has been developed and the pilot phase will be launched early 2004<sup>18</sup>.

**d) Updating and simplifying the Community *acquis***

With the framework action "**Updating and simplifying the Community *acquis***"<sup>19</sup> adopted in February 2003, the Commission launched an ambitious programme to ensure that Community legislation is clear, understandable, up-to-date and user-friendly.

The results of the first phase of implementation of the framework action are mixed but not unsatisfactory<sup>20</sup>. Completion of the consolidation programme is a major service for the ultimate benefit of citizens and operators. Another key achievement is the progressive involvement of different services in efforts to simplify legislation because it demonstrates that a change of regulatory culture is taking place. The weak points mainly concern the short and medium-term actions to reduce the volume of Community legislation (codification and elimination of outdated legislation). However, the Commission is satisfied that the process launched in February 2003 appears to be taking a firm foothold and should continue to produce benefits for citizens and other users of Community legislation.

**e) Choice of instruments**

In its 2002 Action Plan, the Commission stressed the need to pay more attention to the choice of instruments to pursue Treaty objectives and implement Community policies.

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<sup>17</sup> COM(2002)713, 11 December 2002.

<sup>18</sup> For a detailed assessment on collection and use of expertise in 2003, see Annex 4.

<sup>19</sup> COM(2003)71, 11 February 2003.

<sup>20</sup> For a detailed assessment on updating and simplifying, see COM(2003)623 and SEC (2003)1085, 24 October 2003, as well as Annex 5.

First, the Commission proposed reverting to the original definition of a directive<sup>21</sup> by limiting directives to the essential aspects of establishing a legal framework and objectives to be met while leaving the attainment of these objectives more to the Community executive and Member States.

Secondly, the Commission suggested that, besides ‘classical’ instruments such as regulations and directives, the Union could consider using other instruments which may be more flexible and efficient under certain circumstances. As these instruments are not defined in the Treaty, the Commission proposed referring to them as “**alternative instruments**”. On several recent occasions, the European Parliament and/or the Council have questioned or even opposed Commission proposals using such alternative instruments<sup>22</sup>. In other cases, one or both branches of the legislative have invited the Commission to abandon the idea of a directive in favour of “soft-law” solutions such as recommendations. With the IIA on better lawmaking, the three institutions have for the first time established common definitions and agreed on conditions and procedures for use of co-regulation and self-regulation.

Thirdly, the Commission argued in its White Paper on European Governance in favour of **Community agencies** under appropriate circumstances. In order to safeguard fundamental institutional and functional aspects and to facilitate decision-making on the creation of specific agencies, the Commission invited the other institutions to assist in the development of a framework for the so-called regulatory agencies, i.e. those with a direct and formal role in Community regulation<sup>23</sup>. While the inter-institutional discussions on the Commission’s proposed framework have advanced only slowly, the number and importance of agency proposals under discussion has confirmed the underlying trend. Thus, during 2003, the Commission launched proposals for the creation of four new regulatory agencies<sup>24</sup> while the European railway agency was still under inter-institutional negotiation.

Finally, the Commission has proposed **target-based tripartite contracts and agreements** between the Community, the States and regional or local authorities as a flexible way of taking account of specific contexts when framing and implementing Community policies<sup>25</sup>. The basic idea is to empower sub-national authorities to implement specific actions aimed at achieving objectives defined in the Union legislation. The experimental phase was launched in 2003. The Commission decided to go ahead with three pilot projects put forward by local authorities and enjoying the support of the respective Member States<sup>26</sup>. The results will feed the reflection of the Commission on the use of this instrument.

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<sup>21</sup> Article 249 TEC “A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.”

<sup>22</sup> See section 3.3.b).

<sup>23</sup> COM(2002)718, 11 December 2002.

<sup>24</sup> European Agency for the Management of Operational Co-operation at the External Borders; European Centre for Disease Prevention and Control; European Network and Information Security Agency ; European Chemicals Agency.

<sup>25</sup> See the White paper on European governance and COM(2002)709, 11 December 2002.

<sup>26</sup> Birmingham (UK) on urban mobility, Lille (France) on the management of urban greenfield areas, and Pescara (Italy) on urban mobility and air quality



**f) Better monitoring of the application of Community law**

It is the Commission's responsibility to verify that Community legislation is properly implemented and ensure, in close cooperation with Member States, that the legislation's impact is in line with its objectives. Having codified the administrative measures concerning the processing of complaints<sup>27</sup>, the Commission adopted in December 2002 a Communication setting out a series of actions aimed at improving the monitoring of the application of Community law<sup>28</sup>.

Several specific measures are currently being introduced in the Commission's monitoring system. The Commission now systematically includes a provision in draft directives, requiring Member States to notify the Commission of structured and detailed information on how Community law has been transposed into national law (so-called transposition concordance tables). This information is essential for the Commission's monitoring of timely and correct transposition.

Moreover, an on-line site called "calendar for transposition of directives"<sup>29</sup> now allows Member States and citizens to consult on a regular basis the deadlines applicable for transposition of Community directives. This instrument also make for better programming of transposition by the national authorities and should contribute significantly to avoiding infringements procedures for failure to comply with Community law.

The new electronic standard form for notification of national transposition measures is currently being implemented by the Commission's services. A new interface integrated in the Commission's ASMODEE II database (management of Member States' transpositions) will allow national administrations to connect directly to the non-confidential part of the Commission's internal data<sup>30</sup>.

The Commission's annual report on the monitoring of the application of Community law goes into these and related items in greater detail. It will be a complete source of information on transposition and Commission's management of the infringement procedures in 2003.

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<sup>27</sup> COM(2002)141, 20 March 2002.

<sup>28</sup> COM(2002)725, 11 December 2002.

<sup>29</sup> See [http://europa.eu.int/comm/secretariat\\_general/sgb/droit\\_com/index\\_en.htm#echeancier](http://europa.eu.int/comm/secretariat_general/sgb/droit_com/index_en.htm#echeancier)

<sup>30</sup> The Secretariat General of the Commission also provides bimonthly information on Member States notifications of national measures of implementation ([europa.eu.int/comm/secretariat\\_general/sgb/droit\\_com/index\\_fr.htm#transpositions](http://europa.eu.int/comm/secretariat_general/sgb/droit_com/index_fr.htm#transpositions)). Besides, in the run up to EU enlargement, the Commission's services have allowed new Member States access to a new database on pre-notification which gives information on the parts of the "Community *acquis*" that have been already transposed.

## g) Other actions

### *Quality of drafting*

In December 1998, the three institutions involved in the legislative process adopted the Inter-institutional Agreement on common guidelines for the quality of drafting of Community legislation<sup>31</sup>.

Over the last five years, the following measures have been taken in pursuance of that agreement. The Parliament, the Council and the Commission have drawn up and published a Joint Practical Guide for persons involved in the drafting of legislation. The Commission's internal procedures have been organised to permit the Legal Service to make drafting suggestions at an early stage in the process. Training in legal drafting has been organised. Besides the departments responsible for ensuring drafting quality in the European Parliament, the Council and the Commission expanded their collaboration. Cooperation with the Member States was also enhanced through seminars on legislative quality<sup>32</sup>.

### *Review and revision clauses*

In its June 2002 Action Plan, the Commission stated that, without prejudice to its right of initiative, it will take steps to add, where appropriate, a *review clause*, or even a revision clause, to its legislative proposals, particularly those which are subject to rapid technological change, so that legislation can be updated and adjusted regularly.

In policy areas or sectors including environment<sup>33</sup>, energy<sup>34</sup>, automobile<sup>35</sup> and chemicals<sup>36</sup>, clauses referring to future adaptation to technical progress were added almost systematically. Revision clauses were also included in the Commission's proposals regarding intellectual property and immigration<sup>37</sup>.

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<sup>31</sup> OJ C 73, 17 March 1999, p.1.

<sup>32</sup> For a detailed assessment on quality of drafting, see Annex 6.

<sup>33</sup> Monitoring Mechanism Decision COM(2003)51, 5 February 2003; Fluorinated greenhouse gases regulation COM(2003)492, 11 August 2003; Registration, evaluation, authorisation and restriction of chemicals (REACH) COM(2003)644, 29 October 2003.

<sup>34</sup> Proposal on Eco-design requirements for Energy-Using Products COM(2003)453 of 1 August 2003.

<sup>35</sup> For instance, the proposal on the approval of motor vehicles and their trailers (COM(2003)418, 14 July 2003) provides that, no later than 31 March 2007, the Member States will have to inform the Commission on the application of the type-approval system and, where appropriate, the Commission shall propose the amendments deemed necessary to improve the type-approval process.

<sup>36</sup> For instance, the proposed Regulation concerning cadmium in fertilizers, (2003/ENTR/40) contains a revision clause allowing account to be taken of developments in the treatment of phosphate in view of minimising the rate of cadmium.

<sup>37</sup> Council Directive 2003/86/EC of 22 September 2003 on the right to family reunification (OJ L 251, 3 October 2003, p.12) and Council Directive concerning the status of third country nationals who are long-term residents (COM(2001)127, 13 March 2001; political agreement reached in Council on 5 June 2003).

### *Withdrawal of pending proposals*

The Commission remains committed to make greater use of the possibility of withdrawing proposals whenever they have become non-topical. For that purpose, the Commission periodically withdraws series of pending proposals and plans to repeat the exercise in 2004<sup>38</sup>.

In its Action Plan, the Commission announced that, besides 'routine' withdrawal, it will consider resorting to more political withdrawal. It intends exercising its right of initiative through withdrawal of individual proposals whenever the amendments introduced by the Council and the European Parliament change the nature of the proposal or introduce complexity which is incompatible with the provisions of the Treaty. No such case has been reported in 2003.

### **2.3. Action at the level of Community institutions**

Improving the quality of Community legislation requires close collaboration among all institutions involved in the legislative process, starting with the European Parliament and the Council.

Following the invitation made by the European Council of Seville in June 2002, the European Parliament, the Council and the Commission agreed on an **Inter-institutional Agreement on better lawmaking**. This agreement should be adopted and enter into force before the end of 2003. The main objectives of the agreement are to improve the quality of Community legislation and its transposition into national law. The agreement entrenches best practices and sets out new objectives and commitments. The main elements of the agreement include:

- Improvement of inter-institutional co-ordination and transparency. The three institutions will reinforce their coordination through their respective annual legislative timetables with a view to reaching agreement on joint annual programming. Besides, the Commission and the Council undertake to increase their presence and participation in discussions at European Parliament committee meetings and plenary sittings.
- Stable framework for 'soft law' instruments that should facilitate their future use. The three institutions have for the first time established a common definition of co-regulation and self-regulation<sup>39</sup>. They also agreed on general limits and conditions to the use of those methods, defining the role of each institution in the process and ensuring that the prerogatives of the legislative authorities are respected. In particular, co-regulation and self-regulation "will not be applicable where

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<sup>38</sup> The last exercise led to the withdrawal of more than 100 proposals.

<sup>39</sup> The Inter-institutional Agreement on better lawmaking provides the following definitions: Co-regulation: "... the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, NGOs or associations)"; Self-regulation: "the possibility for economic operators, the social partners, NGOs or associations to adopt amongst themselves and for themselves common guidelines at European level (particularly codes of practices or sectoral agreements)". The rules on the functioning of the social dialogue (Articles 138 and 139 TEC) and standardisation according to the "New Approach" are not affected by this agreement.

fundamental rights or important political options are at stake or in situations where the rules must be applied in a uniform fashion in all Member States". Under co-regulation, following notification of a draft agreement prepared by interested parties, the Parliament and the Council will have the right to suggest amendments to the agreement, object to its entry into force and, possibly, ask the Commission to submit a proposal for a legislative act. As for self-regulation, the Commission will keep the Legislators informed by reporting on the practices it regards as effective and satisfactory in terms of representativeness.

- Increased use of impact assessment in Community decision-making. Where the codecision procedure applies, the Parliament and the Council may have impact assessments carried out prior to the adoption of any substantive amendment. The three institutions will also examine the possibility of establishing a common methodology on the basis of experience gained.
- Commitment to set a binding time limit for the transposition of the directives into national law. Each directive should indicate that time limit which should be as short as possible and generally not exceed two years.

The Commission welcomes this agreement as broadly coherent with the initiatives set out in its June 2002 Action Plan. It marks the most ambitious effort yet undertaken to improve regulation by associating the three institutions in an overall strategy for better lawmaking at EU level, while respecting the responsibilities of each institution.

In its June 2002 Action Plan, the Commission also proposed the **creation of a legislative network between the Community institutions** to ensure the quality of legislation. The Commission notes with satisfaction that the existing High-Level Technical Group on Inter-institutional Cooperation will be responsible for implementing and monitoring the agreement.

The IIA on better lawmaking only entered into force in December 2003. It is therefore too early to make a detailed assessment of its impact. In the course of its **implementation**, the Commission intends in particular to pay special attention to:

- procedures for adoption of **simplification** proposals. The IIA acknowledges the importance of simplifying Community secondary legislation, in line with the approach proposed by the Commission. Although it was not possible to agree on concrete procedural rules for inclusion in the IIA, it provides that within 6 months of its entry into force the European Parliament and the Council will modify their working methods by introducing for instance ad hoc structures with the specific task of simplifying legislation.
- the possibility of establishing a common methodology concerning impact assessment, after a review of the respective experiences of the three institutions in this domain.

The IAA complements **three other inter-institutional agreements of importance to better regulation**. The first is the Inter-institutional Agreement of 22 December 1998 on common guidelines for the **quality of drafting** of Community legislation (see above Section 2.2.g).

The second is the Inter-institutional Agreement of 20 December 1994 on an accelerated working method for official **codification** of legislative texts<sup>40</sup>. The Agreement provides a framework for the codification of Community law, but the results have been disappointing. This is largely due to the fact that, despite it being a purely technical exercise, the normal legislative process applies in full. Several years can therefore pass between the preparation of the Commission's proposal for a codified act and its adoption. Although the Agreement refers to an accelerated procedure, only the committee procedures within the European Parliament and the Council have been streamlined. The time has perhaps come, nine years after the Agreement's adoption, for the institutions to examine ways of establishing a truly accelerated procedure for this type of non-controversial legislation.

The third existing Inter-institutional Agreement on a more structured use of the **recasting** technique for legal acts<sup>41</sup> entered into force in March 2002. The Agreement provides for techniques to clearly identify the substantially new elements of draft legislation from those parts of legislation that are only proposed for codification. The Commission's informatics tool conceived specially for recast acts (Legiswrite Codification/Refonte) has been further improved and is in the process of being approved by the Council. The Commission has already adopted several major legislative initiatives pursuant to this Agreement, and these proposals are now being examined by the legislative authority. A correct and efficient application of the Agreement in these pioneering cases should encourage further use of recasting.

Finally, the Commission also envisages to develop a common approach with the other institutions on the **collection and use of expertise**. The ambition of the Commission is that, over time, its guidelines could form the basis for a common approach for all Institutions and Member States<sup>42</sup>. Considering that the guidelines are progressively being put into use by Commission departments, it is too early to identify and codify good practices that could possibly be applied by the other institutions.

#### **2.4. Actions taken by the Member States**

Member States have an important role to play in better lawmaking insofar as they are responsible for applying and, in the case of directives, transposing Community legislation at national level. The Lisbon European Council of March 2000 underlined the importance of their contribution in the perspective of establishing a complete and fully operational internal market<sup>43</sup>.

Subsequently, Member States launched an inter-governmental exercise to develop guidelines for collaboration among themselves. In November 2001, the "Mandelkern Group" presented its recommendations which were endorsed by the Laeken European Council of December 2001. In May 2002 in La Rioja, the Ministers responsible for

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<sup>40</sup> OJ C 102, 04 April 1996, pp. 2-3

<sup>41</sup> OJ C 077, 28 March 2002, pp. 1-3.

<sup>42</sup> Objective stated in the White paper on European Governance and in the Science and Society Action Plan of December 2001.

<sup>43</sup> The Member States have been asked to set out at national level "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 (Presidency conclusions, Lisbon European Council of 24 March 2000, point 17).

public administration adopted a specific mid-term programme partially dealing with better regulation.

Concurrently the Commission has called on Member States to assume their responsibility when it comes to simplifying and improving European regulatory environment. This concerns primarily transposition of Community legislation (as discussed under section 2.2.f) but also covers<sup>44</sup>:

- Impact assessments and public consultations. Following the recommendations of the Mandelkern Group, the Commission has encouraged Member States to carry out impact assessments of draft national legislation notified to it<sup>45</sup>. In line with the strategy defined at the Lisbon European Council, Member States should also ensure that Community acts are transposed in their national legislation correctly and within the set deadline. For that purpose it has been recommended that Member States consult on and evaluate the merits of the various approaches for reaching the objectives set by a directive. Clear standards of consultation and impact assessment were also seen as indispensable. By analogy with what is required from EU institutions, the Commission has particularly stressed the need for Member States to hold consultations and make impacts assessments before submitting EU legislative proposals, in order to ensure appropriate quality<sup>46</sup>.
- Contribution to the Commission's actions in favour of better regulation, including on simplification and transposition of Community legislation.
- Development of good co-ordination between the Commission and the Member States.

The available evidence concerning Member State efforts towards better regulation does not allow a detailed comparison or assessment of progress across Member States. The first attempt to provide a coherent and comparable analysis of Member States' work was made in June 2003 by the Greek Presidency<sup>47</sup>. The picture is as follows:

- The majority of the Member States have introduced and implemented **horizontal policies on better regulation**.
- As far as the **transposition of the European legislation** is concerned, methods and allocation of responsibilities<sup>48</sup> remain quite different.

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<sup>44</sup> Section 3 of the Action Plan, COM(2002)278.

<sup>45</sup> Notifications under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, OJ L 204 of 21 July 1998 (modified by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217 of 5 August 1998).

<sup>46</sup> Member States have a right of initiative concerning police and judicial cooperation in criminal matters (title VI TEU).

<sup>47</sup> Report to the Ministers responsible for Public Administration in the EU Member States on the progress of the implementation of the Mandelkern Report's Action Plan on Better Regulation, ad hoc Group of Directors and Experts on Better Regulation (DEBR), Athens, May 2003.

<sup>48</sup> In some cases the line Ministries are responsible, while in others, the Ministries of Foreign Affairs are supervising the process.

- The majority of Member States have developed standard procedures for **impact assessment**. In some cases, impact assessment is compulsory for new legislative initiative. But there are still questions about quality and systematic use.
- As for **public consultation**, Member States are generally introducing more systematic procedures. However, practices still vary considerably at different levels: consultation is not always compulsory; the time given to respondents ranges from 3 to 12 weeks; publication and use of results also vary. Not all Member States use the Internet for public consultation but it seems that its use is expanding.
- Over the past few years significant efforts to **simplify** existing legislation have been introduced in many Member States. Most now have simplification programmes (often meant to help SMEs), if not comprehensive simplification policies. Member States acknowledged that their widely differing approaches should be seen as a challenge for exchange of know-how and best practices.
- Various measures have been suggested for improving **exchange of information and co-ordination**. The informal group of Directors and Experts on Better Regulation (DEBR), reporting to the Ministers Responsible for Public Administration, is currently the main forum for discussion and initiatives on better regulation between Member States. A mid-term programme has been launched to develop and exchange best practices concerning regulatory impact assessment. There is as yet no general forum for collaboration between the Community and national authorities on better lawmaking, although the option of creating an ad hoc working group of the Council on better regulation has been proposed<sup>49</sup>.

Overall, practices and performances across the Member States remain very diverse and in the absence of common methodology, it is difficult to present definitive data on their performance. The direction taken is nevertheless encouraging. At their meeting in Rhodes in June 2003, the Ministers responsible for public administration unanimously reiterated their backing to reform and welcomed new Community initiatives. The co-operation between the Commission and the Member States as well as among Member States is progressively going beyond an exchange of ideas and experiences, moving towards the development of common actions and instruments.

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<sup>49</sup> Both the Council of Ministers (Competitiveness - 30 September 2002) and Ministers of Public Administrations (Resolution of 6 June 2003) have called for the establishment of a dedicated working group on better regulation within the Council structures. The Commission has recognised the valuable contribution that such a Group could make (Communication on the Internal Market Strategy 2003-2006).

### **3. APPLICATION OF THE PRINCIPLES OF SUBSIDIARITY AND PROPORTIONALITY**

#### **3.1. The legal and institutional framework**

##### **a) The definition given by the Treaties**

Subsidiarity and proportionality are among the main organising principles of the Union. The Treaty on the European Union stipulates indeed that any action taken by the Union to achieve its objectives must be in accordance with the principle of subsidiarity<sup>50</sup>. Article 5 of the Treaty establishing the European Community (TEC) gives a general definition of subsidiarity and proportionality, indicating respectively when and how the Community should act. A protocol annexed to the Treaty of Amsterdam sets precise criteria for applying these principles<sup>51</sup>.

Subsidiarity is a guiding principle for defining the boundary between Member State and EU responsibilities (*Who should intervene?*). If the area concerned is under the exclusive competence of the Community, there is of course no doubt as to who should intervene. If competence is shared between the Community and the Member States, the principle clearly establishes a presumption in favour of decentralisation. The Treaty indeed states that Community action is justified only whether:

- there are transnational aspects which cannot be satisfactorily regulated by national measures (necessity test I);
- national measures alone or lack of Community action would conflict with the requirements of the EC Treaty or would otherwise significantly damage Member States' interests (necessity test II); and
- action at Community level would provide clear benefits compared to national measures (added value test).

Subsidiarity, by essence, is a dynamic or contingent concept. For instance, the capacity of national authorities to control transnational issues varies over time. Their control capacity has decreased over the last decades and has become insufficient on a number of issues. Vice versa, some Community measures introduced in the context of the 1960s do not necessarily have the same added value in 2003. As the Protocol stresses, subsidiarity allows Community action “to be expanded where circumstances so require, and conversely, to be restricted or discontinued where it is no longer justified.” Major changes in the Union and beyond may therefore require a reappraisal of the rules derived from this principle.

Proportionality is a guiding principle for defining how the Union should exercise its competence, once it has been established that it should take action (*what should be the form, nature and extent of EU action?*). In order to establish whether a measure complies with the principle of proportionality, it must be ascertained whether:

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<sup>50</sup> Article 2 of the Treaty on European Union states that “the objectives of the Union shall be achieved as provided in this Treaty ... while respecting the principle of subsidiarity”

<sup>51</sup> Protocol on the application of the principles of subsidiarity and proportionality (see <http://europa.eu.int/eur-lex/en/treaties/dat/amsterdam.html#0173010078>).



- the means employed are suitable for the purpose of achieving the objectives (effectiveness test);
- these means do not go beyond what is necessary to achieve the objectives (efficiency test).

A priori, proportionality leaves considerable discretion to the Union’s legislature<sup>52</sup>. Assessing effectiveness and efficiency is often quite complex. In most cases, there will be a range of options that comply with the proportionality principle. Rightly so, institutions involved in the legislative process will always have to take a political decision in favour of one specific policy option.

This being said, the clarifications offered by the Protocol regarding proportionality set specific limits. Firstly, “the form of Community action shall be as simple as possible” and, whenever legislating appears necessary, “directives should be preferred to regulations” (minimal – legal – constraint test). Secondly, the need to minimise the financial or administrative burden for all levels of government, economic operators and citizens should be taken into account (minimal cost test). The third clarification – Community action should “leave as much scope for national decision as possible” (minimal scope test) – is basically redundant with the conditions already set by the subsidiarity principle. It does however specify that “while respecting Community law, care should be taken to respect well established national arrangements”.

## **b) The obligations of the Institutions**

Application of the principles of subsidiarity and proportionality is a responsibility shared by all institutions of the Union<sup>53</sup>. The Protocol on the application of these principles also sets specific institutional obligations for the Commission, the Council and the European Parliament.

Among other things, the Commission is required – without prejudice to its right of initiative – to consult widely before proposing legislation; to justify explicitly the relevance of its proposals<sup>54</sup> in the accompanying explanatory memorandum; and to take into account the burden falling upon the Community, national governments, local authorities, economic operators and citizens.

The European Parliament and the Council have to verify that the Commission proposals and the amendments they envisage making are consistent with the

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<sup>52</sup> See European Court of Justice, *Case C-84/94 United Kingdom versus Council of the European Union – action for annulment of Council Directive 93/104/EC concerning certain aspects of the organization of working time*, judgment of 12 November 1996.

<sup>53</sup> “In exercising the powers conferred on it, each institution shall ensure that the principle of subsidiarity is complied with. It shall also ensure compliance with the principle of proportionality (...)” Article 1 of the Protocol.

<sup>54</sup> Reasons for concluding that an objective can be better achieved by the Community “must be substantiated by qualitative or, wherever possible, quantitative indicators” (Article 4 of the Protocol). Such reasons may be the divergent evolution of the Member States’ national legislation or the failure of a previous Union measure to produce results (see for instance the proposed directive on consumer credit).

principles of subsidiarity and proportionality<sup>55</sup>. In other words, the current system puts the burden of the proof on the institutions involved in the Union's legislative process (*Who does the defining?*).

### **c) The constitutional debate on subsidiarity and proportionality**

In July 2003, the European Convention proposed a revised framework for subsidiarity and proportionality. This part of the draft constitutional treaty appears to enjoy wide consensus. Provided that the IGC confirms this approach and the result is ratified by all Member States, the system designed by the European Convention could be in place by 2006.

The main innovation of this framework is the obligation for the Legislator to review a proposal whenever a sufficient number of National Parliaments consider that the proposal does not comply with subsidiarity. Under Article 9 of the draft treaty, while “the Union institutions shall apply the principle of subsidiarity”, “National Parliaments shall ensure compliance with that principle” through a new monitoring system. For that purpose the following obligations and procedures would be introduced in a revised protocol on the application of subsidiarity and proportionality: National Parliaments would be systematically informed of all legislative proposals, amended proposals and legislative resolutions upon adoption; they could then decide to activate an early warning system<sup>56</sup>. In addition they would have the possibility, via the Member States, to refer suspected violations of the principles to the European Court of Justice.

The proposed system offers a reasonable balance. On one hand, it involves National Parliaments without slowing down dramatically the decision-making mechanism of the Union. On the other, it fully preserves the Commission's right of initiative and the prerogatives of EU legislature.

### **3.2. Application of the principles by the Commission in 2003**

As it is impossible here to review all the Commission's proposals in the light of the conditions and obligations summarised in section 3.1.b), the report presents a number of representative cases showing how the Commission has applied the principles of subsidiarity and proportionality when drafting, revising or withdrawing a proposal.

In line with the commitment set out in the White Paper on European Governance, the report focuses on the actions corresponding to the political priorities identified in the Commission's Legislative and Working Programme for 2003<sup>57</sup>. A couple of other

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<sup>55</sup> When the co-decision procedure does not apply, the Council has in addition to inform the European Parliament of its position on the application of TEC Article 5 (Article 12 of the Protocol).

<sup>56</sup> National Parliaments would have six weeks for sending a reasoned opinion on the proposal or resolution. Where opinions issued represent at least one third of all the votes allocated to National Parliaments, the Commission has to review its proposal. After such review, the Commission may decide to maintain, amend or withdraw its proposal, but shall give reasons for its decision.

<sup>57</sup> The 2003 Programme identifies three political priorities: an enlarged Europe; stability and security; and a sustainable and inclusive economy (COM(2002)590, 30 October 2002).

actions are nevertheless reviewed in order to give a global impression of the Union's activities.

**a) When subsidiarity calls for Community action to be expanded**

Road safety illustrates most clearly when and why the Union considers that absence of action at EU level can no longer be justified in the light of subsidiarity<sup>58</sup>. The serious transnational consequences of a number of major accidents have stressed the need for uniform, constant and high level of protection in tunnels on the Trans-European Road Network. The nature of these accidents and the problems they posed to national authorities also indicated that action by Member States was clearly insufficient. The Commission therefore reckoned that **minimum safety requirements for tunnels** had to be set at Community level<sup>59</sup>.

On the basis of an in-depth impact assessment, the Commission came to the conclusion that a directive was needed for the most sensitive tunnels (i.e. those over 500 metres long) in order to prevent critical events that endanger human life, the environment and tunnel installations, as well as to guarantee a minimum level of safety in the event of accidents<sup>60</sup>.

Although the European Parliament and the Council asked for a number of amendments regarding the nature of the organisational and technical requirements proposed, there was unanimity on the fact that Community action was plainly justified on the basis of the subsidiarity principle.

Not all cases however are as clear-cut as tunnel safety, as the debate on public services has shown. In March 2002, the Barcelona European Council asked the Commission to examine the usefulness of adopting a framework directive on the "services of general economic interest". The Commission answered in May 2003 with the presentation of a Green Paper aiming in particular at defining the role of the Union in the promotion of high quality public services<sup>61</sup>.

For the Commission, it is a moot point what might be the proper scope of action and instrument in these matters. The Commission therefore thought it necessary to widen the debate to "**services of general interest**"<sup>62</sup> and expand the range of possible approaches assessed. The first step of the analysis was to organise public consultation

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<sup>58</sup> Among other exemplary cases, see Proposal for a Directive on the enforcement of intellectual property rights, COM(2003)46 of 30 January 2003, Proposal on enhancing ship and port facility security COM(2003)229 of 2 May 2003 and Proposal for the amendment of the Community guidelines for the development of the trans-European transport network COM(2003)564, 1 October 2003.

<sup>59</sup> This initiative is part of the Road Safety Action Programme launched by the Commission in 2003, which encompasses three areas: the behaviour of road users, vehicle safety and road infrastructures.

<sup>60</sup> COM(2002)769 of 30 December 2002.

<sup>61</sup> Green Paper on services of general interest (COM(2003)270, 21 May 2003).

<sup>62</sup> The Green Paper clarifies the concept of general interest services, distinguishing between services of general economic interest provided by large network industries (progressively liberalised and subject to internal market rules); other services of general economic interest such as waste collection and broadcasting (under sectoral rules that are partially harmonised); and non-economic services and services without effect on trade (under national rules).

which ended on 15 September 2003. The questionnaire submitted to the public indicated how difficult the application of the principle of subsidiarity can be when it touches on very different political and administrative cultures<sup>63</sup>.

**b) When subsidiarity calls for Community action to be stopped**

If subsidiarity allows Community action to be expanded where circumstances so require, it also demands action to be restricted or discontinued when it is no longer justified. The Commission reckoned that such ‘contraction’ should occur with regard to pre-packaging rules.

In the 1970s, the Community set mandatory or optional **pre-packaging sizes** for a number of products, in order to enhance consumer protection and market transparency, as well as eliminating trade barriers. As part of the SLIM-IV exercise (Simpler Legislation for the Internal Market), the Commission undertook a series of analyses, studies and public consultations with stakeholders designed to evaluate the existing system and desirability of deregulation in this domain. Different policy alternatives (free sizes or fixed sizes) have been assessed. Overall, free sizes and voluntary standardisation appear to score better than fixed sizes, except for certain sectors for which the impacts are still subject of assessment<sup>64</sup>.

In general, the objectives of the current pre-packaging legislation are already covered by existing directives (consumers are protected by unit pricing and the environment by the Pre-packaging Waste directive). Should the ongoing impact assessments justify legislation on fixed sizes in certain sectors, the Commission will take this into account in its proposal on pre-packaging, which is scheduled for 2004<sup>65</sup>.

**c) When proportionality calls for broader association of the Member States**

According to the proportionality principle, the Union must use suitable means that do not go beyond what is necessary. It led the Commission to propose a number of changes aimed at decentralising responsibilities, including in areas under the exclusive competence of the Union. This is illustrated by recent reforms in competition policy.

Regulation No1/2003<sup>66</sup> concerns the implementation of two fundamental rules underlying EU competition policy: the prohibition of agreements between

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<sup>63</sup> Among other questions, the Commission asked: Should the development of high-quality services of general interest be included in the objectives of the Community? Should the Community be given additional legal powers in the area of services of general economic and non-economic interest? Is there a need for clarifying how responsibilities are shared between the Community level and administrations in the Member States? Are there services (other than the large network industries) for which a Community regulatory framework should be established? Is a general Community framework for services of general interest desirable? What would be its added value compared to existing sectoral legislation? Which sectors and which issues and rights should be covered? Which instrument should be used (e.g. directive, regulation, recommendation, communication, guidelines, inter-institutional agreement)? What has been the impact of sector-specific regulation so far? Has it led to any incoherence?

<sup>64</sup> Wine, spirits, coffee, sugar, salt, flour, metal cans and aerosols.

<sup>65</sup> Review of Directive 75/106/EEC Annex 3 and Directive 80/232/EEC.

<sup>66</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty – OJ L 1, 4 January 2003, p.1.

undertakings which “have as their object or effect the prevention, restriction or distortion of competition within the common market” (Article 81 TEC) and the prohibition of abuse of dominant positions (Article 82 TEC). It has increased substantially responsibilities given to national authorities

The previous authorisation system, established by a Regulation adopted in 1962, was highly centralised for all restrictive agreements requiring exemption. While the Commission, national courts and national competition authorities could all apply the prohibition rule of Article 81, the power to apply exemptions, based on the prior notification of restrictive agreements and practices, was granted exclusively to the Commission. Within the changed circumstances of a much larger Union, where the competition culture has much evolved during the past 40 years and where, in particular, national competition laws have been enacted and national competition authorities set up, there was an urgent need to modernise the existing rules in line with the dynamic application of the subsidiarity principle.

Following its 1999 White Paper<sup>67</sup>, the Commission proposed in 2000 a new decentralised system allowing for implementation of the competition rules by both the Commission and the competition authorities and courts of the Member State, while preserving the Commission's specific implementing role<sup>68</sup>. In an attempt to make better use of the Commission resources, it is no longer necessary to notify agreements between undertakings to benefit from the application of Article 81(3) TEC. This means that agreements fulfilling the conditions mentioned in that article are considered to be lawful. The system also reinforces the capacity of Member States' authorities to apply Community law effectively at national level. Horizontal cooperation mechanisms indeed empower national competition authorities to exchange confidential information and assist each other as regards fact-finding. Insofar as the Commission remains the only authority that can act throughout the European Union, it continues to play a central role in the development of Community competition law and policy, ensuring that it is applied consistently and preventing any renationalisation of Community competition law.

#### **d) The simplest form of intervention possible**

According to the Protocol on subsidiarity and proportionality, “the form of Community action shall be as simple as possible”. The proposals on road safety, unfair commercial practices and chemicals illustrate the Commission's reasoning for selecting the appropriate level of constraint<sup>69</sup>.

Improving the safety of the movement of passengers and goods is one of the European Union's key tasks. In its White Paper on European Transport Policy, the Commission

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<sup>67</sup> White Paper on Modernisation of the rules implementing Articles 85 and 86 of the EC Treaty, COM(1999)101, 28 April 1999; Commission Programme No 99/027.

<sup>68</sup> COM(2000)582 of 27 September 2000.

<sup>69</sup> Among other exemplary cases, see Proposal for a Directive implementing the principle of equal treatment between women and men in the access to and supply of goods and services, COM(2003)657, 5 November 2003; Proposal for a Directive on Eco-design requirements for Energy-Using Products, COM(2003)453 of 1 August 2003.

proposed in 2001 that the European Union should set itself the ambitious target of halving the number of road deaths by 2010<sup>70</sup>.

As studies had demonstrated that speeding, drink-driving and non-use of seat belts were the main causes of accidents in all the Member States, on one hand, and that progress could be achieved simply by complying with existing rules, on the other hand, the Commission focused on ways of improving proper enforcement of national laws. In line with the conclusions of the EU **Road Safety** Action Programme of June 2003, it proposed the definition of national enforcement plans embodying best enforcement practices (compliance checks, appropriate sanctions for violations and publicity campaigns) and the establishment of a mechanism for cross-border enforcement organising efficient transfer of information on violations between the authorities entitled to impose sanctions.

The Commission proposed listing these measures in a simple recommendation<sup>71</sup>. Should the data from Member States show that measures taken prove insufficient to achieve the objective set in the White Paper, the recommendation stipulates that measures of a more binding nature would then be proposed.

The issue of **unfair commercial practices** by businesses against consumers exemplifies the possible use of alternative methods of regulatory instruments. Unfair practices pose a problem for the proper functioning of the internal market (distortion of competition) arising from fragmented regulation and a lack of consumer confidence.

In its Extended Impact Assessment, the Commission looked at a range of possible approaches and the trade-offs involved<sup>72</sup>. On that basis, it concluded that a framework directive<sup>73</sup>, allowing a mix of traditional legislation and co-regulation, would suffice to reach the objectives of the Union regarding consumers and the internal market. Its proposal for a framework directive recognises the possibility for groups or associations to establish voluntary codes of conduct in pursuit of the objectives of the directive. . A breach of a code commitment will nevertheless only be considered unfair under very precise conditions (for instance, the misleading representation of a product would have to be such that it materially distorted the consumer's decision about the product).

The proposal on **chemicals** (REACH) put forward on 29 October 2003 is a case where, in the view of the Commission, there is no other option but to go for a regulation or, in other words, where the objective could not be achieved efficiently through any lighter instrument.

The need for major reform in the area of chemicals arose from widespread consensus that existing legislation was no longer suitable for responding efficiently and adequately to public concern about the potential impact of chemicals on health and the environment. Particular problems include insufficient information on chemicals first

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<sup>70</sup> White Paper on European transport policy for 2010: time to decide (COM(2001)370 of 12 September 2001.

<sup>71</sup> C(2003)3861 of 21 October 2003.

<sup>72</sup> SEC(2003)724, 18 June 2003.

<sup>73</sup> COM(2003)356 of 18 June 2003.

marketed before 1981 (properties, uses, risks, and risk reduction measures); heavy burden put on public authorities; as well as the slow and onerous delivering of final risk assessments. To find an appropriate response to the justified concerns of all interested stakeholders, the Commission weighed up very carefully the pros and cons of various instruments, notably in terms of costs to industry and administrative burden<sup>74</sup>.

The Commission eventually concluded that registration, evaluation, authorisation and restriction of chemicals should be organised by one regulation (REACH) and managed by a European Chemicals Agency<sup>75</sup>. The choice of the strongest option on the Union's legal palette was justified on several grounds. A regulation is the best way to prevent distortion of competition, which is crucial because of the economic implications of the action envisaged. Moreover, its legislative follow-up by Member States and its monitoring by the Commission are relatively simple compared to what a directive would require, particularly since the Union will soon comprise 25 Member States. Finally, the use of legislation in this area is justified by the technical complexity – all the more so when potentially hazardous products are concerned. There was therefore no room here for alternative, more flexible, instruments such as co-regulation or self-regulation.

#### e) **Respecting well established national arrangements**

Compliance with the subsidiarity principle requires that “while respecting Community law, care should be taken to respect well established national arrangements”. The proposal on the sensitive issue of **human embryonic stem cell research** shows how the Commission applies that requirement<sup>76</sup>.

The 6th Framework Programme for R&D, adopted by the Council of Ministers and the European Parliament in 2002, allows for the funding of human embryonic stem cell research in relation to the fight against major diseases. The need for Community action was clearly established at the time. The proposal of the Commission aims to set strict ethical rules for funding research projects involving the procurement of stem cells from human supernumerary embryos<sup>77</sup>. With this proposal the Union can make a responsible contribution to advancing this science for the benefit of patients across the world, while at the same time ensuring that such research takes place within a clear ethical framework. Collaborative research at Community level avoids duplication of research and thus helps to reduce the use of human supernumerary embryos for the derivation of stem cell lines. In addition, Community funds stimulate exchanges of results and expertise among research teams from different Member States.

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<sup>74</sup> The starting point of the discussion was the White Paper on the Strategy for a Future Chemicals Policy (COM(2001)88), published by the Commission in February 2001. Subsequently the proposed measures were subjected to extensive consultation with stakeholders in the industry, civil society and NGOs, Member States and Institutions, as well as to an Ex-IA.

<sup>75</sup> COM(2003)644 of 29 October 2003.

<sup>76</sup> Other exemplary cases include the proposal on the establishment of a regime of local border traffic at the external land borders of the Member States (COM(2003)502, 14 September 2003).

<sup>77</sup> COM(2003)390 of 9 July 2003.

This being said, the Union also had to take into account the great diversity among Member States concerning the ethical acceptability of such research, some forbidding it altogether. The proposal of the Commission therefore stipulates that no research involving the use of human embryos or human embryonic stem cells, of any type, will be supported by Community funding to a legal entity established in a country where such research is forbidden. Participants in research projects must conform to current legislation, regulations and ethical rules in countries where the research will be carried out.

### **3.3. Application of the principles in the legislative process**

On the whole, the European Parliament and the Council introduced relatively few amendments referring to subsidiarity and proportionality. When the views of the Parliament and the Commission diverge, the majority of Parliament's amendments were calling for broader and more intensive action on behalf of the Union (cf. merger regulation). The Parliament also found on several occasions that the Union needed to opt for more constraining instruments (cf. the case of pedestrian protection). In other cases however the Parliament asked the scope of the action envisaged to be narrowed down and/or called for the adoption of a lighter form of intervention (cf. oil and gas package).

As the representative of the Member States and guarantor of their powers, the Council takes particular care to ensure that the legislation of the Union strictly complies with the principles of subsidiarity and proportionality. Mostly its interpretation was more restrictive than the Commission's interpretation (cf. criminal justice). Occasionally the Council found however that the Union could and should act more stringently.

More often than not, the inter-institutional dialogue helped to come to a balanced interpretation of the principles, either because the Commission recognised the validity of a number of arguments presented by the Legislator or because the Legislator did not insist on all its amendments.

#### **a) Limiting the scope and intensity of proposed action**

The proposal for safeguarding **security of natural gas supply** offers a good example of a debate where the Parliament found that the proposed action was too intrusive and where the Commission stuck to its reasoning on many points, claiming that the proposed action was necessary to meet the objectives of the Treaty .

In 2002 the Commission proposed an "oil and gas stocks" package, made of four directives and aimed at ensuring security of supply with a view to the completion of the internal market in energy<sup>78</sup>. The proposal on the security of gas supply, among other things, provides for minimum security supply standards, the clarification of the role of the different market players and a solidarity mechanism in the event of major supply problems.

In its opinion delivered on first reading on 23 September 2003, the Parliament tabled six amendments referring to subsidiarity, which were partially rejected by the

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<sup>78</sup> COM(2002)488 of 11 September 2002.



Commission<sup>79</sup>. The institutions disagreed on the precise scope of the action (subsidiarity). For the Commission, the question should be viewed in the wider context of market liberalisation and competition (the directive aims at ensuring the proper functioning of the EU internal market for gas by safeguarding security of supply). Security measures have to be compatible with the requirements of a competitive single market. Standards have therefore to be set. For the Parliament this approach creates a confusion between different subjects and leads to an unacceptable “hard and fast EU catalogue of objectives” for standards for security of supply. The Commission rejected this argument.

Agreement was however found regarding the specific targets to be written into the directive. Article 4 of the proposed directive defines specifically the number of supply days Member States shall ensure to “non-interruptible customers”, with reference to average weather conditions, extremely cold temperatures or cold winters occurring statistically every fifty years. The Parliament suggested replacing all specifications by the obligation of Member States to ensure that security of supply can be maintained to “vulnerable customers in the light of their national circumstances”. The Commission recognised the validity of the argument and declared itself ready to revise its proposal accordingly.

Not surprisingly perhaps, the most restrictive interpretation of subsidiarity and proportionality was to be found in relation to new areas of competence close to the hard core of national sovereignty. **Criminal Justice** is among those<sup>80</sup>. One of the major objectives of the Union is to create an Area of Freedom, Security and Justice. In that perspective, full application of the principle of mutual recognition in the domain of criminal justice and in particular with regard to the final decisions in criminal matters is particularly important (owing to the number of transnational cases).

Some action was obviously needed to reach that objective. Distrust among judicial authorities is indeed relatively high due to discrepancies in the level of procedural safeguards provided in the Member States<sup>81</sup>. Because of the high sensitivity of criminal justice, the Commission paid particular attention to subsidiarity and proportionality when preparing its proposal for action (intensive consultation, publication of a green paper<sup>82</sup> and an extended impact assessment).

Different policy options with regard to the introduction of common safeguards were analysed: no policy change; a wide-ranging proposal; and a proposal limited to ‘basic’ safeguards in the first instance, with a commitment to cover the other areas later on. The last option emerged as the best approach. Various instruments were then reviewed: common position, convention and framework decision foreseen in Article

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<sup>79</sup> Commission’s Communication of 17 October 2003 SP(2003)3410/2.

<sup>80</sup> For another exemplary case on divergent views held by the Commission and some Member States, see Proposal for a Regulation on persistent organic pollutants, COM(2003)333 of 12 June 2003.

<sup>81</sup> The main problems include: access to legal assistance and representation both before and at trial; access to interpreting and translation; notifying suspects and defendants of their rights; proper protection for especially vulnerable groups; and consular assistance to foreign detainees.

<sup>82</sup> Green Paper from the Commission, Procedural Safeguards for Suspects and Defendants in Criminal Proceedings throughout the European Union, COM(2003)75 of 19.02.2003.

34 TEU. A framework decision appeared to be the most adequate instrument for achieving a concrete result in the shortest possible time, while being consistent with the Tampere Conclusions. Among other advantages were the possible recourse to the European Court of Justice, the relatively simple implementation procedure and the possibility for the Commission to retain a role in supervising and monitoring implementation in national legislation.

On the basis of those findings, the Commission concluded that a framework decision setting minimal standards of procedural safeguards for suspects and defendants in criminal proceedings throughout the EU was a precondition to mutual recognition.

While the European Parliament reacted positively to the proposal<sup>83</sup>, some Member States took the opposite stance, challenging the need for such a measure. They consider that the organisation of the criminal justice system remains a matter of national sovereignty and that the European Convention on Human Rights is sufficient as far as “common minimum standards” are concerned. It was also suggested that setting common minimum standards at EU level might lead to a lowering in standards, as some countries might take this opportunity to downgrade their national legislation.

#### **b) Asking for broader and more intensive actions**

Union intervention in favour of **pedestrian protection** exemplifies situations where the Parliament argued in favour of stronger means of action<sup>84</sup>. Owing to the large number of pedestrian and cyclist victims of road accidents, the Commission decided in 2001 to take steps to improve their protection through the gradual introduction of safer designs in frontal structures of passenger cars. The Commission obtained clear commitments from European, Japanese and Korean automobile manufacturers that they would modify vehicle front parts in order to limit injuries to pedestrians in case of collision. In July 2001, the Commission presented these commitments to the Council and the Parliament and deferred to them the decision whether to accept the commitments or to propose legislation based on the latter’s contents<sup>85</sup>.

On 13 June 2002, the European Parliament took the view that the Union could not abandon its legislative powers to third parties when the protection of citizens was at stake. The voluntary agreement signed by the car industry was also considered to be inappropriate for other reasons. Since the industry commitments mainly concern the construction of passenger cars which are covered by EC type-approval system, they had to become part of this system. Moreover harmonised rules are necessary in this area not only to ensure the free movement of goods but also to guarantee fair competition between manufacturers, by preventing the marketing of sub-standard vehicles. Consequently the European Parliament asked the Commission to introduce

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<sup>83</sup> On 21 October 2003, its Committee on Citizens' Freedoms and Rights, Justice and Home Affairs fully supported the idea of a framework decision. MEPs made a number of recommendations aimed at fleshing out the Commission's proposal, some of which the Commission considered in contravention with the subsidiarity principle (for example the recommendation relating to conditions of prisons).

<sup>84</sup> Among other exemplary cases, see Proposal for Regulation of the European Parliament and of the Council on official feed and food controls, COM(2003)52, 5 February 2003.

<sup>85</sup> COM(2001)389, 11 July 2001.

legislative measures with regard to the tests for frontal parts of cars<sup>86</sup>. The Commission proposed a framework directive, due to be supplemented with a Commission directive setting out the detailed test requirements<sup>87</sup>. The Directive has been adopted on 4 November 2003.

The proposal for amending the **Merger regulation** offers a good example of a debate where the Parliament found that the proposed action was giving too much power to the national level and where the Commission stuck to its reasoning on most points because the Parliament's amendments would create an imbalance in favour of the Union.

Since 1990, merger transactions are monitored through a 'one-stop shop' system for the entire European Union. The Merger Regulation<sup>88</sup> removes the need for companies to seek clearance from several national authorities for mergers having a "Community dimension" and ensures that all such mergers receive equal treatment.

Based on the experience gained over the last 12 years, the Commission decided to recast the Merger Regulation and presented at the end of 2002 a Proposal<sup>89</sup> aimed at optimising the allocation of merger cases between the Commission and national competition authorities. In line with the principle of subsidiarity, the Commission considered that this objective could be achieved most efficiently through a streamlined system of referrals, without modifying the current turnover thresholds criteria for allocation of merger cases. The new system therefore is to be based on an enhanced recourse to the Merger Regulation's referral mechanisms, including their improvement and use at a pre-notification stage. Given their superior knowledge of the circumstances of the case, the notifying parties would get an exclusive right of initiative at this stage of the procedure. In other words, before notifying the merger at national levels, undertakings wishing to merge would have the possibility of requesting a referral of the case to the European Commission.

The European Parliament, in the opinion it delivered on 9 October 2003, suggested a number of amendments mainly designed to set stricter requirements for referrals of Community dimension mergers to Member States, while at the same time simplifying the mechanism of referrals of national mergers having cross-border effects to the Commission.

The Commission has rejected these amendments because the overall system of re-allocation of cases between the Community and the Member States proposed by Parliament would have been too unbalanced in favour of referrals to the Commission, and thus appeared to be detrimental to the subsidiarity principle. The Council's final decision is scheduled for the end of 2003.

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<sup>86</sup> See Council's conclusion at the 2389th meeting of 26 November 2001, European Parliament's Resolution of 13 June 2002.

<sup>87</sup> COM(2003)67 of 19 February 2003.

<sup>88</sup> Council Regulation (EEC) 4064/89 of 21 December 1989, OJ L 395, 30 December 1989.

<sup>89</sup> Proposal for a Council Regulation on the control of concentrations between undertakings COM(2002)711 of 11 December 2002.

#### 4. CONCLUSIONS

##### *Better lawmaking in 2003*

Much has been done in the Union to improve the quality and accessibility of legislation. In late 2002 and early 2003, the Commission's efforts were mainly devoted to detailing its Action Plan "Simplifying and improving the regulatory environment", while defining in parallel with the European Parliament and the Council an inter-institutional agreement laying the foundations of an overall strategy for better lawmaking. Both processes have been successfully completed. The Union now has a global policy for ensuring a clear, up-to-date and effective body of law for the ultimate benefit of citizens and operators.

However, 2003 and 2004 are transitional years in the implementation of most actions and the present report can therefore only take stock of first experiences. Globally, this initial phase of implementation has not revealed any need for a major review of the Commission's approach, and this view appears to be shared by the other institutions, Member States and stakeholders.

- The key Commission initiatives on **impact assessment**, collection and use of **expertise** and **public consultation** have shown satisfactory progress. The Commission welcomes the quality of impact assessments carried out in 2003 but also notes the difficulties encountered in ensuring reliable programming and execution of impact assessments. Standards regarding publication of consultations on a single access point, time limits for responses and acknowledgement of results have been properly applied in almost all cases. Despite the additional work demanded by these new obligations, the number of consultations increased. However, the Commission has identified certain weaknesses in the implementation of these actions that will require corrective action.
- Regarding the **choice of instruments** to pursue Treaty objectives and implement Community policies, the Commission is satisfied that the Inter-institutional Agreement on Better Lawmaking sets a clear framework for co-regulation and self-regulation. It hopes that this will facilitate their future use. Besides the Commission looks forward to rapid progress on the development of a framework for regulatory agencies and development of tri-partite contracts.
- Strict monitoring of the ambitious framework action "**updating and simplifying the Community *acquis***" has revealed mixed but not unsatisfactory results. Completion of the consolidation programme and the progressive change of regulatory culture in the Commission and beyond are major achievements. Significant improvements in accessibility to Community legislation are underway, but weak points have been detected in implementing the actions aimed at reducing the volume of Community legislation (codification and elimination of outdated legislation).
- As far as **reinforcing checks on the transposition of Community legislation** is concerned, the Commission has implemented several of the planned actions to

improve transposition. It is preparing new procedures aimed at speeding up the review of complaints.

- For many better regulation initiatives, the Commission also notes significant **resource and time implications** – in particular for impact assessments and the new standards for public consultations and use of expertise.
- The Commission welcomes that the other institutions acknowledge better lawmaking as a **shared responsibility** and that an inter-institutional agreement has been concluded on actions requiring coordinated or joint action. Focus should now turn to implementation of this agreement. The Commission also welcomes the efforts deployed by **Member States** in response to the recommendations of the Commission and of the Mandelkern Group, although the progress is variable.
- Finally, the Commission acknowledges the need to develop indicators and other means to ensure that sufficient **evidence** is available to ensure continued monitoring.

### *Application of subsidiarity and proportionality in 2003*

On the whole, the application of the principles of subsidiarity and proportionality has been satisfactory in 2003. The small number of legal actions before the Court of Justice invoking the violation of these principles and the absence of judgments condemning the Union on that ground tend to confirm this assessment. The fact that, even though the Union's obligations have considerably increased, there were less than 400 legislative proposals launched in 2003 (half the 1990 figure) is another indirect indication of strict application of the principles. The review of the contents of these proposals also supports this appraisal: regulations and detailed measures were by far the exception; strong arguments in favour of such options were systematically advanced.

The quality of the inter-institutional dialogue in 2003 was good. This dialogue helped to find a balanced solution in most cases. The Commission has often recognised the merits of the arguments put forward by the European Parliament and the Council, and amended its proposals accordingly. However, on several occasions, the Commission felt that the amendments suggested by the Legislator were increasing the complexity and did not therefore take the principles of subsidiarity and proportionality sufficiently into account. The Commission intends to remain vigilant throughout the legislative process, including when the European Parliament and the Council reach an agreement during the conciliation stage.

Subsidiarity, in essence, is a dynamic concept. It allows Community action to be expanded where circumstances so require, and conversely, to be restricted or discontinued where it is no longer justified. This year provided examples of expansion and contraction. But as the Commission stated in its 1997 Work Programme, "subsidiarity and proportionality must not be used as pretexts to call into question all that the Community has already achieved or to return to the intergovernmental method". Democracy and efficiency would both lose.

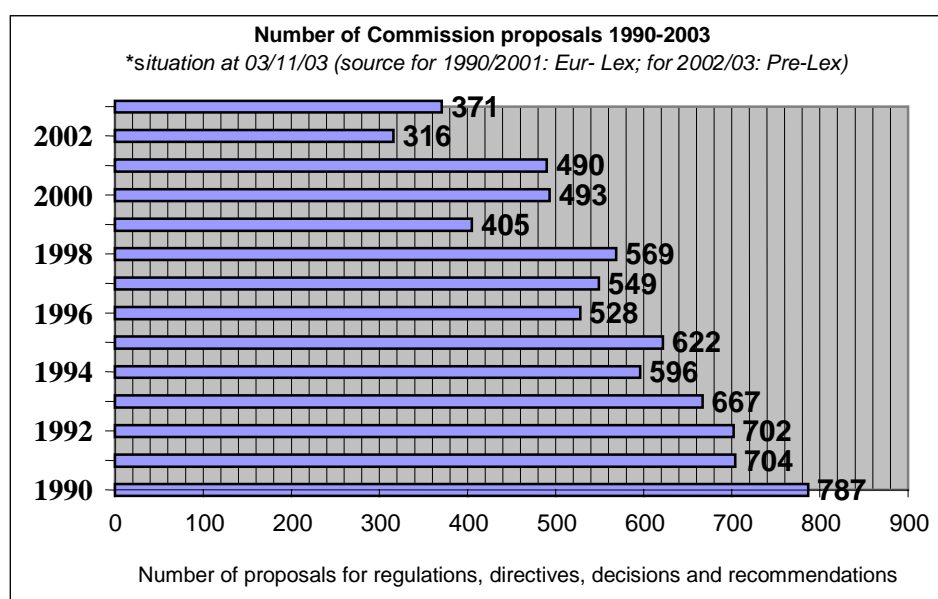
Vigilance is needed on all sides. The adoption of the framework for subsidiarity and proportionality designed by the European Convention would have the advantage of

increasing that vigilance by involving National Parliaments, but without slowing down dramatically the decision-making mechanism of the Union.

## Annex 1: Legislative activity in 2003

Aggregated figures for 2003 confirm the trend observed since the completion of the internal market: the volume of annual legislative activity has significantly decreased, staying for the second year in a row clearly below 400 proposals<sup>90</sup>.

Sector-wise, one third of the legislative activity in 2003 was geared towards the external relations of the Union (mainly its common commercial policy) and its enlargement. Next to these sectors, the most active areas were in descending order: agriculture and fisheries, health, industry, transport and energy, and environment. The output at these levels is in line with previous years' records<sup>91</sup>.



<sup>90</sup> The figure for 2003 covers proposals adopted between 1 January and 3 November.

<sup>91</sup> For an evolution of that pattern, see the previous annual reports: COM(1993) 545 of 24 November 1993; COM(1994) 533 of 25 November 1994; COM(1995) 580 of 20 November 1995; ESC(1996) 7 of 27 November 1996; COM(1997) 626 of 26 November 1997; COM(1998) 715 of 1 December 1998; COM (1999) 562 of 3 November 1999; COM(2000) 772 of 30 November 2000; COM(2001) 728 of 7 December 2001; and COM(2002) 715 of 11 December 2002.

## Annex 2: Public consultation in 2003

Public consultation is an indispensable tool for improving the quality of policy proposals and policy implementation (the risk of misunderstanding and hostile reaction – i.e. poor policy landing – decreases with early involvement of interested parties). It allows better identification of the need for an action, of the expectations and of the types of action to be taken. All this is particularly important for policy areas where the Commission has large powers, which are still in a development phase or which require constant legislative action.

The Commission has a long tradition of extensive consultation<sup>92</sup> through various channels: Green Papers, White Papers, communications, forums (such as the European Energy and Transport Forum), workshops and consultations on the Internet<sup>93</sup>. The Commission is also engaged in various forms of institutionalised dialogue with interested parties in specific domains, the most developed being the social dialogue.

In **2003**, the Commission produced **5 Green Papers and 142 Communications**. It also published **73 reports** and organised **60 Internet consultations** through “Your Voice In Europe”, the Commission’ single access point for consultation<sup>94</sup>. In addition, the Commission is working towards the creation of a European Business Test Panel (EBTP) which will be used to sound out business opinion on new legislative proposals, the application of current rules and policy initiatives (<http://europa.eu.int/yourvoice/ebtp>).

These figures show how serious the Commission is about providing full information about its activities and policy reflection and about consulting. The number of Green Papers and Communications in particular has increased significantly<sup>95</sup>. Figures for the last 10 years are equally eloquent: all sectors combined, the Commission released 43 Green Papers, 19 White Papers, more than 1350 communications and nearly 1500 reports on Community actions.

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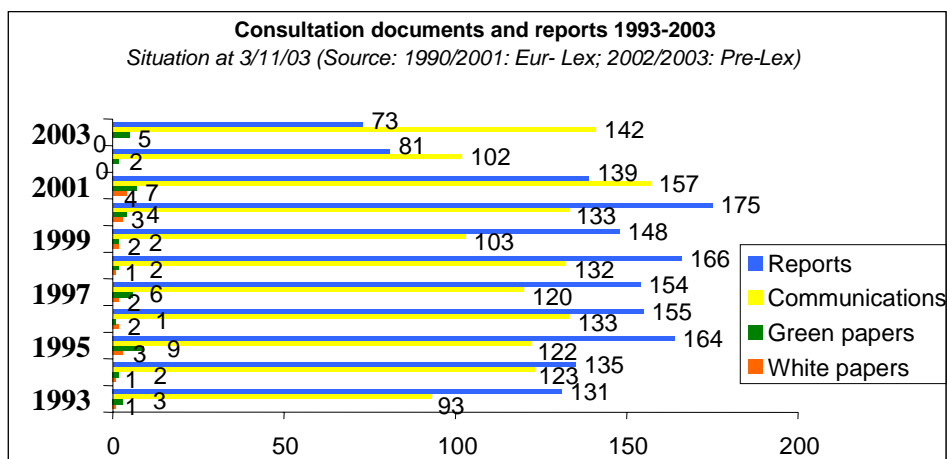
<sup>92</sup> ‘Consultation’ refers to the processes used by the Commission during policy shaping phase in order to trigger input from outside interested parties before taking a decision.

<sup>93</sup> See in particular the Interactive Policy Making initiative (<http://europa.eu.int/yourvoice/ipm>). The IMP consists of two Internet-based instruments collecting spontaneous information from citizens, consumers and businesses about their daily problems relating to different EU policies. In February 2003, the Commission-wide Feedback Mechanism was launched. Thousands of cases are collected annually and several Directorate Generals have already started to use it as an input for policy making.

<sup>94</sup> See [http://europa.eu.int/yourvoice/consultations/index\\_en.htm](http://europa.eu.int/yourvoice/consultations/index_en.htm).

<sup>95</sup> Communications adopted between 1 January – 3 November: 142 in 2003; 96 in 2002; 125 in 2001; 112 in 2000; and 77 in 1999.





The sectoral pattern of consultation for 2003 is globally in line with previous years' patterns. The largest number of consultations concerned, in descending order, agriculture, employment and social policy, external relations, industry, justice and home affairs, transport and energy, environment, economic policy and information society.

By contrast, the Commission's implementation of public consultations changed substantially at the procedural level in 2003. In accordance with the commitments made in the White Paper on European Governance, the Commission has introduced **minimum standards for its public consultation** which apply to major policy initiatives<sup>96</sup>. As a first step, these standards were applied to all proposals requiring extended impact assessment.

The main innovations are: the definition<sup>97</sup> of a minimum consultation period, the obligation to report on the results, the obligation to give appropriate feedback to comments received and the establishment of a single access point for public consultations.

Based on a review of the extended impact assessments completed by 3 November 2003, the Commission observes that minimum standards regarding publication on the single access point, time limits for responses and report on the results have been properly applied in almost all cases. The time given to respondents was often above minimum standard. The choice of targeted groups was only challenged on very few occasions. Special efforts however still need to be made to improve feedback to contributors. In most cases, too little was said on how comments were taken into account in the proposal or why they were discarded. Responses from services also indicate that the new standards were applied beyond consultations linked to Ex-IA. In

<sup>96</sup> Communication from the Commission 'Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission' COM(2002)704, 11 December 2002. These new standards were adopted after wide consultation during which the Commission applied by anticipation the best practices it was proposing. Before adopting this Communication, the Commission indeed sought the opinion of citizens, interest groups, associations and operators (see COM(2002)277, 5 June 2002); reported on the results and gave a feedback on the comments received.

<sup>97</sup> At least 8 weeks for reception of responses to written consultation or 20 working days' notice for meetings.

a limited number of cases, delay in the adoption of a proposal was attributed to the application of the standards. Causal links between the introduction of the new standards and the number of contributions received or their representativeness could not be established<sup>98</sup>.

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<sup>98</sup> The quantity of contributions varied widely. From 30 for consultation on highly technical topics to more than 6400 for proposals on environmental and human health issues such as the regulation concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH).

### Annex 3: Impact Assessment

In 2002, the Commission adopted a new method of assessment for all major Commission initiatives, that takes into account not only the economic impact, but also the social and environmental impact of the proposal concerned<sup>99</sup>. It consists of two main steps: a Preliminary Impact Assessment and, for a selected number of significant proposals, a more in-depth analysis called **Extended Impact Assessment (Ex-IA)**. Used alongside formal consultations, it provides the European Parliament and the Council with a solid basis for legislative discussions. Ultimately it should increase the quality and coherence of EU policies.

The approach chosen was to introduce this new procedure gradually, starting in 2003. For the first year, the Commission planned to apply the procedure to 17% of its priority proposals (cf. List 1 of the Commission's Work and Legislative Programme for 2004). In 2004, approximately half of the Commission's major initiatives will be drafted on the basis of an Ex-IA<sup>100</sup>.

Quantitatively speaking, the Commission's estimate is that approximately 50 % of the Ex-IAs initially planned will be completed by the end of December 2003<sup>101</sup>. This relatively low implementation rate seems to be part of a general problem linked to optimistic planning, lack of resources and political difficulties<sup>102</sup>. In a limited number of cases however, Commission services reported that Ex-IA were partly to blame for delay in the adoption of proposals. An extended impact assessment is a demanding exercise and services have had to adapt to the new procedure.

Qualitatively speaking, the direct and indirect consequences of the introduction of the new procedure were largely positive. First of all, the new procedure was rigorously applied. Directorates-General have adopted a constructive approach, devoting existing human and financial resources to this exercise as well as co-operating actively with other Commission services. Impact Assessment has in many cases considerably facilitated inter-service co-ordination, a fact acknowledged for instance on the chemical legislation recently proposed. On the whole, Ex-IAs have prompted the Commission and its services to "think outside the box" and contributed significantly to identifying more balanced solutions<sup>103</sup>.

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<sup>99</sup> COM(2002)276, 5 June 2002.

<sup>100</sup> In absolute terms, the difference is less significant (43 Ex-IA planned for 2003 against 46 for 2004). This is linked to the fact that the Commission decided to keep its list of 2004 priorities limited to 72 proposals.

<sup>101</sup> The most important proposals based on Ex-IA include: Legislation on the Kyoto flexible instruments, Review of the Sugar regime, Review of the Tobacco regime, Guidelines on the Trans-European Networks and Legislation on Chemicals (REACH).

<sup>102</sup> By mid-November 2003, the implementation rate of the Commission's Work plan was indeed roughly the same for proposals based on Ex-IA and for proposals that did not require full impact assessment. It should also be noted that many Ex-IA have been postponed only a few months for adoption at the beginning of 2004.

<sup>103</sup> The formulation of the following proposals, for instance, has been directly influenced by Ex-IA. In the case of the Legislation on the Kyoto Flexibility mechanism, the impact assessment

On the basis of this trial year, it appears that the Commission needs to address a number of teething problems. First, the capacity of services to evaluate impact beyond their policy field is naturally often limited. As a consequence, while most Ex-IAs nominally address all dimensions of sustainable development, detailed analysis tends to be limited to one aspect only. Environmental and social levels are especially underdeveloped. Secondly, Ex-IAs should include more thorough discussion of the principles of subsidiarity and proportionality, in particular of the respective merits of different regulatory approaches. Third, analyses tend to focus on one policy option. Policy alternatives should be examined more thoroughly.. Fourth, there is so far limited quantification, let alone monetisation of the impacts. This affects the credibility of some impact assessments. Fifth, effort should be made to rendering Ex-IAs more accessible to the general public.

In order to address the quantitative and qualitative shortcomings, the Commission's Secretariat-General with other horizontal services will push forward a range of new initiatives. They will continue to offer advice and guidance to operational services responsible for undertaking Ex-IAs, as well as encourage services to pool their assessment capacity to a larger extent. They will carry out quality control of the impact assessments (ensuring in particular that they cover all dimensions in a balanced manner and evaluate systematically all viable policy options, in order to prepare the ground for informed political decisions). Training on impact assessment will be offered to up to 400 Commission officials. Furthermore, officials will be equipped with the "Indicators and Quantitative tool" currently under development by external contractors working for the Commission. .

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helped to find a solution that balanced economic and environmental considerations. In the case of the Directive on unfair (trading) practices, a new option with fewer costs for business was introduced after the impact assessment. Also, the REACH proposal on Chemicals was based on an impact assessment which took account of the costs to business as balanced against environmental and human health objectives.

#### **Annex 4: New guidelines on the collection and use of expertise**

Proper collection and use of expertise are both crucial and delicate. Clearly, it is crucial that policy choices are based and updated on the best available knowledge. But on occasions, the questions to be addressed, the evidence considered and the interpretations may be highly controversial. In order to ensure credibility, it is then particularly important, on one hand, to demonstrate that the expertise collected is of appropriate quality and, on the other hand, to be transparent on how experts are identified and chosen, as well as how results are used. The collection and use of expertise must not only be credible, it must above all be effective. Given that resources are limited, arrangements have to be in proportion to the task in hand.

Following the commitment made in the White Paper on European Governance and the Commission's Science and Society Action Plan, the Commission adopted in December 2002 a Communication defining principles and guidelines that encapsulate good practices regarding expertise<sup>104</sup>. Promoting quality, openness and effectiveness, these practices apply whenever Commission departments collect and use advice from external experts.

Implementation of the new guidelines has started at various levels. First, the need for maximum openness has been taken into account in the definition of the new "standard explanatory memorandum" and the framework for "extended impact assessment". Where the Commission has relied on external expertise for the preparation of a proposal, the memorandum attached to the proposal must include a short summary describing the methodology used, the list of experts consulted, the advice received, how the advice was taken into account and, where appropriate, indicate how to access the report(s) of the expert(s). As for extended impact assessments, they too must include precise information on the collection and use of expertise<sup>105</sup>.

In addition initiatives aimed at widening and systematising the collection of expertise in specific domains have been taken<sup>106</sup>. Twelve "advisory groups" have been set up to

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<sup>104</sup> Communication from the Commission on the collection and use of expertise by the Commission, COM(2002)713, 11 December 2002.

<sup>105</sup> See for instance, Tobacco regime (pp. 50-54); Reforming the European Union's sugar policy (pp.37-40); Proposal amending Decision N° 169/96/EC on the trans-European transport network (p.51); Directive of the EP and of the Council amending Directive establishing a scheme for greenhouse gas emission allowance trading within the Community, in respect of the Kyoto Protocol's project-based mechanisms (p. 31); Communication on immigration, integration and employment (p. 16).

<sup>106</sup> In 2003, the European Food Safety Authority issued over 100 scientific opinions on animal health, animal welfare and plant health, task previously performed by various scientific committees of the Commission. A programme has also been launched for improving scientific and technical advice for Community fisheries management, among other things, by strengthening its cooperation with the Member States and scientific institutions (COM(2003)625, 27 February 2003). Other initiatives having required special use of external expertise include the "Clean technologies Action Plan" to be presented by DG environment in December 2003 and the proposal to recast the Council Regulation on the European Monitoring Centre on Racism and Xenophobia, COM(2003)483, 5 August 2003.

advise the Commission on the various themes of the sixth Framework Programme for R&D. Their work in 2003 focused on the revision and updates of the work programmes in the run-up to the launch of the next set of calls for proposals. The new guidelines have also been applied in preparing the so-called “3% Action Plan” launched by the Barcelona European Council in March 2002<sup>107</sup>. Last but not least, the Commission has made significant progress regarding “Scientific Support for Policies”, one of the priorities of the Framework Programme. The SINAPSE e-network (Scientific INformAtion for Policy Support in Europe) has been developed and the pilot phase will be launched early 2004. Open to all scientists, scientific organisations and anyone with an interest in science, this electronic network mainly pursues a triple ambition: increasing dissemination and use of scientific advice by developing an electronic library of available scientific opinions and advice issued in Europe and elsewhere; enabling the Commission to conduct informal scientific consultation; and giving the scientific community and other stakeholders the possibility to send early warning signals to public authorities Europe-wide and raise their awareness of scientific issues.

Finally, insofar as implementation of the principles and guidelines is seen by the Commission as an evolutionary process, a system for monitoring and review has progressively been put in place. Directorates-General have reported on their experience in implementing the guidelines and inter-departmental collaboration has been established in order to pool experience on the collection and use of expertise.

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<sup>107</sup> The aim of the action plan is to increase investment in research and technological development to 3% of the Union’s GDP by 2010.

## Annex 5: Updating and simplifying the Community acquis

With the framework action “Updating and simplifying the Community acquis”<sup>108</sup> adopted in February 2003, the Commission launched an ambitious programme to ensure that Community legislation is clear, understandable, up-to-date and user-friendly. Conceived as the beginning of a long-term process, the programme foresees an intensive start-up period of 2 years divided into 3 phases: Phase I from February to September 2003; Phase II from October 2003 to March 2004; and Phase III from April to December 2004. The Commission presented a first progress report in October 2003<sup>109</sup>.

The objectives of the programme are to simplify the contents of the acquis, to up-date it and to reduce its volume (through consolidation, codification and removal of obsolete legislation)<sup>110</sup>, and to provide more reliable and user-friendly organisation and presentation of the acquis. The finality of this exercise is not to deregulate but to replace past policy approaches with better-adapted and proportionate regulatory instruments.

*Simplifying the acquis* is clearly the biggest challenge. Having defined priority indicators<sup>111</sup> to help identify opportunities and needs for simplification, the Commission is currently screening nearly 20 policy sectors for simplification potential. Around 170 directives and regulations have already been identified as confirmed or potential candidates for simplification and are currently under active examination by the Commission<sup>112</sup>. By the end of Phase I, the Commission had adopted 18 proposals for simplification. During Phase II (October 2003 to March 2004), the Commission is planning to adopt 23 additional proposals with simplification implications.

With regard to the *reduction of the volume of the acquis*, June 2003 saw the completion of the programme of consolidation<sup>113</sup> launched in 1996. More than 2200 families of legislative acts<sup>114</sup> have been consolidated and are available on-line via

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<sup>108</sup> COM(2003)71, 11 February 2003.

<sup>109</sup> The first interim report outlines achievements during Phase I and the work programme for Phase II, see COM(2003)623 and SEC (2003)1085, 24 October 2003.

<sup>110</sup> This objective is in line with the target set in 2001 by the President of the Commission to reduce the volume of the *acquis* by 25% before the end of his term in office.

<sup>111</sup> Pursuant to the multiannual programme for enterprise and entrepreneurship adopted by the Council on 20 December 2000 (OJ L 333, 29 December 2000, p.84), the Commission is planning to conduct a further study to improve the consistency and quality of these indicators.

<sup>112</sup> The Commission has invited Member States and stakeholders in general to screen Community legislation and indicate where there is a need for simplification. The task force for better regulation, an independent body set up by the British government, has announced its intention to present proposals in 2004 on areas of European legislation requiring simplification.

<sup>113</sup> Consolidation consists of editorial assembling, outside any legislative procedure, of the scattered parts of legislation on a specific issue (in other words, bringing into a single text the original act and subsequent amendments). This clarification exercise does not entail the adoption of a new instrument and the resulting text therefore has no formal legal effect.

<sup>114</sup> A family is an ensemble of original and related amended legal texts.

EUR-Lex. It should be noted that this exercise has been conducted on a multilingual basis and that, with enlargement, the number of official languages has increased from 11 to 20.

The even more demanding codification<sup>115</sup> programme launched in November 2001 is now at cruising speed and is set, despite significant obstacles, to be completed by the end of 2005 as planned. During Phase I the Commission adopted 7 codified Commission acts and 15 proposals for codified acts to be adopted by the European Parliament and the Council. During Phase II the Commission plans to adopt or propose some 150 codifications.

As for updating the *acquis*, reinforced efforts to remove obsolete legislation through formal repeal or by an additional instrument of “declaration of obsolescence” are beginning to give concrete results, although delays have occurred. Phase I efforts should result in the elimination of 30 obsolete legal acts. Some 600 more are under consideration and could in part be eliminated during Phase II.

*Improvement of the organisation and presentation of the acquis* has been taken forward. Measures to offer more user-friendly access to Community law will be enacted before the end of 2003. Subsequent measures include presentation more focused on the secondary legislation actually in force and generally applicable (via CELEX and EUR-Lex).

In line with its commitment to a *transparent* process, the Commission is presenting progress reports after completion of each of the above 3 phases, including a scoreboard on progress made with regard to codification, repeals and declarations of obsolescence.

The results of the first phase of implementation of the framework action are mixed but not unsatisfactory. Completion of the consolidation programme is a major service for the ultimate benefit of citizens and operators. Another key achievement is the progressive involvement of different services in efforts to simplify legislation because it demonstrates that a change of regulatory culture is taking place. The weak points mainly concern the short and medium-term actions to reduce the volume of Community legislation (codification and elimination of outdated legislation). However, the Commission is satisfied that the process launched in February 2003 appears to be taking a firm foothold and should continue to produce benefits for citizens and other users of Community legislation.

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<sup>115</sup> Codification involves the adoption of a new legal instrument which incorporates and repeals the instruments being consolidated (basic instrument + amending instrument(s)) without altering their substance. It could also be defined as formal or official consolidation.



## Annex 6: Quality of drafting

The 1997 Intergovernmental Conference annexed a declaration to the Amsterdam Treaty inviting the European Parliament, the Council and the Commission to establish – by common accord – guidelines for improving the quality of the drafting of Community legislation.

On 22 December 1998, the three institutions involved in the legislative process adopted the Inter-institutional Agreement on common guidelines for the quality of drafting of Community legislation<sup>116</sup>. They committed themselves to taking the following measures to ensure that the guidelines are applied: drawing up of a Joint Practical Guide for persons involved in the drafting of legislation; organisation of internal procedures; creation of drafting units; provision of training in legal drafting; development of information technology tools to assist drafting; collaboration between the departments responsible for ensuring drafting quality in the European Parliament, the Council and the Commission; and cooperation with the Member States.

Drawn up in 2000, the *Joint Practical Guide* was edited for publication in 2002. It will shortly be made available to the general public on EUR-Lex (the legislative page of the EUROPA internet site). As for the *organisation of internal procedures*, the inter-service consultation offers the possibility of improving drafting quality when texts are still in early draft form. The legal revisers now make drafting suggestions at this stage which are incorporated in the opinion of the Legal Service (1100 drafts covered in 2002 and 1750 in the first 11 months of 2003). The commitment regarding *drafting units* have also been met. Commission services with major legislative activity now have their own legal units that centralise expertise in drafting. All Directorates-General have legislative co-ordinators whose functions include monitoring the quality of the legislative proposals and draft legislation they produce. Legal revisers have been giving *training in legal drafting* since 2001 to Commission's Directorates-General which are most often involved in the legislative process. The plan for the next stage is to offer more advanced courses focusing on the actual texts produced by the departments. Finally the Commission has developed an *information technology tool* to harmonise and improve the basic presentation of legislative acts called LegisWrite. The tool is being further developed and its use extended.

Besides, *collaboration between the Legal Revisers of the three institutions* involved in the legislative process has been strengthened. Further impetus to such contacts is being given by the need to finalise the Community acquis in the languages of the candidate countries. Closer links are also being established with the relevant departments of other actors such as the European Central Bank and OPOCE.

Finally *cooperation with the Member States* has been enhanced by a series of seminars on legislative quality for Commission and Member States officials involved in the legislative process.

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<sup>116</sup> OJ C 73, 17 March 1999, p.1.