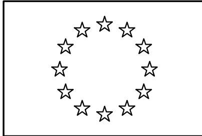

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Annex to the

**Report from the Commission "Better Lawmaking 2004"
pursuant to Article 9 of the Protocol on the application
of the principles of subsidiarity and proportionality (12th Report)**

{COM(2005) 98 final}

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1. INTRODUCTION

The first part of this working document is mainly concerned with the progress made in 2004 in implementing the Commission action plan of June 2002 entitled "Simplifying and improving the regulatory environment"[1] and the Inter-institutional Agreement (IIA) on "Better Lawmaking" of December 2003[2]. Progress in the individual Member States is merely mentioned owing to the diversity of situations.

The second part of the document relates to the application of the principles of subsidiarity and proportionality. It describes the legal and institutional framework in place and summarises the changes proposed by the Constitutional Treaty signed in October 2004. It then reviews the way in which the principles have been interpreted and applied by the Commission, Parliament and Council during the past year. Finally, it examines action taken by the Committee of the Regions and national parliaments and also looks at the case law of the Court of Justice of the European Communities.

2. BETTER REGULATION

Owing the division of responsibilities within the Union, improvement of the regulatory environment requires joint efforts on the part of the European Parliament, the Council, the Commission and the Member States. The following sections analyse the main developments in 2004, with reference to the various players (Commission, other EU institutions, Member States).

2.1. Actions taken by the Commission

The Commission has special responsibility at three levels: legislative preparation and proposal (with exclusive right of initiative for EC policies); participation in legislative deliberation; and implementation of the legislation. The presentation of the progress made within the framework for 'better lawmaking'[3] and the action plan adopted in 2002 follows that order.

2.1.1. Consultation of interested parties

In 2004**,** public consultation figures have significantly increased, showing how serious the Commission is about consulting and providing information on its thinking[4]. It produced **6 Green Papers** (+1)**, 1 White Paper** (+1) **and 159 Communications** (+17). It also published **110 reports** (+37) and organised **95 Internet consultations** (+35) through "Your Voice In Europe", the Commission' single access point for

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1 Referred to subsequently as the "action plan" (COM(2002) 278, 5 June 2002). This action plan follows up the White Paper on European Governance (COM(2001) 727, 25 June 2001). It takes into account the recommendations made by the Group on Regulatory Quality chaired by D. Mandelkern, presented to the Laeken European Council in December 2001. For more information on the eight specific communications detailing its objectives, see the annual report "Better Lawmaking 2003", COM(2003)770, 12 December 2003.

2 OJ C 321, 31 December 2003, p.1.

3 COM(2002) 704, 11 December 2002.

4 For a detailed assessment on public consultation in 2004, see Annex 2.

consultation[5]. In addition, the Commission launched the European Business Test Panel (EBTP), which is used to sound out business opinion on new legislative proposals, the application of current rules and policy initiatives[6].

A review of the preparation of major policy initiatives (i.e. those preceded by an extended impact assessment) shows that most minimum standards for consultation have been properly applied[7]. Compliance with obligations regarding publication of open consultations on the single access point, time limits for responses and reporting on the consultation process and results was particularly good. The number of consultations posted on the single access point for consultation increased by almost 60 % from the year 2003. In most cases, the consultation process was spread over a long period and was based on a combination of tools (open internet consultations, workshops, hearings and advisory groups).

However, in a few instances of open consultations, the representativeness of responses or their number was not satisfactory. For some consultations, the fact that the questionnaire and/or background documents were only available in a limited number of languages had a clear impact[8]. For others, the low response rate seems to indicate "consultation fatigue" among certain stakeholders and inadequate advertising[9]. There is at that level a clear trade-off: increasing the number of consultations decreases resources available to advertise proactively each launch. The number of consultations and the level of detail required should take these elements into consideration.

Besides, in two thirds of the cases reviewed, too little was said on how comments were taken into account in the proposal or why they were discarded. There were also several cases of targeted consultations (for instance when the Commission consulted via conferences and hearings) for which information on the parties consulted was relatively vague. All in all, the Commission still needs to make additional efforts on feedback to respondents and, to a lesser extent, on transparency.

2.1.2. Impact assessment

In 2002, the Commission decided that the economic, social and environmental impact of all major initiatives would have to be assessed in an integrated manner, defining detailed guidelines for conducting these **Extended Impact Assessments** (Ex-IA)[10].

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5 See http://europa.eu.int/yourvoice/consultations/index_en.htm.

6 See http://europa.eu.int/yourvoice/ebtp.

7 The Commission's implementation of public consultations changed substantially at the procedural level in 2003, with the introduction of **minimum standards for public consultation** designed to better identify the need for an action, expectations and types of action to be taken (COM(2002)704, 11 December 2002). When the Commission entrusts the organisation of the consultation to a third party, compliance with the standards is part of the latter's mandate. It was for instance the case with the consultation on air navigation entrusted in 2004 to Eurocontrol.

8 When the number of responses was high, reweighting was possible by basing the analysis on an adjusted sample of responses – as in the case of the public consultation concerning the "Future guidelines for the new multi-annual programme on the establishment of an area of freedom, security and justice".

9 A more systematic use of electronic bulletins will be envisaged to advertise consultations.

10 COM(2002) 276, 5 June 2002.

Quantitatively speaking, 2004 offered mixed results. On the positive side, the number of Ex-IA completed in the year increased significantly: 29 against 21 in 2003. Moreover several other Ex-IA are expected to be finalised in the early part of 2005. Besides, Ex-IA were interrupted or postponed when initial findings indicated that there was no need for action or that action should be taken at another level. The number of officials with expertise and experience is rising, which should have a positive knock-on effect in future impact assessment work. On the negative side, the rate of completion remained below 50% (with 2003 carry-overs the Commission had planned to complete 70 Ex-IA in 2004). A number of factors contributed to this situation: optimistic planning, lack of resources and, last but not least, the delay in the new Commission taking office. In some cases, the impact assessment was not completed because it appeared at an early stage that action at EU level was not necessary or because last minute developments required further investigation.

As for the overall quality of the Ex-IA, it continued to improve during 2004, particularly with respect to the range of options reviewed and the information on the consultation processes feeding the analysis or impact assessment. Inter-service co-ordination at an earlier stage helped in identifying more balanced solutions. However too many Ex-IA still failed to give sufficient attention to social and environmental dimensions or to quantify the likely impacts.

In order to draw the lessons of the first Ex-IA, an inter-service working group was established in April 2004. The Commission set out to examine how the method and procedures could be refined in order to tackle some of the problems outlined above. Its work was summarised in a Commission Staff Working Document, "Impact Assessment: Next steps - In support of competitiveness and sustainable development", which was presented to the Council in October 2004[11]. Overall, it was found that the basic approach used was sound. It also appeared that there was a need for the list of impacts for review to be refocused, the objectives of the Lisbon and Sustainable Development Strategies more firmly anchored in the assessment, and technical tools further developed.

In line with these recommendations, further work has been done to develop technical tools. The I.Q. Tools project is on course for completion by the end of 2005[12]. Important work was also done on how to take into account more systematically the administrative costs imposed by legislation (administrative burden) when assessing the possible impact of new initiatives and when simplifying existing legislation. A Commission Staff Working Document was prepared to explore the possibility of designing a common EU methodology and launch a test phase (this document will be sent to the Spring European Council). . Besides the Commission's impact assessment working group examined how to better screen competition impacts in general, in order to identify and address possible regulatory barriers to competition, with the aim to create new opportunities for market entrants and to spur investment and innovation.

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[11] SEC(2004) 1377.

[12] Developed for the Commission by a consortium of universities and research centres with the support of the Sixth Research Framework Programme, the I.Q. Tools project will provide, among other things, an inventory of key indicators and models as well as a decision-support tool.

In order to improve programming, it was also decided to require for each item put on the 2005 Commission's Legislative and Work Programme a 'Roadmap' setting out the issue to be tackled, the policy options to be considered, the range of likely impacts, the need for consultation with stakeholders, as well as the required level of resources for the impact assessment. The previous distinction between 'Preliminary Impact Assessment' and 'Extended Impact Assessment' has been abandoned.

As an aid to transparency and to encourage early stakeholder involvement in the consultation process, the Roadmaps will be published along with the Commission Legislative and Work Programme. Besides, general background documents on the Impact Assessment procedure as well as the completed Impact Assessments have been made easily available on an 'Impact Assessment' page on the Europa website[13].

Overall, the process of adaptation to the new approach is certainly gathering pace, but more has to be done to ensure that sufficient time and resources are set aside for impact assessment. It is particularly urgent to address this problem insofar as the Commission decided that, from 2005 on, all initiatives listed in its Work Programme will be subject to an impact assessment, with the exception of Green Papers and consultations with social partners.

2.1.3. 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** promoting quality, openness and effectiveness, whenever Commission services collect and use advice from **external experts**[14]. In 2003, these practices have been integrated in the Commission's format for impact assessment and for explanatory memorandum accompanying legislative proposals ("standard explanatory memorandum").

In 2004, the collection of expertise in specific domains has been systematized thanks to the sixth Framework Programme for R&D (2002-6 - "Scientific Support for Policies" priority). The technical development of a web application allowing for greater dissemination and use of scientific advice (SINAPSE e-network - Scientific INformAtion for Policy Support in Europe) has been completed. In November 2004, Commission services and scientific organisations have been invited to register in view of the official launch of this electronic network in March 2005[15]. In addition, initiatives aimed at widening and systematising the collection of expertise in specific domains have been taken[16].

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13 http://europa.eu.int/comm/secretariat_general/impact/index_en.htm.

14 COM(2002) 713, 11 December 2002.

15 http://europa.eu.int/comm/research/science-society/science-governance/sinapse_fr.html & www.europa.eu.int/sinapse

16 The collection of expertise has been systematically pursued in specific domains such as Research & Development. Besides the work asked to the twelve "advisory groups" associated with different issues dealt with by the sixth Framework Programme for R&D (FP6), experts have been called in to carry the mid-term review of the new instruments set up for the FP6 (the Marimon report) as well as the five year assessment of the implementation of the FP.

Following the commitments made in July 2004 by President Barroso to the European Parliament, work has started on improving **transparency on expert groups established by the Commission**. It will result in the publication early 2005 of a list of these groups and in the launch, later that year, of a register providing the Parliament and the public at large with standard information on all expert groups.

2.1.4. Explanatory memorandum

The explanatory memorandum accompanying the Commission proposals is a very important document as far it enables the Commission to inform the legislator and the citizen, and to demonstrate that it exerts its right of initiative in a responsible way. New drafting rules reflecting the undertakings made in the Commission's Action Plan and in the Inter-Institutional Agreement on better lawmaking have been approved by the Commission in December 2003.

In order to improve compliance with this standard explanatory memorandum, the Commission has developed a computerised form which structures the required information and reminds services of key obligations. The pilot phase showed a marked improvement in the quality of explanatory memoranda, in particular with regard to reasons for concluding that proposals respect the principles of subsidiarity and proportionality. This will also allow for effective monitoring and reporting on a significant number of Better Regulation measures. The new system will be introduced early 2005.

2.1.5. Updating and simplifying the Community acquis

With **its framework action "Updating and simplifying the Community acquis"**[17] adopted in February 2003, the Commission launched an ambitious programme to simplify the contents of the acquis, update it, reduce its volume (through consolidation, codification[18] and repeal of obsolete legislation) and improve its presentation. Conceived as the beginning of a long-term process, the programme foresaw an intensive start-up period of almost 2 years, from February 2003 to December 2004.

By the end of Phase II (October 2003-March 2004), the Commission had adopted 12 initiatives with simplification implications and identified 12 new candidates for simplification for Phase III (April-December 2004)[19]. At the end of the year, 18 legislative simplification proposals were pending before the Parliament and the Council. The Commission also started examining the priority list submitted by the Council in November 2004, in order to decide in the course of 2005 on the appropriate follow-up. Codification had progressed well at the technical level[20], while

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[17] COM(2003) 71, 11 February 2003.

[18] Codification consists of the adoption of a new instrument, which is published in the L series of the Official Journal, and which incorporates and repeals the previous instruments (i.e. the basic act and all intervening amending instruments).

[19] The Commission will report on the implementation of the framework action to update and simplify the community acquis late Mach-beginning of April 2005.

[20] By the end of December 2004, some 800 acts, representing some 24 500 pages of the Official Journal, have been or are being processed. Fifty acts were pending before the Council and the European Parliament and 40 before the Commission, finalised in 11 languages and awaiting

nearly 900 legal acts were under examination to determine the correct approach for their withdrawal from the acquis. There was no consolidation backlog (pm the entire acquis was entirely consolidated for the first time in mid-2003).

The weak points of the implementation of the framework action remain the short and medium-term actions to reduce the volume of Community legislation (in particular, codification and, to a lesser extent, elimination of outdated legislation). Progress in 2004 was thus delayed by a number of factors[21] and the 25% reduction planned for end-2004 could not be reached. The objective is however likely to be realised within a reasonable period thereafter given the progress made at the technical level for each of the operations concerned.

The final report, taking stock of the entire start up period, is due for adoption in March 2005[22]. It will be also the occasion for the Commission to up-date its rolling programme for simplification[23] and establish a new framework for 2005-9. That new framework will combine the horizontal approach set out in February 2003 with sectoral initiatives. The Commission is also reflecting on how the experience and know-how gained in the 2004 enlargement can be used in particular to prepare for future enlargements of the Union.

2.1.6. Choice of instruments

In its Action Plan, the Commission stressed the need to pay more attention to the choice of instruments for pursuing Treaty objectives and implementing Community policies, including the use of alternative regulatory instruments (self-regulation and co-regulation), the decentralisation of tasks to agencies and the conclusion of tripartite contracts between the Community, the States and regional or local authorities.

Its desire to develop the use of alternative regulatory instruments having been expressed at several levels, the Commission has prepared an inventory of the co-regulation mechanisms put in place by the Union and the forms of self-regulation with a Community dimension already being monitored by its own departments. This inventory will be used as a basis for the first report on the use of co-regulation and self-regulation at Union level which the Commission has undertaken to produce as

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the 9 new language versions. Another 140 acts are finalised in 11 languages and are ready to move into the final legislative procedural stages once the 9 new language versions are available. Most of the remainder should be finalised by the end of 2005.

[21] The first was the moratorium stipulating that no codified act was to be adopted and published during a period of nine months prior to the May 2004 enlargement. A period of relative stability in the acquis was indeed necessary in order to prepare the publication of the acquis in the new official languages. The Commission also encountered unforeseen problems which were, for a large part, beyond its control. In particular, it proved impossible for the new Member States to complete the translation of the *acquis* into the new languages by the date of accession. Besides delays in the translation and publication processes, codification work was stalled by technical difficulties experienced by the Office for Official Publications in the production of consolidated texts in the new official languages.

[22] The second progress report and programme update was presented in June 2004 COM(2004) 432, 16 June 2004.

[23] As foreseen by the Framework Action, steps have been taken to integrate, from 2005 on, simplification initiatives in the annual programming cycle and include them in the Commission's Work Programme.

part of the process of implementing the IIA on "Better Lawmaking" and which will be presented in 2005. The Commission has also opened discussions with the European Economic and Social Committee (EESC) to establish synergies between the two institutions as regards collection of information on self-regulation and co-regulation. In particular, these discussions are covering the use of the PRISM database set up by the EESC's Single Market Observatory (SMO)[24]. More specifically, the Commission has also proposed on several occasions that use should be made of these alternative instruments, but this has not always been followed up by the legislator, and vice versa (see section 3.2).

Moreover, the Commission continued to argue and act in favour of decentralising some highly detailed executive tasks to European regulatory agencies[25]. In order to safeguard fundamental institutional and functional aspects and to facilitate the creation of such agencies, the Commission issued a Communication on the operating framework for European Regulatory Agencies in December 2002[26]. Inter-institutional discussions accelerated notably towards the end of 2003 and in the first half of 2004. The Parliament and the Council both welcomed the Commission's Communication in their respective Resolution[27] and Conclusions[28], inviting the Commission to submit a proposal for a framework.

In the meantime, the Commission proposed the creation of a European Chemicals Agency as part of the REACH (Registration, Evaluation and Authorisation of Chemicals) package[29] and the setting-up of the Community Fisheries Control agency[30]. At the time of writing, these proposals are still under inter-institutional negotiations. Regulations establishing, respectively, the European Network and Information Security Agency[31], the European Centre for Disease Prevention and Control[32], the European Railway Agency[33], GNSS Supervisory Authority[34] and the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the EU[35] were all adopted in 2004. A Council joint action also established the European Defence Agency[36]. As a result, the total number of Community / EU agencies has grown to 26.

Finally, progress was made on **target-based tripartite contracts and agreements** between the Community, the States and regional or local authorities[37]. The first agreement was signed by the Commission, the Italian State and the Lombardy region

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24 See http://www.esc.eu.int/Omu_Smo/Prism/default.htm.
25 Communication on European Governance: Better lawmaking, COM(2002)275, 5 June 2002.
26 COM(2002) 718, 11 December 2002.
27 Doc P5_TA(2004)0015.
28 Doc. 17046/04.
29 COM(2003) 644 final, 29 October 2003.
30 COM (2004) 289 final, 28 April 2004.
31 European Parliament and Council Regulation (EC) n° 460/2004 of 10 March 2004.
32 European Parliament and Council Regulation (EC) n° 851/2004 of 30 March 2004.
33 European Parliament and Council Regulation (EC) n° 881/2004 of 29 April 2004.
34 Council Regulation (EC) n° 1321/2004 of 12 July 2004.
35 Council Regulation (EC) n° 2007/2004 of 26 October 2004.
36 Council Joint Action of 12 July 2004.
37 *Rapport sur la gouvernance européenne (2003-2004)*, SEC(2004) 1153, 22 September 2004. http://www.europa.eu.int/comm/governance/index_fr.htm

in Milan in October 2004. Agreement projects presented by the cities of Birmingham, Pescara and Lille are under examination. A more sustained commitment on the part of the central, regional and local authorities concerned is desirable. The results of this experimental phase will allow this instrument to be assessed for its value added in terms of taking specific contexts into account when framing and implementing Community policies.

2.1.7. Better monitoring of the application of EU law

The Commission has the responsibility to ensure the timely and full implementation of Community legislation, in close cooperation with Member States. This function is vital in a Community based on the rule of law and is important to public confidence in the functioning of the European Union. The 2002 Communication on *Better monitoring of the application of Community law*[38] sets out a series of actions aimed at improving the effectiveness of the work being done. These actions are now in the process of implementation. The Commission's 21st annual report on the monitoring of the application of Community law in 2003 goes into these and related issues in greater detail[39].

In parallel, steps have been taken to bring the 10 new Member States into the system for the control of the application of Community law (on-line system for the advance notification of their national measures to transpose directives before their accession, etc). The new Member States are now fully integrated into the regular monitoring process. A procedure has also been established to ensure monitoring and review of the overall impact of enlargement.

Moreover, actions have been undertaken to further improve the implementation of directives more generally. A requirement for Member States to provide concordance tables, linking the articles of the directive with the provisions that implement them into national law, are being systematically included in Commission proposals for new directives with a view to improved transparency and easier monitoring of the conformity of national measures by the Commission. Greater use is being made of early follow-up with Member States after the adoption of directives, including the use of interpretative communications, the early identification of likely problem issues and various forms of technical assistance. The method for the notification of national implementing measures has also been significantly upgraded through the introduction of the new on-line system, now being used by 22 of the Member States.

Formal infringement procedures are lengthy, but the Commission is making its best efforts to accelerate their internal processing and obtain rapid corrections to the incriminated legal system. Therefore the use of less formal measures instead of, or alongside, these procedures has been promoted in accordance with the specific

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[38] COM(2002) 725, 16 May 2003.

[39] COM(2004) 839, 30 December 2004. PM. The Commission also monitored the transposition of framework decisions and decisions adopted in the realm of police and judicial cooperation in criminal matters (COM(2004)54 on the standing of victims in criminal proceedings; COM(2004)230 on money laundering; COM(2004)346 on fraud and counterfeiting of non-cash means of payment; and COM(2004)409 on terrorism; and COM(2004)457 on the setting up of Eurojust).

characteristics of each issue in each area of law. SOLVIT, the Internal Market's problem-solving network, is an example of such an instrument[40]. Moreover the Commission has prepared the launch in 2005 of a new internet-based tool to facilitate the filing of complaints by citizens and businesses concerning non-compliance with Community law.

Transparency being essential for improving the application of Community law, the on-line site called "Calendar for transposition of directives" has been regularly updated, allowing Member States and citizens to consult on a regular basis the deadlines applicable for transposition of Community directives[41].

2.1.8. Regulatory indicators

The Commission currently has a number of monitoring instruments partially based on indicators, including the Better Law-making report and different Commission Scoreboards (Enterprise Policy Scoreboard, the report on the functioning of product and capital markets (Cardiff Report), etc.). The Commission repeated on various occasions the need to rationalise and complete the monitoring and reporting mechanisms on Better Regulation (BR). The development of a set of legislative and regulatory indicators is also one of the objectives of the presidency of the Council and the Council[42].

In 2004 the Commission took several concrete steps to prepare for such an improvement. Demand and supply of legislative statistics were evaluated. In order to improve comparability and put the volume of EU acquis into perspective, several requests were made to and accepted by the European Forum of Official Gazettes. Other measures will follow in 2005.

Besides the new computerised form for drafting explanatory memoranda was designed to feed several key indicators on the quality of the proposals presented by the Commission (see subsection 2.1.4). Other types of regulatory indicators were reviewed in a "Study on indicators of regulatory quality" conducted for the Commission by the Centre for European Studies of the University of Bradford (Prof. Radaelli) and completed in December 2004[43]. The Commission also intends to collect information on indicators of real-world impact, i.e. on how economic operators perceive the ongoing work to improve the regulatory environment. To this end a questionnaire has been developed with the view to consulting European businesses via the EBTP on a regular basis to detect trends and developments. The first consultation is planned for the beginning of 2005.

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[40] http://europa.eu.int/solvit/site/index.htm

[41] See http://europa.eu.int/comm/secretariat_general/sgb/droit_com/index_en.htm#echeancier

[42] Cf. *Joint Initiative on Regulatory Reform,* 27 January 2004 (endorsed by Ireland, the Netherlands, Luxemburg and the UK); and *Advancing Regulatory Reform in Europe*, 7 December 2004 endorsed by the four previous, plus Finland and Austria). Conclusions of the Competitiveness Council of 17 and 18 May 2004.

[43] The study is part of the Multiannual Programme for Enterprise and Entrepreneurship (2001-2005). Council Decision (2000/819/EC) of 20 December 2000, OJ L 333/84, 29.12.2000.

2.1.9. *Other actions*

Quality of drafting

In 2004, new efforts were made on accessibility of drafting guidelines, presentation of legislative acts, revision of the translation of the acquis in the new official languages of the Union, revision of draft proposals and training. The *Joint Practical Guide for persons involved in the drafting of legislation* was made available to the general public on EUR-Lex, the legislative page of the EUROPA internet site[44]. Its translation into the new official languages was made available to all staff within the institutions pending its finalisation for general publication. LegisWrite, the IT tool used to harmonise and improve the basic presentation of legislative acts, has been extended to include the new official languages and further developed. Besides, the legal revisers have consolidated their role in the consultation procedure between DGs, which enables them to improve drafting quality when texts are still in early draft form (some 1900 drafts were covered in 2004). Moreover, the legal revisers have extended their programme of training in legal drafting to new sectors within the Commission. Collaboration with the Legal Revisers of the Council has also developed for finalisation of the Community acquis in the new official languages. Finally cooperation with the Member States has been maintained in particular by the series of seminars on legislative quality for Commission and Member States' officials involved in the legislative process. In June 2004 the seminar on *Quality of legislation: challenges facing a common-law system* attracted nearly 300 participants.

Review and revision clauses

As foreseen in the Action Plan, the Commission paid particular attention to the need for review, revision or automatic suppression of legislation[45]. Review and revision were frequently proposed in policy areas or sectors such as competition, social affairs, environment, energy, visa policy and border management[46]. Sunset clauses, although rarer, were also proposed in these sectors[47]. The European Parliament and/or the

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[44] http://europa.eu.int/eur-lex/en/about/techleg/index.html.

[45] This is particularly necessary where legislation is based on scientific advice or where there is scientific uncertainty and significant risk (cf. Communication on the precautionary principle COM(2000) 1).

[46] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings; Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services; proposed directive amending Directive 2003/88/EC concerning certain aspects of the organisation of working time COM(2004) 607, adopted on 22 September 2004; proposed regulation concerning the Visa Information System (COM(2004)835 final of 28 December 2004); Council Regulation (EC) No 2007/2004 of 26 October 2004 establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (standard provision in the regulations establishing Community agencies); proposed Regulation on medicinal products for paediatric use - COM(2004) 599.

[47] Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (due to expire on 10 April 2014); amended proposal for a regulation amending Council Regulation 3922/91 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation, COM(2004) 73 final, 10 February 2004; proposed directive laying down rules on nominal quantities for pre-packed products COM(2004) 708, 25 October 2004.

Council also requested the inclusion of review or revision clauses in a number of cases[48].

The Commission also designed a mechanism to automatically remind its services of the need to consider the inclusion of such clauses. This mechanism will also allow monitoring the number of times the Commission proposes to include these clauses and in which sectors. This mechanism will be put in place early 2005.

Withdrawal of pending proposals

Following its periodic review of pending proposals, the Commission has adopted a list of 102 proposals withdrawn due to obsolescence[49]. This represents a substantial fall compared to the previous list published in 2001. It can be interpreted as the direct consequence of better preparation, better drafting and better programming coordination between the Commission and the Legislator[50]. The fact that the Commission proposals have declined in number (549 proposals in 1997 against 371 in 2003) and possible variation in the quality of the review process must also be taken into account.

In its Action Plan, the Commission also announced that it will consider resorting more often to political withdrawal of individual proposals, whenever the amendments introduced by the Council and the European Parliament denature the proposal or introduce complexity which is incompatible with the provisions of the Treaty. That option was publicly envisaged following Council's amendments to the proposed directive on takeover bids, which was eventually adopted on 21 April 2004[51]. The Commission did not exclude any option in the negotiations over its proposed directive on the patentability of computer-implemented inventions, following amendments adopted by the Parliament in its first reading on 24 September 2003[52].

Accessibility

Accessibility to documents was greatly improved in 2004, mainly thanks to the completion of two initiatives. Firstly, the main databases on European law – CELEX and EUR-LEX – were merged. The new EUR-Lex site was opened on 1 November 2004[53]. It is now possible to follow, free of charge, all legislative steps on one site. The database covers EU and EC treaties, international agreements, EC legislation in force (incl. consolidated texts), preparatory acts, parliamentary questions, case law and European Court reports, as well as all sections of the Official Journal. Secondly,

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[48] These include the proposed Directive on Eco-design requirements for Energy-Using Products, COM(2003) 453, 1 August 2003; and the proposed Council framework decision to strengthen the criminal law framework for the enforcement of the law against ship-source pollution, COM(2003) 227, 2 May 2003.

[49] COM(2004) 542 and COM(2004) 1179.

[50] Lists of pending proposals withdrawn for obsolescence: 34 proposals withdrawn in 1997, 58 in 1999, 108 in 2001 and 102 in 2004. If one takes into account intervals between the publication of the lists, the number of proposals withdrawn has decreased by more than a third.

[51] COM(2002) 534, 2 October 2002 and Directive 2004/25/EC.

[52] COM(2002) 92, 20 February 2002.

[53] http://europa.eu.int/eur-lex/lex/.

the first page of the Europa website offers a single portal with links to the registers of all EU institutions and bodies[54].

2.2. Actions at the level of EU institutions

No strategy for better regulation can fully succeed without the strong and continued political commitment of the European Parliament and the Council which have a critically important responsibility when deliberating, amending and adopting legislative proposals. Good cooperation between Parliament and Council, and between them and the Commission is equally important.

In 2004, **the Council and its presidency** were proactive on a number of "better regulation" items. On 26 January, the Ministers of Economy of the countries holding the presidency in 2004-5 – Ireland, the Netherlands, Luxembourg and the UK – released their *Joint initiative on regulatory reform*. This initiative was updated and prolonged by a second statement *Advancing regulatory reform in Europe* released on 7 December 2004, signed by the previous four plus Finland and Austria, who will hold the presidency in 2006. The presidencies were calling for special efforts on the reduction of administrative burden, impact assessment, simplification and greater use of regulatory alternatives (self- and co-regulation). Studies on cumulative burden on the automotive sector and on how to take into account the competitiveness impact of proposed legislation on business were prepared at the request of the Competitiveness Council. A significant achievement during 2004 was the adoption under the Dutch presidency of a list of 15 priorities for simplification by the (Competitiveness) Council, selected on the basis of suggestions from Member States following the invitation made in early June by the Irish Presidency[55]. The Council also selected the proposed directive on batteries and accumulators[56] to make its first ever impact assessment prior to the adoption of substantial amendments (see sub-section 3.2.4). Welcoming the conclusions of the ECOFIN Council on the issue, the European Council of November 2004 invited the Commission to develop a common European methodology for assessing administrative burden.

On the negative side, the pace of adoption of codification and simplification proposals remained very slow. Out of 30 proposals for simplification tabled by the Commission, the Council adopted only 10 and that too many amendments were not transparently analysed. The Commission also regrets that, for a significant number of directives, the Council decided not to require concordance tables from Member States (see subs-section 2.1.7).

At bilateral level, **the Parliament and the Council** agreed on a Memorandum of Understanding allowing joint signature of legislative acts (adopted by co-decision)

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54 http://europa.eu.int/index_en.htm.

55 The list of proposals adopted in November 2004 includes the following priorities: plant protection products; annual accounts; twelfth company law directive; waste oils; waste directive; hazardous waste; incineration of waste; food labelling; international vs. EU motor vehicle rules; construction products; medical devices; pressure vessels; health and safety at work; and structural business statistics.

56 COM(2003) 723, 21 November 2003.

and their publication in the Official Journal within two months. The MoU was first applied in February 2004.

At trilateral level, the Parliament, the Council and the Commission started implementing the **Inter-Institutional Agreement on Better Lawmaking** adopted in December 2003[57]. Firstly, discussions have been initiated on ways to reinforce coordination through the respective annual legislative timetables. Secondly, the Commission took initial steps to improve its monitoring of the use of co-regulation and self-regulation, in particular those practices it regards as effective and satisfactory in terms of representativeness (see sub-section 2.1.6 Choice of instruments). Thirdly, although the Agreement provides that, where the codecision procedure applies, the Parliament and the Council may have impact assessments carried out prior to the adoption of any substantive amendment, Parliament carried out no such assessment. As for the Council, it carried out one pilot project, but did not draw as yet lessons to be learnt from it (see above and sub-section 3.2.4). The possibility of establishing a common methodology was also considered, but this will need to be further discussed. The Commission believes that a common methodology on impact assessment should be based on the cross-sectoral and integrated approach introduced in 2002 and used since then for more than 60 Extended Impact Assessments. It also underlines the central importance of the principle of proportionate analysis (the scope and depth of analysis has to match the significance of the impacts). Additional impact assessments cannot indeed become a way to stall decision-making. Finally, despite commitment to the contrary, the Parliament and the Council did not manage to modify their working methods for the adoption of simplification proposals[58]. Insofar as this is a key element for the success of the simplification programme launched in February 2003 (see sub-section 2.1.5), the Commission hopes that the legislator will rapidly define adapted methods for the adoption of simplification proposals.

The **other trilateral inter-institutional agreements** of importance to better regulation had different fortunes in 2004. The implementation of the Inter-institutional Agreement of 22 December 1998 on common guidelines for the **quality of drafting** of Community legislation was satisfactory (see sub-section 2.1.9). The results of the Inter-institutional Agreement of 20 December 1994 on an accelerated working method for official **codification** of legislative texts remained disappointing (see sub-section 2.1.5)[59]. Only the committee procedures within the European Parliament and the Council have been streamlined. Progress on the Inter-institutional Agreement of March 2002 on a more structured use of the **recasting** technique for legal acts[60] was slow. A review of its operation has been launched by the Legal Services of the European Parliament, Council and Parliament. Their report is due for publication at the end of March 2005. Since the entry into force of the agreement, the Commission submitted 9 recast proposals to the legislative authority, of which just one has been

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[57] The High Level Technical Group, responsible for monitoring the implementation of the IIA, met in June at the initiative of the Parliament and in October at the initiative of the Council.

[58] The deadline was within 6 months of its entry into force, i.e. end of June 2004.

[59] OJ C 102, 04 April 1996, pp. 2-3

[60] OJ C 077, 28 March 2002, pp. 1-3. Recasting legislation means combining amendment to the substance with codification.

adopted so far[61]. These agreements should be complemented by fast track inter-institutional procedures for the abrogation of obsolete acts.

2.3. Actions taken by the Member States

Member States have an essential role to play in better regulation insofar as they are responsible for applying and, in the case of directives, transposing EU legislation at national level. The Ministers responsible for Public Administration set up in November 2000 a group of experts on better regulation chaired by Dieudonné Mandelkern. One of its tasks was to recommend to national governments practices to improve their policy-making process in general and implementation of European law in particular. Its final report, released in November 2001, made the following recommendations: always consider the full range of possible policy options; base policy on impact assessment and wide consultation; set up a systematic programme of simplification and consolidation; provide easy access to legislation (through Information Communication Technologies); and set up appropriate supporting structures for the promotion of better regulation[62]. In May 2002 in La Rioja, the Ministers responsible for public administration adopted a specific mid-term programme which deals, inter alia, with better regulation.

Concurrently the Commission called on Member States to carry, among other things, impact assessment and to consult interested parties before the adoption of national legislation transposing EC acts[63]. Progress seems to have been made at that level, although no reliable data are available. By analogy with what is required from EU institutions, the Commission also stressed the need to hold consultations and conduct an impact assessment before submitting EU legislative proposals[64]. In 2004, there were no examples of either of these.

Actions were launched and/or evaluated in the framework of the DEBR (Directors and Experts on Better Regulation), an informal network amongst Member States. In 2004 the Group met in The Hague (19-20 February), in Dublin (12-13 May) and Luxembourg (9-10 December). The Irish government also organised a seminar on “The Contribution of Better Regulation to Competitiveness and Social Progress” in Dublin, while Dutch authorities held a workshop on “Quantifying administrative burden” in The Hague, followed by a conference on “Simple is Better” in Amsterdam. Coordinated actions concentrated mainly on regulatory impact assessment and assessment of administrative burden[65]. The meetings of the DEBR confirmed the high

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61 Council Regulation (EC) 139/2004 on merger controls.

62 http://www.cabinetoffice.gov.uk/regulation/docs/europe/pdf/mandfinrep.pdf.

63 Section 3 of the Action Plan, COM(2002) 278.

64 Member States have a right of initiative concerning police and judicial cooperation in criminal matters (title VI TEU).

65 The report on “*Comparative Analysis of Regulatory Impact Assessments in Ten EU Countries*” was presented in May 2004, concluding the first phase of the initiative launched during the 2003 Italian Presidency and supported by Italy, Ireland and the Netherlands. The next phase of the project will be a comparison of impact assessments performed by Member States on a draft EU Directive on which the European Commission has also carried out an impact assessment (the Groundwater directive was chosen). The result of this second phase is expected to be presented in the spring of 2005. With regard to administrative burden, various experiments with the Standard Cost Model developed by the Netherlands have been initiated.

level of interest in regulatory reform on the part of national authorities and provided an opportunity to observe the remarkable progress made in the new Member States. While most Member States have now put in place initiatives to improve their regulatory environment, only a minority have a legislative simplification programme (for a summary of the state of play, see Annex 3). Implementation remains uneven.

In addition, the German government held a workshop entitled "the environmental dimension of Impact Assessment" in June 17-18, which confirmed the need for more systematic assessment of environmental impacts and for an integrated approach.

3. APPLICATION OF THE PRINCIPLES OF SUBSIDIARITY AND PROPORTIONALITY

3.1. The legal and institutional framework

3.1.1. The definition given by the Treaties

Subsidiarity and proportionality, indicating respectively when and how the Community should act, are among the main organising principles of the Union. According to the Treaty on European Union, any action taken by the Union must be in accordance with the principle of subsidiarity[66]. The general definition of both principles is provided in Article 5 of the Treaty establishing the European Community (TEC).

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 no doubt as to who should intervene and subsidiarity does not apply. If competence is shared between the Community and the Member States, the principle clearly establishes a presumption in favour of decentralisation: the Community shall take action only if the objectives of the proposed action cannot be sufficiently achieved by the Member States (necessity test)[67] and can be better achieved by the Community (value-added test or compared effectiveness).

Contrary to common belief, subsidiarity as defined in the TEC does not say that action should be taken as closely as possible to citizens. It is by essence a dynamic concept,

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[66] 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"

[67] The Protocol introduced by the Treaty of Amsterdam and now annexed to the TEC provides guidelines for examining whether the necessity condition is fulfilled. It states that Community action is justified whether there are transnational aspects which cannot be satisfactorily regulated by national measures; whether national measures alone or lack of Community action would otherwise significantly damage Member States' interests; or whether action at Community level would produce clear benefits by reason of its scale. The Protocol also mentions that Community action is justified whether national measures alone or lack of Community action would conflict with the requirements of the EC Treaty. It must be underlined, however, that acting in order to comply with the requirements of the Treaty is a general obligation which, *per se*, is not linked with subsidiarity. It is therefore not helpful to refer to this obligation when defining the essence of subsidiarity. (Protocol (No 30) on the application of the principles of subsidiarity and proportionality, http://europa.eu.int/eur-lex/en/treaties/dat/amsterdam.html#0173010078, OJ C 340, 10.11.1997, p. 105).

allowing EU action "to be expanded where circumstances so require, and conversely, to be restricted or discontinued where it is no longer justified." In other words, subsidiarity refers to the most appropriate level of action. It should therefore not be confused with the 'proximity principle', even if the application of the subsidiarity may lead to bring action close to citizens.

Proportionality is a guiding principle for defining how the Union should exercise its – exclusive and shared – competences (*what should be the form and nature of EU action?*). Article 5 TEC provides that the action shall not go beyond what is necessary to achieve the objectives of the Treaty. In other words, it is not enough to establish a correspondence between actions and objectives. The decision must lean in favour of 'minimal proportionality'. This is confirmed by the Protocol's guidelines[68]. Although 'minimal proportionality' is obviously more restrictive than 'proportionality', this principle still leaves considerable discretion to the Union's legislature[69]. In most cases, there will be a range of minimalist options with different trade-offs (i.e. where minimising the burden for one group would increase the burden put on another group). Decision-makers will then have to pass a political choice.

3.1.2. Modes of application, comment and control

While all institutions of the Union are requested to comply with both principles when exercising their powers, some of them are subject to specific procedural obligations. These obligations have been set out in the Interinstitutional Agreement of 1993 on subsidiarity[70] and the above-mentioned Protocol of 1997.

Among other things, the Commission is required – without prejudice to its right of initiative – to consult widely before proposing legislation; to state in the explanatory memorandum of each legislative proposal the reasons for concluding that the proposal complies with subsidiarity and proportionality[71]; 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 ensure that the amendments they intend to make are consistent with the principles of subsidiarity and proportionality. If one of their amendments affects the scope of Community action, they must provide a justification regarding subsidiarity[72]. Besides, when the consultation procedure or the

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68 Firstly the Protocol states that "the form of Community action shall be as simple as possible" and, whenever legislating appears necessary, "directives should be preferred to regulations". Secondly, the need to minimise the financial or administrative burden for all levels of government, economic operators and citizens should be taken into account. Thirdly "while respecting Community law, care should be taken to respect well established national arrangements".

69 This is confirmed by the case law of the European Court of Justice (see judgment of 12 November 1996, case C-84/94).

70 Interinstitutional Agreement between the European Parliament, the Council and the Commission on Procedures for Implementing the Principle of Subsidiarity, adopted 17 November 1993, OJ C 329, 6 December 1993, p.132.

71 Reasons for concluding that an objective can be better achieved by the Community must in addition "be substantiated by qualitative or, wherever possible, quantitative indicators" (Article 4 of the Protocol).

72 Section 2, point 3 of the Interinstitutional Agreement on subsidiarity of 1993.

cooperation procedure applies, the Council has to inform the European Parliament of its position on the application of subsidiarity and proportionality in a statement of reasons[73]. In other words, the current system puts the burden of proof on the institutions involved in the Union's legislative process.

Each of these institutions has, in addition, to examine if the other two apply the principles properly. The European Parliament and the Council must consider whether the Commission's proposals[74] and each other's amendments are consistent with Article 5 TEC, and oppose any violation of the principles. The Commission must do the same with the amendments of the legislator, if need be by withdrawing its proposal. The Commission must also submit an annual report on compliance with both principles. This report (that is, the Better Lawmaking report) has to be discussed by the other institutions and taken into account by the European Council for its own report on the state of the Union.

The application of these principles can also be commented on during the legislative procedure by the different players, for example the European Economic and Social Committee and the Committee of the Regions, either when they are consulted or in own-initiative opinions. The COSAC can also express an opinion on the application of the principle of subsidiarity[75].

Finally, ex-post judicial control is practised by the Court of Justice and the Court of First Instance of the European Communities. Annulment proceedings may be initiated in these courts on the grounds of contravention of treaty provisions on the principles of subsidiarity and proportionality.

3.1.3. The revised framework proposed by the Constitutional Treaty

The Constitutional Treaty signed in October 2004 and currently under ratification proposes a number of changes which, by and large, follow the framework set by the European Convention for subsidiarity and proportionality. The definition of the principles has been slightly reworded, mainly to include a reference to the various levels of authorities within Member States (central, regional and local). The notion that decisions shall be taken as closely as possible to the citizen has been set in a separate article (paragraph 3 of article I-46 – The principle of representative democracy). The most important innovations though concern the introduction of a political control *ex ante* and the judicial control *ex post*.

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73 Article 12 of the Protocol.

74 The Protocol provides that this should be an integral part of the overall examination of Commission proposals. The reason is simple: the TEC gives the right of initiative to the Commission; it means that, although the legislator can reject the Commission's proposals, it cannot refuse to examine them.

75 The COSAC (Conference of European Community Affairs Committees) is a body on which the European affairs committees of the national parliaments are represented. In accordance with point 6 of the Protocol on the role of national parliaments in the European Union annexed to the Treaty of Amsterdam, the COSAC "may address to the European Parliament, the Council and the Commission any contribution which it deems appropriate on the legislative activities of the Union, notably in relation to the application of the principle of subsidiarity".

Ex ante political control is provided by the introduction of an early warning mechanism allowing National Parliaments to send a reasoned opinion whenever they consider that a European legislative project[76] does not comply with the subsidiarity principle. Under the new Protocol on the application of subsidiarity and proportionality, National Parliaments will be systematically informed of all legislative proposals. Then each of them will have six weeks to send a reasoned opinion on whether a legislative project complies with the principle of subsidiarity. Save in urgent cases, no agreement may be established on the proposal during that period. Where the number of negative opinions represent at least one third of all the votes allocated to "National Parliamentary systems", the initiator of the legislative project – in most cases the Commission – has to review its project[77]. After such review, it may decide to maintain, amend or withdraw its project, but shall give reasons for its decision. As for judicial review, National Parliaments – via the Member States – and the Committee of the Regions will have the possibility to refer suspected violations of the principles to the European Court of Justice.

3.2. Application of the principles in 2004

On the whole, the European Parliament and the Council introduced relatively few amendments referring explicitly to subsidiarity and proportionality[78]. As it is impossible here to review all proposals and acts adopted in the light of the conditions and obligations summarised in section 3.1.2, the working document limits itself to cases exemplary of 2004 developments in the application of the principles.

3.2.1. When subsidiarity calls for (proposed) Community action to be expanded

Union intervention to ensure the creation of a **Single European Sky** and the enforcement of **intellectual property rights** illustrate most clearly when and why subsidiarity calls for EU intervention[79].

Despite the cooperation between several Member States, the performance of air traffic management in Europe has continued to worsen (in 1999, air traffic delays reached catastrophic proportions, with one flight in three being delayed). The Commission set up a High-Level Group on the Single European Sky which identified the fragmentation of the air management system into national islands of rules, procedures,

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76 This concerns the proposals of the Commission, but also the initiatives of a group of Member States (cf. penal cooperation), the initiatives of the European Parliament, the requests of the European Court of Justice, the recommendations of the European Central Bank and the requests of the European Investment Bank aimed at the adoption of a European legislative act.

77 Each national parliamentary system gets two votes. In the field of police and judicial cooperation in criminal matters, the number of negative opinions required for triggering a review is a quarter of all votes.

78 For instance, in 2004, the Parliament referred explicitly to subsidiarity to justify its legislative amendments in only 9 of these reports. As for the proportionality principle, the Parliament used it to justify its legislative amendments in only 5 reports.

79 Other cases include the proposal for a Council Framework Decision on certain procedural rights in criminal proceedings throughout the European Union, COM(2004)328, 28 April 2004 ; Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security; and Decision No 884/2004/EC amending Decision No 1692/96/EC on Community guidelines for the development of the trans-European transport network (OJ L 167, 30/04/2004).

markets and performance levels as the main impediment to making substantial progress in this industry. The Commission proposed to tackle these different forms of fragmentation with the **Single European Sky package,** consisting of a Framework Regulation and three technical Regulations on the provision of air navigation services, organisation and use of the airspace and the interoperability of the European air traffic management network[80]. Thanks to Community action, it will be possible to restructure the airspace on the basis of traffic instead of national frontiers. This will enhance the overall efficiency of air traffic in Europe, which national or intergovernmental solutions have failed to deliver.

Enforcement of intellectual property rights is another area where increased Union intervention can easily be justified on the basis of the subsidiarity principle. The proposal for a Directive adopted by the Commission on 30 January 2003 started from two premises: first of all, piracy and counterfeiting are on the way to becoming a serious problem for the free movement of goods and maintenance of fair competition within the internal market; secondly, action by individual Member States does not offer a sufficiently high and uniform level of protection of intellectual property rights (differences in legislation and levels of implementation)[81].

Following examination at first reading, Parliament and the Council have acknowledged the need for Community intervention and even widened the Directive's scope. They have agreed to include industrial property rights (trademarks and patents) and all infringements of intellectual property rights (the initial proposal was limited to illegal activities for commercial purposes). The Commission has agreed to the amendments tabled by Parliament and the Council, considering that they do not jeopardise the overall balance of the text[82].

Not all cases, however, are as clear-cut. In the case of the proposed **directive concerning oil stocks**[83], the Parliament and the Council did not accept the Commission's arguments in favour of Community mechanisms aiming at avoiding discontinuity in oil supply in the event of a crisis[84]. The draft directive was proposing to increase the minimum volume of stocks to be maintained in each Member State, and to give the EU the possibility to decide how these stocks are used, not only in the event of a physical break in supply but also in the event of a perceived risk which would trigger dangerous market volatility. Both the Parliament and the Council considered that existing mechanisms and instruments should perhaps be updated, but had proved sufficient in the light of recent international events. Faced with the reluctance of both co-legislators, the Commission decided on 20 October 2004 to withdraw its proposal, whilst reserving its right to come forward at a future date with

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[80] Respectively Regulation (EC) No 549/2004, Regulation (EC) No 550/2004, Regulation (EC) No 551/2004, Regulation (EC) No 551/2004 and Regulation (EC) No 552/2004 of 10 March 2004 (OJ L 96 of 31.3.2004).

[81] COM(2003) 46 of 30 January 2003.

[82] Directive 2004/48 on the enforcement of intellectual property rights, adopted on 29 April 2004.

[83] COM (2002) 488 of 11 September 2002.

[84] Parliament Resolution of 19 November 2003, doc. A5-0297/2003; Council Conclusions of 10 June 2003, doc. 9317/03.

other initiatives that will enable the EU to cope with the new oil situation and guarantee the smooth running of its internal market in energy.

3.2.2. When subsidiarity calls for (proposed) Community action to be ruled out, discontinued or narrowed down

While subsidiarity allows Community action to be extended if circumstances so require, it also means such action must be limited or ended when it is no longer justified[85]. In 2004 the Commission concluded that such a “contraction” was called for with regard to the pre-packaging rules. Under SLIM-IV (Simpler Legislation for the Internal Market), the Commission carried out a series of analyses, studies and stakeholder consultations with a view to assessing the need to maintain the system of harmonised **pre-packaging sizes** put in place in the 1970s for a certain number of products. The diversity of national measures at the time posed numerous problems in connection with consumer protection, market transparency and free movement of goods.

These analyses and consultations led to the conclusion that, generally speaking, the objectives of this legislation were also covered by more recent directives[86]. The Commission has therefore decided to propose that a large number of provisions on nominal quantities for pre-packed products be repealed[87].

The proposed directive on **road charges for the use of certain infrastructures** offers an example of where the European Parliament considered that, pursuant to the principle of subsidiarity, the proposed scope of action should be narrowed down. Differences between the Member States in road charges distort competition. The present situation is also unsatisfactory because existing arrangements regarding charges do not reflect the costs to society and are an obstacle to optimal choice among various types of transport. The Commission therefore proposed in 2003 to amend the Eurovignette Directive 1999/62/EC and create a framework for road charges that addresses these problems[88]. Under this framework, Member States would be allowed to impose charges on other sections of the main road network, after informing and consulting the Commission. In accordance with the principle of subsidiarity, they would retain total freedom of action for roads that do not belong to the main road network. In addition, the proposal states that the revenue from the charges must be ploughed back into maintenance of the road infrastructure concerned and into the transport sector as a whole, taking due account of the balanced development of the transport networks. In the Commission’s view, this is the only conceivable and

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[85] Among other high-profile cases for which this notion is of paramount importance, see the White Paper on services of general interest (COM(2004) 374).

[86] Extended impact assessment, SEC(2004) 1298. Consumers are protected by unit pricing, and the environment by the Directive on packaging waste.

[87] Proposal for a Directive laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC, COM (2004) 708, 25 October 2004. However, for a very limited number of products, such as wine, coffee, sugar and aerosols, the Commission is proposing to retain or introduce complete harmonisation of sizes in order to ensure free movement of goods and protect producers against pressure from large distributors.

[88] COM(2003) 448, 23 July 2003.

realistic solution for funding the remaining sections needed to link up the trans-European transport networks.

In the Parliament's view, Member States should not be required to seek the Commission's assent for introducing charges on other roads of the primary road network[89]. They should instead consult the local and/or regional authorities responsible for these roads and ensure that those charges are compatible with any other charging system applied at local or regional level. As yet, the Council has not reached agreement on the proposal.

3.2.3. When minimal proportionality calls for the most constraining types of action

There are cases where the most constraining type of action is the only way to reach the objectives of the Union. Regulations and directives then become the lightest and most economical options. This is illustrated in particular by the **Single European Sky package** presented under sub-section 3.2.1. Without Regulations, the package would not succeed in eliminating the various forms of fragmentation of the air management system which inhibit the ability to provide new capacity in a timely and efficient manner.

3.2.4. When minimal proportionality allows to opt for the lightest types of action

According to the Protocol on subsidiarity and proportionality, "the form of Community action shall be as simple as possible". The solution for tackling **unfair commercial practices** gives a good example of the approach taken to satisfy this condition. Regulation of unfair commercial practices by heterogeneous national rules generates obstacles to the proper functioning of the internal market by creating compliance cost for business in cross-border marketing and by damaging consumers' confidence in cross-border shopping. Having assessed several options in its impact assessment[90], the Commission concluded that a framework directive, which harmonises some aspects of marketing law but leaves room – under certain conditions – for codes of conduct drafted by traders, would suffice to solve both problems[91]. The European Parliament and the Council broadly endorsed the mixed approach proposed by the Commission[92].

Eco-design requirements for energy-using products offer a similar example of co-regulation. The objective here was to ensure the free movement of energy-using products in the internal market as well as to contribute to environmental protection policy and security of energy supply. The Commission proposed to establish a framework directive that does not create immediate obligations, setting only the general principles and criteria for the establishment of eco-design requirements, but leaving the development and adoption of implementing measures for individual

89 Resolution A5-0220/2004, 23 March 2004.
90 SEC(2003) 724, 18 June 2003.
91 COM(2003) 356, 18 June 2003. Traders would be invited to establish voluntary codes of conduct in pursuit of the objectives of the directive. The directive would also put in place legal remedies in case of violation of these voluntary commitments.
92 Parliament's legislative report of 18 March 2004 (rapporteur : Fiorella Ghilardotti), doc. A5-0188/2004. Common position of the Council, 17 November 2004, doc. 11630/2/2004.

products to the Commission, assisted by a regulatory committee[93]. Its proposal also provides that such implementing measures should not be adopted where the industry has established alternative mechanisms likely to deliver the policy objectives faster or more cheaply than mandatory requirements.

The European Parliament was not opposed to the mix of legislative and alternative regulatory instruments as proposed by the Commission. However, in its first reading[94], it called for the self-regulatory agreements to be monitored, scrutinised and assessed on the basis of "minimum eligibility criteria for self-regulatory initiatives" and backed up by command-and-control-alternatives. The Council rejected these amendments[95].

The Protocol on subsidiarity and proportionality also provides that the Commission should "take duly into account the need for any burden, whether administrative or financial, … to be minimised". This was a particular concern in the debate over batteries and the Eurovignette[96]. In the case of **batteries and accumulators**, the Commission proposed to make the Member States responsible for collecting, recycling and waste monitoring of portable batteries, including those containing cadmium[97]. Studies carried for and by the Commission had indeed concluded that this option would offer a level of environmental protection equivalent to a total ban, but at a lower cost, in particular for industry. They had also concluded that there was no reliable alternative to cadmium batteries for cordless power tools[98].

In the Council, a large majority regarded the proposal as imposing a disproportionate administrative burden on national administrations. The Council proposed to opt instead for a partial ban on portable cadmium batteries, exempting those used for cordless power tools and certain other products (exemption subjected to a four-year review)[99]. The Commission accepted this revision on the grounds that there was new information available which showed that its proposal could have entailed higher costs to industry and national administrations than initially estimated.

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[93] Proposal for a Directive on Eco-design requirements for Energy-Using Products, COM(2003) 453, 1 August 2003.

[94] Resolution of 20 April 2004 (rapporteur: Astrid Thors), doc. A5-0171/2004.

[95] Common Position of 29 November 2004, doc. 11414/1/04. It must however be underlined that the Council has introduced in the proposal a reference to a Communication of the Commission where very similar eligibility criteria are listed (Communication on Environmental Agreements at Community level within the Framework of the Action Plan on the Simplification and Improvement of the Regulatory Environment, COM(2002) 412, 17 July 2002, chapter 6).

[96] The issue of costs imposed by legislation was also at the centre of the debate regarding the REACH initiative (registration, evaluation, authorisation and restriction of chemicals) launched in 2003 (COM(2003) 644, 29 October 2003). The COREPER decided in particular to set up an ad hoc group to look at this issue.

[97] COM(2003) 723, 21 November 2003.

[98] Extended Impact Assessment, SEC(2003) 1343, 24 November 2003. BIO Intelligence Service, "Impact Assessment on Selected Policy Options for Revision of the Battery Directive", July 2003.

[99] Political agreement was reached on the basis of the Council's first pilot impact assessment which, for the record, contains no explicit reference to the principle of proportionality. Document No. 14943/04, 22 November 2004.

In the case of the draft directive amending the **Eurovignette** Directive 1999/62/EC presented in sub-section 3.2.2, the Commission proposed the creation in each Member State of an independent infrastructure supervision authority[100]. This authority would guarantee that the calculation of charges on the trans-European network and roads competing with this network and the use of revenue are in accordance with the provisions of this Directive. In its resolution, the European Parliament stated that it was not necessary to set up an independent infrastructure supervision authority in each Member State in order to reach the Directive's objectives[101].

3.2.5. 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". Actions on intellectual property rights, air traffic controller licences and local border traffic at the external land borders of the Member States show how the Commission works to meet that requirement[102].

In the case of the Directive on enforcing **intellectual property rights** referred to in sub-section 3.2.1, Parliament and the Council have preferred not to include the obligation to impose criminal sanctions for infringements of these rights. The Directive provides only for civil law penalties, leaving Member States free to decide whether or not to apply criminal sanctions, in line with their national traditions.

Concerning the **air traffic controller licence**, the Commission considered that, contrary to the rest of the Single European Sky package, it was not necessary to propose a regulation. A directive was seen as sufficient to guarantee a high level of safety[103]. By harmonising the levels of competence of European air traffic controllers, the directive will allow for mutual recognition of licences issued in each Member State. By the same token, it will preserve social traditions of the Member States with regard to the issuance of a licence.

General competence as regards crossing the external borders of the Member States was granted to the Community by the Treaty of Amsterdam. This subject assumes special importance by reason of the large volume of cross-border movements between the new Member States and their neighbours. Effective common rules on **local border traffic** were necessary in order to make life easier for bona fide border residents, promote the development of border regions and address the problems of illegal immigration and cross-border criminal activities. The Commission has therefore proposed a Regulation setting up a specific scheme for local border traffic. However, it felt it was appropriate to delegate the responsibility for implementing such a scheme to the Member States, which should enter into bilateral agreements taking account of local circumstances[104]. The opinion delivered by Parliament on 20 April 2004 as part of the consultation procedure constituted overall approval of this

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[100] COM(2003) 448, 23 July 2003.

[101] Resolution A5-0220/2004, 23 March 2004.

[102] Other examples include the proposed regulation on medicinal products for paediatric use - COM(2004) 599.

[103] COM(2004) 473, 12 July 2004.

[104] COM(2003) 502, 14 September 2003, replaced by COM(2005) 56 of 23 February 2005.

application of the principle of subsidiarity[105]. The Council has not yet expressed an opinion.

4. OPINIONS, CONTRIBUTIONS AND EX-POST CONTROL OF THE APPLICATION OF THE PRINCIPLES IN 2004

4.1. Opinions and contributions in 2004

In the opinions it delivers as part of the Union's legislative process, the Committee of the Regions has shown special interest in the application of the principles of subsidiarity and proportionality from the point of view of local and regional authorities. The vast majority of its opinions recognise the legitimacy of Union action, but on two occasions it has called on the European Commission to review its choice of tools in order to improve the way it complies with the principle of proportionality[106]. These recommendations have led to the adoption of an approach allowing closer involvement of local and regional authorities in implementing Community legislation. The Committee of the Regions has also adopted a general document entitled "The application and monitoring of the principles of subsidiarity and proportionality: issues and prospects for the Committee of the Regions"[107] and initiated the organisation of annual conferences on subsidiarity, the first of which was held on 27 May 2004 in Berlin under the aegis of the Bundesrat.

The Committee of the Regions intends to systematise its assessment of compliance with the subsidiarity principle in 2005 by preparing a subsidiarity evaluation grid to be annexed to its opinions and by progressively creating a network of local and regional authorities with a view to monitoring subsidiarity.

As for COSAC, it started investigating various models for the scrutiny of subsidiarity. At its XXXI session in Dublin in May 2004, it welcomed the new provisions on subsidiarity proposed by the constitutional Treaty. COSAC's "second biannual report on EU procedures and practices" subsequently included information on how national Parliaments see the future development of their respective systems for scrutiny of subsidiarity. That point was further discussed at the XXXII session of COSAC in The Hague in November 2004. Delegations from national Parliaments also agreed to launch a pilot-project on the "third railway-package" as a first test of their capacity to deliver a reasoned opinion within six weeks. The experience gained will be compared at the XXXIII COSAC in Luxembourg in May 2005. There may then be a further experiment based on the Commission's Green Paper on the "Approximation, mutual recognition and enforcement of criminal sanctions in the European Union".

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[105] Doc. A5-0142/2004, opinion based on the report of 11 March 2004 (rapporteur: Carmen Cerdeira Morterero).

[106] Opinion on the proposal for a Directive on energy end-use efficiency and energy services, COM(2003) 739 final (CdR 92/2004 fin); opinion on the Communication from the Commission "Towards a thematic strategy on the urban environment", COM(2004) 60 final (CdR 93/2004 fin).

[107] CdR 107/2004. The Committee of the Regions recommends that a new impact analysis culture be adopted, with greater emphasis on the financial and administrative burden on local and regional authorities.

4.2. Ex post control in 2004

As regards ex-post judicial control, the principle of subsidiarity was referred to in six judgments and orders delivered by the Court of Justice and the Court of First Instance of the European Communities[108], which confirm the Court's previous case law. In particular, they emphasise that the implementation and monitoring of assistance in connection with the Structural Funds should be primarily the responsibility of the Member States on the basis of the principle of subsidiarity. No judgment has concluded that the treaty provisions on this subject have been wrongly applied[109]. As of 31 December 2004, the case law of the Court of Justice and the Court of First Instance did not include any judgments to the effect that the principle of subsidiarity had been contravened or that there was a lack of motivation in applying this principle.

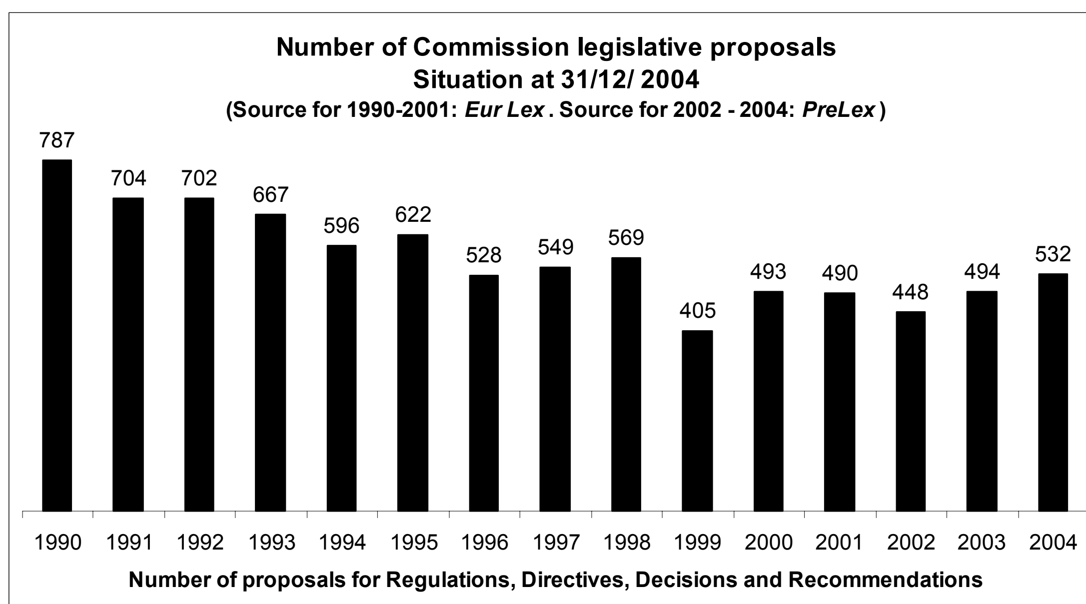
[108] Number of judgments and orders of the Court of Justice and the Court of First Instance referring to the principle of subsidiarity since the entry into force of the Maastricht Treaty: 7 in 2003, 3 in 2002, 2 in 2001, 4 in 2000, 0 in 1999, 4 in 1998, 2 in 1997, 5 in 1996, 4 in 1995 and 2 in 1994.

[109] Judgment of the Court of 22 January 2004, case C-271/01; order of the Court of First Instance of 8 July 2004, case T-341/02; judgment of the Court of 11 March 2004, case C-240/02; order of the Court of First Instance of 15 March 2004, case T-139/02; order of the Court of First Instance of 15 March 2004, case T-66/02; order of the Court of First Instance of 8 July 2004, case T-341/02; judgment of the Court of First Instance of 30 November 2004, case T-168/02.

Annex 1: Legislative activity in 2004

Aggregated figures for 2004 show an increase in legislative proposals. This however is imputable to the larger number of decisions (+49) and recommendations (+4). The number of proposed regulations and directives actually fell compared to 2003 (-15). Available databases do not distinguish between new legislation and – simple – amendments. A survey of 2004 proposals suggests however that a majority of the proposed regulations and directives concerned fairly limited and technical amendments to existing legislation, sometimes aimed at simplification.

Taken together, external relations (including the common commercial policy and the enlargement of the Union) were, with 198 proposals, the most active legislative sector. Next came in descending order: taxation and the customs Union, fisheries, transport and energy, agriculture, enterprise, justice and home affairs, environment, employment and social policy, health and consumer policy, and internal market. The legislative activity of all the other sectors remained marginal, with 10 proposals or less[110].



110 To see how that pattern has evolved, refer to 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; COM(2002) 715 of 11 December 2002; and COM(2003) 770 of 12 December 2003.

Annex 2: Public consultation in 2004

The Commission has a long tradition of extensive consultation[111] through various channels: Green Papers, White Papers, communications, forums (such as the European Energy and Transport Forum or the European Health Forum), workshops, permanent consultative groups[112] and consultations on the Internet[113]. The Commission is also engaged in various forms of institutionalised dialogue with interested parties in specific domains, the most developed being the social dialogue. The civil dialogue between the Commission and organisations from civil society was held in cooperation with the European Economic and Social Committee. Last but not least, a regional dialogue was launched in 2004 in cooperation with the Committee of the Regions.

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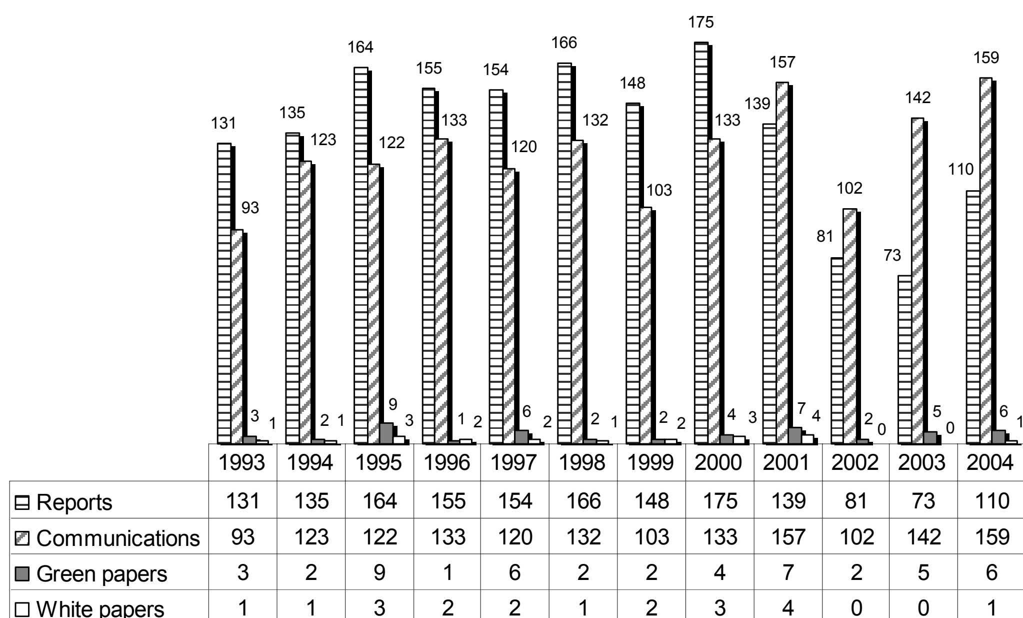
111 'Consultation' refers to the processes used by the Commission during the policy-shaping phase in order to trigger input from outside interested parties before taking a decision.

112 For the list of formal or structured consultative bodies, in which civil society organisations participate, see database for Consultation, the European Commission and Civil Society (CONECCS) http://europa.eu.int/comm/civil_society/coneccs/index_en.htm.

113 See in particular the Interactive Policy Making initiative (http://europa.eu.int/yourvoice/ipm). The IPM 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 Directorates-General have already started to use it as an input for policymaking.



	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Reports	131	135	164	155	154	166	148	175	139	81	73	110
Communications	93	123	122	133	120	132	103	133	157	102	142	159
Green papers	3	2	9	1	6	2	2	4	7	2	5	6
White papers	1	1	3	2	2	1	2	3	4	0	0	1

In 2004, the most active sectors in terms of consultation and information (based on the number of green papers, white papers, communications and reports) were, in descending order : justice and home affairs, economic and financial affairs, agriculture, environment, employment and social policy, education and culture, external relations, information society, development, transport and energy, internal market and regional policy. By and large, discrepancies between the number of consultations and the number of proposals result from the specific nature of some sectoral activities. For instance, in external relations, a large share of proposals concerned decisions to amend international agreements of a technical nature. Public consultation would have made little sense in these instances.

Annex 3: Better Regulation actions in Member States in 2004

In some cases, implementation is only partial.

	Existence of a Better Regulation programme	Impact assessment of proposed legislation[114]	Existence of consultation procedures	Existence of a legislation simplification programme	Initiative for reducing administrative Burden
Belgium	Yes	Yes	Yes	Yes	Yes
Czech Rep.	Yes	Yes	?	Yes	No
Denmark	Yes	Yes	Yes	Yes	Yes
Germany	Yes	Yes	Yes	No	No
Estonia	No	Yes	No	?	?
Greece	Yes	No	Yes	No	Yes
Spain	Yes	Yes	No	No	No
France	Yes	No	Yes	Yes	Yes
Ireland	Yes	Yes	Yes	?	?
Italy	Yes	Yes	Yes	Yes	?
Cyprus	No	No	No	?	?
Latvia	Yes	Yes	Yes	?	?
Lithuania	?	Yes	?	?	?
Luxembourg	Yes	Yes	Yes	Yes	Yes
Hungary	Yes	Yes	Yes	No	Yes
Malta	Yes		Yes	?	?
Netherlands	Yes	Yes	Yes	?	Yes
Austria	Yes	Yes	Yes	?	?
Poland	Yes	Yes	Yes	Yes	Yes
Portugal	No	No	No	?	?
Slovenia	Yes	?	?	?	?
Slovakia	?	?	Yes	?	?
Finland	Yes	Yes	Yes	No	No
Sweden	Yes	Yes	Yes	Yes	Yes
UK	Yes	Yes	Yes	Yes	Yes

Table based on data collected in *Policy Trends in Regulatory Reform in 2003-2004: OECD Country Submissions,* Paper presented at the Public Governance Committee of the OECD on 27-28 September 2004; Report for DG ENTR MAP project: *Indicators of regulatory quality*, forthcoming January 24th 2005; *Report on the implementation of the European Charter for Small Enterprises in the Member States of the European Union*, forthcoming 2005.

[114] Impact assessment based on guidelines and conducted in almost every case.