

Mandelkern Group on Better Regulation

Final Report

13 November 2001

EXECUTIVE SUMMARY

At the Lisbon European Council, the EU set itself the goal of becoming the most competitive and dynamic knowledge-based economy in the world. There and at Santa Maria de Feira, the important role that better regulation will play in achieving this was clearly established.

Regulation is essential to achieve the aims of public policy in many areas, and better regulation is not about unthinking removal of such regulation. Rather, it is about ensuring that regulation is only used when appropriate, and about ensuring that the regulation that is used is high quality. Improving the quality of regulation is a public good in itself, enhancing the credibility of the governance process and contributing to the welfare of citizens, business and other stakeholders alike. High quality regulation prevents the imposition of the unnecessary burdens on businesses, citizens and public administrations that cost them time and money. It helps avoid the damage to firms' competitiveness that comes from increased costs and market distortions (particularly for small firms). Indeed, studies from various sources have estimated the burden of regulation to fall in the range 2-5% of GDP in Europe. Whilst these figures can only be estimates, nonetheless they do indicate the importance of this issue to European economies. High quality regulation assists in the restoration of confidence in government and is better able to accomplish its desired purpose. Implementation of such regulation is also less problematic for public administrations and compliance is easier for citizens. For all these reasons it is strongly in the public interest to improve the quality of regulation at both national and EU levels.

Better regulation needs high-level and cross-governmental political support and appropriate resources to be successful. It must address the whole life cycle of policy (inception, design, legislation, implementation and review) across all fields of public policy. A piecemeal approach risks being ineffective – an overall strategic approach is essential. It should seek to involve both the executive and the regulatory authorities, using tools such as impact assessment, simplification, consolidation and consultation and promoting a change in culture. And it must be underpinned by appropriate administrative and organisational structures: both within national governments and the EU Institutions such structures should co-ordinate, support and monitor the programme and, additionally in the EU, promote mutual learning between its Institutions and with the Member States.

Better regulation is a drive to improve the policymaking process through the integrated use of effective tools, not an attempt to impose further bureaucratic burdens on it. Its effective use will deliver welfare gains far in excess of any costs of governing in such an efficient way. To this end, this Report proposes an Action Plan with deadlines, the implementation of which would contribute significantly to achieving the required improvements. It describes a comprehensive overall approach with a set of seven core principles: necessity, proportionality, subsidiarity, transparency, accountability, accessibility and simplicity. It recommends practices in topics applicable to both national governments and the European Commission. It also makes recommendations to the Institutions of the EU in those areas and in the area of implementation of European law. The seven key areas that result are:

- **Policy implementation options.** EU and national policymakers should always consider the full range of possible options for solving public policy issues and choose the most appropriate for the circumstances: though regulation is often the

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most appropriate option it should not be automatically the only choice in all circumstances.

- **Impact assessment.** Regulatory impact assessment (RIA) is an effective tool for modern, evidence-based policy making, providing a structured framework for handling policy problems. RIA should be an integral part of the policy making process at EU and national levels and not a bureaucratic add-on. It does not replace the political decision: rather it allows that decision to be taken with clear knowledge of the evidence.
- **Consultation.** Consultation is a means of open governance, and as such early and effective consultation of interested parties by EU and national policymakers is an important requirement. This does not usurp the role of civil servants, Ministers or Parliamentarians in the policymaking process but supplements the information they have to hand. Correctly done, consultation can avoid delays in policy development due to late-breaking controversy and need not unduly hinder progress.
- **Simplification.** There is a constant need to update and simplify existing regulations. But simplification does not mean deregulation. It is aimed at preserving the existence of rules while making them more effective, less burdensome, and easier to understand and to comply with. This entails a systematic, preferably rolling and targeted programme of simplification, covering the regulation that impacts on citizens, business and the public bodies that have to implement it. Such programmes need to be established at both EU and national levels.
- **Access to regulation.** Those affected by European or national regulation have the right to be able to access it and understand it. This means the coherence and clarity of regulations must be enhanced through consolidation (including codification and recasting) and access improved by better practical arrangements (especially using ICT). The former should be achieved through EU and national level programmes of consolidation and the latter through provision within each Member State and at European Union level of a public access service (either free or for a small fee).
- **Structures.** Better regulation needs the appropriate supporting structures charged with its promotion to be successful. The best arrangement at EU or national level will depend on the relevant circumstances and charging a single unit at or near the centre with this should certainly be considered, but an effective solution must be found for each.
- **Implementation of European regulation.** High quality regulation forms a chain from the earliest stages of its preparation through to its implementation. More attention should be paid at European level to implementation concerns to ensure that the full consequences are understood and considered. Member States should accord implementation of European regulation higher priority.

The Mandelkern Group on Better Regulation commends this Report and Action Plan to the European Parliament, to the Commission, to the Council and to the Member States of the EU. The Group considers that implementation of the programme described in this Report, in addition to other work underway or proposed, will make a significant contribution to increasing the competitiveness of the European economy and the welfare of its citizens and to improved credibility and legitimacy of government.

ACTION PLAN

In the context of the Lisbon process and the open method of co-ordination, the European Parliament, Commission, Council and Member States should continue to work to improve the regulatory environment in the EU. To this end, the Group invites them, each in accordance with their responsibilities, to implement an overall strategy for Better Regulation as set out in this report as soon as possible.

General

- As of 2003, the Commission should produce an annual report to the European Parliament and to the spring European Council on developments in better European regulation by the EU and each Member State, bringing together existing reports in overlapping areas (e.g. Better Lawmaking, better regulation elements of the Cardiff report).
- The Commission, European Parliament, Council and Member States should establish new or improve existing joint training programmes at European level for officials on aspects of better regulation such as impact assessment, use of alternatives, consultation, simplification and codification (and other forms of consolidation).
- Within their respective responsibilities, the Commission, European Parliament, Council and Member States should take further practical steps to ensure their internal co-ordination and the coherence between European regulatory policies by June 2002.
- The Commission to propose by June 2002 a set of indicators of better regulation.
- Recognising their full sovereignty, Parliaments should be invited to take an interest in the process of better regulation, and to contribute to an overall system of regulatory review.

Impact Assessment

- Establishment by the Commission by June 2002 of a new, comprehensive and suitably resourced impact assessment system covering Commission proposals with possible regulatory effects. This system should be based primarily on the recommendations in this report, including an initial screening process followed by a more detailed, proportionate assessment in appropriate cases.
- Commitment by the Council not to consider proposals for regulation made after December 2002 that have not been subjected to the agreed impact assessment system, except in cases of urgency.
- Commitment by the European Parliament not to consider proposals for regulation made after December 2002 that have not been subjected to this impact assessment system, except in cases of urgency.
- Agreement by all Member States that from June 2002 they will submit the relevant national RIA, where it exists, alongside regulation notified to the Commission and other Member States.
- Agreement by all Member States that from June 2002 wherever possible they will indicate the likely broad impacts of significant and substantial amendments

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(where appropriate in co-operation with the Commission) they wish to make during negotiation of draft European regulation.

- All Member States to introduce by June 2003 an effective system of impact assessment for national regulation adapted to their circumstances.

Consultation

- Adoption by the Commission of a standard minimum consultation period for its proposals of 16 weeks from March 2002.
- Adoption by the Commission by March 2002 of a Code of Practice for its consultations, including the relevant key elements of this report.
- Establishment by the Commission by June 2002 of a central, web-based register of all ongoing EU consultations, which should themselves be available online.
- For EU consultations from June 2002, a presumption that, insofar as practicable, all comments received will be made available online unless respondents explicitly request otherwise.
- All Member States should ensure by June 2003 that they have adequate consultation procedures that allow those affected or interested to contribute and the general public to access the comments made.

Simplification

- Launch, by June 2002, of a Commission-led systematic, targeted and preferably rolling programme of simplification of existing European regulation in all areas. This programme should be articulated into annual steps setting out clear priorities and targets and should involve interested parties in setting those priorities.
- Agreement between the Commission, European Parliament, Council and Member States by June 2002 of the conditions under which proposals resulting from the simplification programme will be fast-tracked through the codecision process according to existing Treaty provisions for agreement after First Reading.
- All Member States should establish by June 2003 a coherent simplification policy (including for regulation transposing European legislation) adapted to their circumstances. This should be implemented through concrete measures, which could include a systematic simplification programme and the innovative use of ICT.
- Adoption by March 2002 of the Inter-Institutional Agreement on recasting.

Structures

- Creation by the Commission by June 2002 of a single, effective better regulation network in all regulatory DGs, supported centrally as appropriate. This network to be charged with carrying out the relevant tasks in this report.
- All Member States should establish by June 2003 a coherent simplification policy (including for regulation transposing European legislation) adapted to their national circumstances. This policy should be implemented through concrete measures such as a systematic simplification programme and the innovative use of ICT.

Alternatives

- Drawing up by the Commission, in close co-operation with the European Parliament and the Council of general guidelines on the use of alternatives to regulation for the pursuit of European policies, by June 2002.
- Implementation of these guidelines by December 2002.

Access to regulation

- The Commission, European Parliament and Council to develop, by June 2002, a concerted plan for codifying existing European regulation, to result in a 40% (as compared to 31/12/01) reduction in the number of European acts and in the number of pages of European legislation by June 2004.
- Appropriate resource allocation to codification and recasting of European regulation by the Institutions and the Member States.
- The Commission to present to the European Parliament and Council by December 2002 a review of the effectiveness of the Inter-Institutional Agreement on codification and, if appropriate, proposals for its revision.
- The Commission to present to the European Parliament and Council no later than December 2002 a review of the implementation of the Inter-Institutional Agreement on common guidelines for the quality of drafting of Community legislation.
- Member States and the Commission should each seek to establish by June 2003 a public service (either free or for a reasonable fee) giving access to the texts of laws and regulations in their jurisdiction.

Transposition

- Improvement of the existing online Commission database of regulation requiring transposition by December 2002 and of the current state of play in each Member State.
- Free access to this database by December 2002.
- Setting up by December 2002 of the necessary processes for Member States to notify their transposition of regulation by electronic means to a single point in the Commission.
- All parties should pay more attention to the precision, clarity and coherence of European legislation during the negotiating process. This should include early and continued consideration of transposition by the Member States and a better balance between detailed and technical regulation on the one hand and national freedom of choice and form on the other.

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PART I INTRODUCTION

1 General

The EU has set itself the strategic goal of becoming the most competitive and dynamic knowledge-based economy in the world. Achievement of this goal will depend in part on improving Europe's regulatory environment to avoid unnecessary burdens on businesses, citizens and public administrations. Improving the quality of regulation is also a part of the widespread movement to improve governance as it enhances the credibility of the latter. Therefore, high quality regulation must be seen as a public good and action must be taken at both EU and national levels within a comprehensive strategic approach to realise it.

The Mandelkern Group has identified the six main aspects of a successful better regulation programme:

- Policy implementation options;
- Regulatory impact assessment;
- Consultation;
- Simplification;
- Access to regulation; and
- Effective structures.

These are set out in this Report along with practical, concrete recommendations for action. Part II does this for all administrations – national governments and the European Commission; Part III addresses the specific nature of the European Union and in addition addresses the question of the implementation of European regulation. They are summarised in the proposed Action Plan, which is designed to provide the co-ordinated strategy for further action requested by the Lisbon European Council.

2 The Mandelkern Group Mandate

2.1 Origin of the mandate

The desire to simplify regulation has been expressed both at European level and within individual Member States since 1985, as a prerequisite for the achievement of the EU-wide single market.

But it is only since the middle of the 90's that the search for better quality regulation took on a more systematic form and a series of initiatives on improving the quality of regulation were adopted at both national and European level. In particular, in the latter case, a protocol annexed to the Treaty of Amsterdam (1995) was adopted, setting out the principles of good regulation to be respected at European level.

It gradually became apparent that action co-ordinated between the European and national levels was necessary in order to improve the "regulatory chain" right from the conception of the regulation up to the actual application stage. This was the approach taken by the Lisbon European Council, which asked the Commission, the Council and the Member States, each in accordance with their respective powers:

“To set out by 2001 a strategy for further co-ordinated action to simplify the regulatory environment, including the performance of public administration, at both national and Community level.”

In implementation of these conclusions, Ministers for Public Administration from EU Member States, meeting on 6 and 7 November 2000 in Strasbourg approved a Resolution on improving the quality of regulation within the European Union. Following the terms of this Resolution, a high-level advisory group consisting of regulatory experts from the Member States and the Commission was charged with taking an active part in the preparation of the strategy demanded by the European Council in Lisbon.

2.2 Organisation of the work

The high-level Advisory Group was formed in December 2000 when 16 experts were appointed to it, representing each of the 15 countries of the Union and also the Commission. From the time it was formed, it was known by the name of its Chairman, M. Mandelkern, the French representative and Honorary Section Chairman within the Council of State.

Under the Strasbourg Resolution, the Mandelkern Group was given a “mandate to develop a coherent approach to this topic and to submit proposals to the Ministers, including the definition of a common method of evaluating the quality of regulation.”

The Resolution also suggested a few avenues to explore, at both national and European level:

- The systematic use of impact studies;
- Transparency in the consultation process prior to the drafting of texts;
- Simplification of the texts adopted;
- Wider use of codification.

Guided by a desire to take a pragmatic approach, the Group immediately decided to add another topic: the type of structures that would make sure that the procedures to ensure improvements in the quality of regulation were effectively implemented.

This is the basis which was used to produce a series of principles and guidelines which were presented in an initial report submitted to the European Council in Stockholm, in accordance with the wishes of the Ministers meeting in Strasbourg.

In accordance with its mandate, the Group endeavoured to ensure that its recommendations could be applied at both national and European level. However, as it wished in its final report to formulate effective proposals for the specific area of the regulatory chain within the European Union, it endeavoured to make a particular study of the topics of transposition and the effective application of regulation originating from the European Union.

On all these topics, the Group tried to put forward a set of recommendations which could be implemented in the near future.

2.3 Consistency with existing European approaches

The Strasbourg Resolution asked the Mandelkern Group “in accordance with the Lisbon mandate, [to...] work in close co-ordination with the European Commission, ensuring the reciprocal and regular exchange of information about each of their work on improving the quality of regulation.”

With this in mind, the Commission was associated with the Mandelkern Group in the same way as the Member States. Exchanges of information between the Group and the White Paper on Governance team also took place on several occasions, in particular as part of the preparations for the Stockholm and Laeken summits.

Similarly, links were established with the Council (and also with the Parliament) concerning the various topics involved in regulatory quality.

3 Common Principles

3.1 Necessity

This principle demands that, before putting a new policy into effect, the public authorities assess whether or not it is necessary to introduce new regulations in order to do this.

This would for example involve comparing the relative effectiveness and legitimacy of several instruments of public action (regulation, but also the provision of information for users, financial incentives and contracts between public authorities and economic and social partners) in the light of the aims they wish to achieve.

3.2 Proportionality

Any regulation must strike a balance between the advantages that it provides and the constraints it imposes. The various instruments of regulation (primary and secondary regulation, framework Directives, co-regulation etc.) enable the public authorities to take action in different ways, depending on the aims they wish to achieve. It is the responsibility of the Member States and the Commission, when selecting from the regulatory instruments available to them, to identify those which are most proportionate to the aims they wish to achieve.

3.3 Subsidiarity

In the context of the EU and of its Treaties, the principle of subsidiarity is intended to ensure that decisions are taken at a level as close as possible to the citizen, whilst checking that any action to be undertaken at European level is justified compared with the options available at national level. That is, in concrete terms, checking that the objectives of the proposed action cannot be sufficiently achieved by Member States' action in the framework of their national constitutional system and that they can therefore be better achieved by action on the part of the European Union.

3.4 Transparency

In order to improve the quality of regulation by being more effective in identifying unforeseen effects and taking the points of view of the parties directly concerned into consideration, the drafting of legislation should not be confined within the narrow bounds of the public administration bodies. Participation by and consultation with all parties who are interested or involved prior to the drafting stage is the first requirement of the principle of transparency.

This participation should itself satisfy the transparency criteria. It should be organised in such a way as to facilitate broadly based and equitable access to the consultations, the constituent elements of which should be made public.

3.5 Accountability

The authorities responsible for regulation should give consideration to the question of its applicability.

All parties involved should be able to clearly identify the authorities that originated the policies and the regulation applying to them. Where appropriate, they should be able to inform them of difficulties with the implementation of policies or regulation, so that they can be amended.

3.6 Accessibility

Consistent, comprehensible regulation, which is accessible to those to whom it is addressed, is essential if it is to be implemented properly.

Consideration should be given to accessibility with every piece of regulation, but this should also be done as a general principle so that users are provided with a consistent body of regulations.

The principle of accessibility may demand a particular effort of communication on the part of the public authorities involved, for example targeted at those persons who, because of their situation, have difficulty in asserting their rights.

3.7 Simplicity

The aim should be to make any regulation simple to use and to understand, as this is an essential prerequisite if citizens are to make effective use of the rights granted to them – regulation should be as detailed as necessary and as simple as possible.

Simplicity in regulation is also a major source of savings both for enterprises and the intermediary agencies to which it applies and for the public administrations themselves.

The principle of simplicity demands active efforts to combat excessive detail from the very start of the regulation drafting process and when existing texts are revised.

PART II RECOMMENDED PRACTICES

This part of the report sets out the six main elements of a successful better regulation programme as they apply to all governments or administrations – European, national, regional or local. Part IV of the report looks in more detail at how these elements should be developed at the EU level, taking into account the latter’s specific nature. The recommended practices come from a variety of sources such as existing European and national experiences (see Annex C) and OECD and other guidance.

Section 1 discusses the idea of a common method of evaluation and in this context examines the concepts of “ex ante” and “ex post” evaluation. The next three sections on policy implementation options (**Section 2**), regulatory impact assessment (**Section 3**) and consultation (**Section 4**) – together with evaluation of the process itself – form the essential components of ex ante evaluation: a system to ensure better regulation in the policy process. As described below, carrying out each of the three elements should be the responsibility of the relevant policy officials. However, monitoring the overall process is something that should be done separately, by the body/structure charged with promoting better regulation (Section 7). Use of a simple monitoring system such as a checklist can be very helpful in this. This ex ante evaluation helps increase confidence in the quality of the advice received. It can be applied, adapted to circumstances, to all Member States and the European Union.

An ex post evaluation will furnish the reviewer with relevant information on existing regulations. **Section 5** (simplification) and **Section 6** (access to regulation) look at tools to improve the quality and accessibility of such regulation where the review determines that this is the appropriate course of action. However, the Group has concluded that it is neither desirable nor feasible at this time to recommend a more detailed common method of ex post (as opposed to ex ante) evaluation, given the very great differences in national structures, legal systems, institutions and constitutional arrangements. Use of a checklist such as that of the OECD (Annex A) is potentially helpful.

Section 7 deals with the issue of structures to support a better regulation programme and promote a change in culture. This element is key to the success of the entire enterprise.

1 Evaluation

1.1 Common method of evaluation

Amongst other tasks, the Group was asked to make proposals on specifying a common method for evaluating the quality of regulation. The Group considers that the combination of examining policy implementation options, performing regulatory impact assessment, conducting consultation and checking that all this occurs correctly forms a common method of ex ante evaluation. However, the Group’s work has shown that it is currently not possible to extend this to ex post evaluation given the great differences in national structures, legal systems and institutional arrangements. Nonetheless, some guidance can be given (Section 1.3). Ex post

evaluation should be encouraged, as should the use of similar methods in order to facilitate comparisons over time and with other evaluations.

1.2 *Ex ante evaluation*

The purpose of ex ante evaluation is to ensure that those who take the final decisions have to hand all the relevant information and high quality advice. The Group considers that this requires that all relevant policy implementation options be considered, that a regulatory impact assessment is carried out and that appropriate consultation is undertaken. A check on whether these steps have been carried out correctly is therefore desirable. This part of the ex ante evaluation is only focussed on the process; it thus does not contain any of the elements covered by RIA, consultation or other measures. Instead, it simply verifies that they have been carried out properly. In its simplest form this evaluation consists of a checklist where all the steps required in the process can be ticked off. Whatever form it takes, the results of this evaluation should form part of the dossier supplied to the decision-maker. It can be applied, adapted to circumstances, to all Member States and the European Union.

This part of the ex ante evaluation could for example be done by the body/structure charged with promoting better regulation (Section 7).

1.3 *Ex post evaluation*

The Group considers that a very good way to proceed with an ex post evaluation is to apply a checklist such as the one developed by the OECD (Annex A). This has been used in a number of Member States and other countries with good results. But there are other approaches available and there is room to apply ones that are tailor-made for certain situations.

Ex post evaluation can contribute significantly to the effective review of existing regulation. Done well, it provides clear information on the effectiveness and appropriateness of the regulation, disclosing weaknesses and other shortages, enabling the review to decide what action, if any, to take. If action is deemed appropriate it may take the form of simplification as described in Section 5, consolidation (Section 6.3), repeal of the regulation or revision of the policy itself.

Ex post evaluations should be carried out when general reviews of existing legislation take place, for instance in the context of the simplification programme mentioned in 5.3.1. In other cases the time when the ex post evaluation should take place may be decided on when the new regulation is being prepared and can in appropriate circumstances be included in the legal text (see also Section 2.3). This may, for example, be particularly appropriate where there is considerable uncertainty about the risks being addressed by the regulation or about its effects, such as when the precautionary principle is being relied upon. In other circumstances, the appropriate time for an ex post evaluation may be decided upon later, based on agreed criteria. It is, in any case, essential that the time of evaluation be chosen so that the effects of the regulation can be measured, or new information about the circumstances of the regulation can be incorporated in the review. When a regulation

has been in force a while it should also be possible to measure any behavioural changes of those affected by the regulation.

2 Policy implementation options

2.1 Introduction

When seeking the best method of achieving a policy aim one needs to consider the full range of options. Is traditional regulation the best method, or can an alternative deliver the desired results as well or better? If regulation is the best route, are there any considerations as to the form and structure of the instrument?

This section of the report examines the range of alternatives to regulation available to the policymaker at national and European level, then discusses the role of sunset and review clauses in traditional (national and European) regulation. Section 2 in Part III looks at arguments in the debate on the use of Regulations or Directives for European legislation.

2.2 Alternatives to regulation

Regulation is one of the main ways of implementing public policy. It must therefore meet with a series of quality requirements. However, for the public authorities, regulation is not necessarily the best way of solving a given problem nor is it the only way. On the contrary, excessive use of regulation damages its credibility and effectiveness. In many cases, solutions that increasingly combine regulation with the involvement of intermediary bodies may be considered, provided that they respect clearly defined conditions. Therefore questions concerning the appropriate use of regulation in comparison with or as a complement to other public policy instruments must first be asked.

2.2.1 Use and misuse of regulation

2.2.1.1 Use of regulation

- a) **Authority.** Using regulation is one of the basic attributes of democratic sovereignty. Regulations established by democratically appointed authorities are in principle not subject to challenge in their authority to express the general interest. From this point of view, they have a more solid basis than self-regulation, which comes from economic players or groups whose specific interest may contribute to the general interest without necessarily coinciding with it in the long-term.
- b) **Equality in the treatment of users.** Regulation becomes necessary when equality in the treatment of users has to be achieved through the strictly uniform application of identical measures in a certain area. This is especially true in the case of competition regulations within the domestic market. Equality in the treatment of users can also be expressed by inequalities designed to correct an imbalance (this is the case in social or tax fields), which can only be imposed by regulation.

- c) **Ability to impose sanctions.** The ability to insist that rules be respected may be a result of the free accession to a Code of Conduct by the parties involved. Both Codes of Conduct and other self-regulation instruments can include mechanisms for imposing sanctions on any parties who refuse to conform to the rules (for example withdrawal of certification). However, in many circumstances only the public authority, using regulation, has stringent enough sanctions (particularly under criminal law) to prevent non-conformity.
- d) **Need to take into account the existing legal system.** Choosing to use regulation is not only the result of the immediate advantages which it provides, it is also the result of the legal framework within which the political action falls. Thus the national traditions of Member States can lead to a greater or lesser use of regulation.

In the same way, the European Union is not necessarily free to choose an alternative to regulation in a given field when Member States intervene in this field through regulation.

2.2.1.2 *Misuse of regulation*

- a) **Excessively lengthy regulatory processes.** In some fields, the time it takes to adapt regulations is incompatible with the speed at which technology evolves. If regulation is used inappropriately, particularly when it has to meet with quality requirements (consultation, impact study, etc) this may necessarily take some time which can compromise its effectiveness because it will be unlikely to achieve its objective in the required time.
- b) **Disproportionate cost of drafting and implementing.** Drafting a regulation sometimes requires the mobilisation of skills (in various technical fields) and resources whose cost is excessive compared with the expected benefit (for example the certification of certain industrial products). In the same way, in some cases, there is a risk that introducing monitoring of implementation of detailed regulations (for example on the safety of commercial vessels) will be much more expensive than fixing global objectives coupled with appropriate obligations (for example compulsory insurance).
- c) **Taking responsibility away from the players.** If regulation intervenes excessively in the internal organisation of economic and social players or in the obligations imposed upon citizens, there is a risk that spontaneous initiative, the sense of responsibility or the civic sense will be suppressed.
- d) **Loss of credibility of regulatory processes.** This is an indirect effect. As soon as a regulation is adopted and inappropriately implemented, the propensity to criticise it and the level of non-compliance with it increase. Consequently, the effectiveness of the regulation in question is ultimately reduced but also, to a lesser extent, regulation itself loses its general credibility.

2.2.2 Main alternatives and their use in implementing policy

2.2.2.1 Alternatives and regulatory impact assessment

- a) **Clear formulation of objectives.** The best way of choosing an appropriate tool from the array of instruments available for implementing public policies is to clearly formulate the objectives. The public authority responsible for resolving the problems that it faces effectively, must begin by studying the relevance and the purpose of any possible action: do the public authorities wish to intervene in the activities of the players involved? Is it a matter of guaranteeing the stability of an existing situation or on the contrary correcting it?
- b) **Study of alternatives prior to the decision process.** The answers to these questions lead one quite naturally, when action is necessary, to consider a broad spectrum of means and methods. This is the range of relevant means of action, whether or not involving the use of regulation, which should be analysed and compared.

This should be done clearly and thoroughly prior to the decision process. It is, therefore, as part of the regulatory impact assessment that the various alternatives to regulation should be considered (Section 3).

2.2.2.2 Possible alternatives

The alternatives to regulation are spread over a broad spectrum. It is possible to outline a typology, which allows the objectives of promoting responsibility on the part of the players involved or, on the contrary, ensuring the equal treatment of users and the legitimacy of the public authority to be pursued to varying degrees.

- a) **Do nothing.** Not acting when faced with a given problem may be necessary and should be considered as being a possible alternative. It is a way of placing confidence in existing regulations whilst avoiding implementing a solution too early which might turn out to be untimely.
- b) **Incentive mechanisms.** These may be in the form of information campaigns to make citizens and companies aware of their rights and obligations. They may also be in the form of educational or preventative campaigns intended to have an effect on behaviour enabling the effective implementation of regulations which are known but have not been put into practice. Lastly they may also be financial incentives (bonuses or surcharges) encouraging people to change their behaviour (for example differential taxation of unleaded petrol).
- c) **Self-regulation.** This instrument of regulation is unique to the private sector. In the form of quality standards, certification, codes of conduct, groups of economic players can seek to improve their technical quality and/or their commercial performance. This form of regulation can contribute to the general interest by the simple benefits (price, safety, etc) that it provides for the consumer. It may also include wider interests (in particular by taking into account the demands of environmental protection associations). In as much as user satisfaction can be

achieved using this method, the public authorities do not need to intervene in the domain covered by self-regulation.

- d) **Contractual policies.** Contractual regulation can link public authorities to players in the private sector (companies, associations, individuals). These can be financial rewards given in return for complying with quality standards (for example environmental protection) or activities contributing to the public service (particularly in the social domain). The same methods can be used to link different public authorities (for example to implement European structural funds or for relations between States and decentralised levels of authority). Finally, this form of regulation can involve private sector players. The conclusion of a contract establishing rules common to partners with different interests (for example employers' representatives and employees unions) shows that some of the objectives which are characteristic of regulation (the general interest) have begun to be taken into account without the automatic intervention of the public authority.
- e) **Mechanisms to ensure the assumption of responsibility.** For the implementation of public policies it may be desirable to introduce mechanisms guaranteeing that, even in the absence of regulation, the players involved effectively assume their responsibilities and fulfil their obligations. Setting up compulsory insurance systems (such as civil liability or motor vehicle insurance) provides a non-contentious guarantee that risks will be taken care of by a third party. Legal or arbitration procedures are also a way of applying civil or criminal law sanctions where these responsibilities have not been met.
- f) **Mutual recognition.** In Europe a relevant example of an alternative to regulation can be found in the mutual recognition of national rules even when these differ from one country to the next. This is particularly the case when validating professional qualifications or diplomas. Lastly, with regard to alternatives to regulation at the European Union level, it is worth underlining the benefits of the "open co-ordination method" which allows Member States to work towards common objectives together with the help of methods implemented at the national level and the mutual exchange of information.
- g) **Improving existing regulation.** In some cases, the implementation of new regulations is the result of not applying existing regulations. It is worth studying the methods which would enable the rules either to be implemented effectively (by resolving the specific problems which prevent them from being applied) or revised (in particular by periodically revising regulations).

2.2.3 Regulation and user responsibility

Finding the most appropriate ways of implementing public policies efficiently should lead us to seek solutions that better combine public authority objectives and the responsibility of users or groups of users. It is in this sense that particular attention can be focussed on "co-regulation".

2.2.3.1 *Co-regulation*

There is no **one** single definition of co-regulation. On the contrary, the effective implementation of public policies may, in order to achieve the same objective, lead to combining legislative or regulatory rules and alternatives to regulation. Several approaches can contribute to this.

- a) **Setting of objectives by the regulatory authority and the delegation of the details of implementation.** An initial approach involves establishing, by regulation, global objectives, the main implementation mechanisms and methods for monitoring the application of a public policy. At the same time, the intervention of private players is requested in order to define the detailed rules. This method means that regulations can be avoided which are too general or which are too unwieldy to be applied precisely in fields which require adaptability and flexibility.
- b) **Regulatory validation of rules stemming from self-regulation.** A bottom to top approach may also prove effective. If necessary, co-regulation may lead to a non-compulsory application method established by private partners being changed into a mandatory rule by the public authority. Similarly the public authority may penalise companies' failure to honour their commitments without giving any regulatory force to those commitments.

2.2.3.2 *Conditions for co-regulation*

- a) **Maintaining the primacy of the public authority.** Co-regulation does not mean that the responsibility for the rules being implemented is shared. The primacy of the public authority remains intact.
- b) **Necessary guarantees.** Co-regulation cannot be used in all areas. This is particularly the case where safety, fundamental rights or citizen equality are at stake. In general, one should first ask whether the proposed option is appropriate and proportionate to the intended objectives. Co-regulation implies that public authorities may act in partnership with credible and representative players. Criteria establishing their representativeness should be used to identify professional or social organisations capable of contributing to the implementation of public policies within the framework of co-regulation. Co-regulation does not mean that the regulatory (or legislative) authority is no longer concerned with the effective application of the rule. On the contrary, supervisory mechanisms must be set up.

2.3 ***Sunset and review clauses***

Sunset is when a new piece of regulation is time-limited and actually expires, in whole or in part, after a fixed period. This is written in to the legal provisions in the form of a sunset clause. A variant is where the piece of regulation contains a **review clause**. These are requirements in regulations for reviews to be conducted within a certain period, and can be seen as a weaker form of sunset. Unlike sunset, in this case a rule will continue unless action is taken to remove it. Such ex post review requirements can act as a powerful adjunct to ex ante regulatory impact assessment (Section 3) by checking the performance of regulations against initial assumptions. A

third variant is a political commitment to review the actual effect of regulation in practice. This can have a similar effect and can be less bureaucratic, though it would generally be considered only to bind the government that made it.

The **advantage** of sunset or review clauses is that they force the administration and Parliament to look anew at the necessity for a particular regulation. If adopted systematically for all new regulation, they would ensure a rolling review of regulation, with the opportunity of weeding out or streamlining provisions that are no longer needed.

A significant **disadvantage** of the widespread use of sunset or review clauses is that this is very expensive in terms of legislative time. Although sunset or review clauses may be a good way of forcing an allocation of legislative time to be made for the purposes of review, it is impractical to think that the whole body of regulation could simply be allowed to disappear and have to be re-enacted. In addition, combined with pressure on legislative time, the presence of a sunset clause can be misused to obstruct progress, especially at EU level.

A further disadvantage is that, in some circumstances, sunset (and to a lesser extent review) clauses would increase uncertainty and thus have an adverse effect on the investment climate and on individuals' confidence in the protection afforded them by regulation. This would be particularly the case where the regulation required investment in new equipment or facilities or dealt with the rights of individuals or businesses. Even when a track record had been established of reviews leading to improvements and a reduced burden of regulation, an element of this would still remain.

Given these reasons the blanket use of sunset or review clauses, or their use in certain areas such as fundamental rights, is not appropriate. However, it is possible to identify some areas for regulation where a presumption in favour of sunset or review clauses could be appropriate, subject to a case-by-case rebuttal. These could include:

- Regulation introduced at short notice in response to a crisis – this may not benefit from as much detailed prior analysis as usual and may well be created as a precautionary measure;
- Regulation more generally introduced based on a precautionary motive – where further scientific work would provide a firmer basis for revised regulation in the future;
- “State of the art” regulation – where technology or market conditions are specified in areas subject to rapid development;
- Legislative pilot projects; and
- Regulations which conferred rights on the state (as opposed to citizens or business).

2.4 Recommendations

1. The Member States and the Commission should systematically, as part of the impact assessment system and prior to the adoption of any significant regulation, carry out a comparative analysis of the relevant alternatives to regulation.
2. The Member States and the Commission should, each in their own spheres, define the methods by which the drafting and implementation of regulation involve greater responsibility on the part of citizens, regional and local communities, economic players and intermediary bodies.

3 Regulatory Impact Assessment

3.1 Introduction

Regulatory impact assessment (RIA) can play a significant role in improving the regulatory environment. It can be an effective tool for **modern, evidence-based policy making**. It provides a structured framework for informing the consideration of the range of options available for handling policy problems and the advantages and disadvantages associated with each. It does not replace the need for a political decision – rather, it provides in a structured manner some of the factual information essential to a good policy development process and a well-informed final decision. This can include not only the impacts on business, but also on the environment, on social exclusion and specific social groups, the administration as such and on regions – the full range of sustainable development issues. It also provides an opportunity for working with external bodies, interest groups, business representatives and representatives of civil society such as NGOs, to consider how the policy might be best designed.

A good RIA should enable policy solutions to be created in a way that minimises unnecessary or undesirable impacts or burdens whilst maximising the positive impacts and hence achieving the policy objectives in an effective way. It helps identify whether more output-orientated or objective-led regulation would work better than a law with too much rigidity or detail, or whether or not a legislative approach would be less effective than alternative approaches such as co-regulation, consumer information or economic instruments.

The exact detail of the most appropriate form of regulatory impact assessment depends heavily on the **administrative, legal and constitutional framework** in which it operates. It is therefore not possible to describe here in great detail what system a given Member State might adopt, beyond the main principles.

3.2 Prerequisites for successful RIA

The rest of this Chapter discusses RIA in some more detail, but there are some prerequisites for RIA to be successful in improving the regulatory environment:

- The RIA process needs to be an integral part of an overall strategy to improve the regulatory environment;

- There must be high-level political support for the concept of RIA and its practical application;
- The analytical effort to be put into each RIA should be proportionate to the likely effects of the proposal being assessed;
- Preparation of a RIA should, wherever possible, be by the policy officials concerned and should start as soon as possible in the policy development process, continuing as a fundamental part of it;
- The results of the assessment need to be informed by and subject to both informal and formal consultation of interested parties and others (see Section 4);
- This work is most effective when it is overseen by a specific structure dedicated to better regulation (see Section 7) and supported by clear advice, guidelines and training; and
- Sufficient resources (in terms both of quantity and quality) must be allocated to policy units and the better regulation structure to make the system work

3.3 Content of an RIA

There is a growing body of work on what should be covered by a RIA. As an example, Annex A sets out the ten questions the **OECD's** 1995 *Checklist* recommends. Many EU and OECD countries have similar systems based on similar principles. The variations in national models exist for a number of reasons – these include varying likelihood of legal challenge, different legislative processes and diverse administrative traditions or constitutional systems. But most include:

- Consideration of what the risk or problem to be addressed actually is and whether action is appropriate
- Consideration of what options exist for addressing the risk or problem – is regulation is the best method to address the problem, if so in what form, or would an alternative approach be better (see Section 2.2).
- Assessment of the impact of the options (in most cases both benefits and costs)
- Recognition of the need for transparency and openness in the process and consultation of the right stakeholders (see also Section 4)

In addition, several of the models include the need to consider compliance and enforcement aspects. Also, and again depending upon the constitutional and legal situation, some models have a legally binding requirement to complete a RIA.

3.4 Assessing the impacts

The most rigorous framework in which the impacts – both positive and negative – of various policy options are assessed is Cost Benefit Analysis (CBA). Its methodology allows the objective comparison of the quantifiable advantages and disadvantages of any number of implementation options, over any policy lifetime and regardless of the timing of the benefits and costs. Issues of equity can also be highlighted in the detail of the analysis. Other, less rigorous methods include:

- Cost Effectiveness Analysis, which does not explicitly consider the benefits in its framework;
- Compliance Cost Analysis, which concentrates on estimating the likely costs of complying with proposed regulations; and
- Techniques that “weight and score” the different policy impacts, which can suffer from subjectivity and where the importance of the timing of the costs and benefits may be lost.

The methods of estimating the benefits and costs to be used in the CBA framework are crucial in good policy assessment. Whilst estimating the **financial** benefits and costs of a policy proposal may be relatively straightforward, estimating benefits for some **non-monetary goods** is more difficult, and can be sensitive. For example, how to put a value on a human life, a forest or a whale or how to estimate the benefit of a policy that reduces sulphur dioxide in the atmosphere. There are techniques that can be employed to assess such “non-marketed” goods, such as calculating people’s willingness to pay for the whale or for avoiding the risk of death or serious injury, though these are often difficult and controversial. Other techniques use people’s observed behaviour – i.e. how far they will travel and what they will forgo to visit the forest. These and other techniques, whilst they may not be perfect, can at the least give ranges, orders of magnitude or rough estimates of these important benefits and thus provide a more balanced picture than just assessing the financial aspects. Where even this degree of quantification is impossible, it is still vital to give at least a qualitative assessment of benefits to avoid a one-sided, cost-focused picture.

Also important in policy appraisal is the ability to take into account the different times when benefits and costs accrue. CBA can deal successfully with this aspect, through “discounting”. Policy options that defer expenditure are less costly in a growing economy. There are some issues surrounding this discounting principle, and CBA can face difficulties in assessing rare uncertain catastrophic events in the distant future.

Issues of estimating benefits and costs and of discounting are not always easy to address, but CBA can still play an important – but not sole – part of the policy-making process. Even the simple process of asking the right questions in order to prepare for the CBA can add value and understanding to policy development, and the level of complexity and effort in it can increase as expertise develops and resources are made available.

3.5 The RIA process

As mentioned above, RIA should be an **integral part of the policy making process** rather than a bureaucratic add-on. This means much of the assessment needs to be done by or in close co-operation with the policy officials concerned and from as early as possible in the policy development process. One of the earliest steps should be some assessment of the current situation – in other words, the advantages and disadvantages of doing nothing. This can be difficult to achieve if an external agency carries out the assessment alone, though advice, guidance and a quality control role can usefully be offered by such a body (see Section 7). This close and continuing

analytical input to policy formulation enables the initial and ongoing results of such analysis to be fed objectively into the advice to political decision-makers as the policy develops. Of course, for particularly complex issues, it can be useful to bring in outside expertise through experienced consultants, but the main responsibility needs to lie firmly with the policy officials.

Nonetheless external bodies or interest groups should not be excluded – on the contrary, it is essential that RIA be informed by **consultation** (see Section 4) with the affected sectors, economic actors and civil society more widely. Indeed, as mentioned above, one benefit of RIA can be the framework it provides for such involvement of stakeholders. The consultation should start as early as possible in the policy development process and, as far as practicable, continue throughout. In addition, it can be extremely helpful for the final consolidated assessment to be subject to public scrutiny, both because this helps inform the public debate and because it encourages administrations to produce high-quality assessments through external quality control of methods and data used and assumptions made.

Although conceptually RIA should be seen as an ongoing, integral part of the policy making process, it can nonetheless be helpful to identify particular stages. A preliminary assessment, carried out at the earliest point in the policy development process, should identify the main risks/problems, the probable impact, the possible options and the sectors/actors affected. This can form part of early, informal consultations and can be used to determine whether the policy meets the test of significance (see below). If the test of significance is met and hence the effort required is proportionate, a more detailed assessment can be prepared at that point. This assessment should be based on coherent guidelines across all policy areas within the administration and should include the following elements:

- A clear statement of the risk or problem being addressed and of a) why action is necessary and b) why action at that level of government is appropriate (i.e. compliance with the principle of subsidiarity);
- A description and justification of different options considered, including alternatives to regulation (see Section 2.2);
- For each relevant option, identification of affected parties (private and public) and a quantitative (if possible) or qualitative (as a minimum) assessment of impact on them – both advantages and disadvantages;
- A summary of who has been consulted, when and how, plus the results of such consultation (e.g. summary of or access to comments and an indication of resulting changes) (see Section 4);
- The estimated lifetime of the policy or options¹, plus a justification of why no review clause is proposed if that is the case;

¹ That is, for how long the proposed policy approach is expected to be valid – for fundamental protections this could be unlimited, but for fast-moving or uncertain fields this could be relatively limited. Such an estimation allows the benefits and costs to be calculated on an annual basis and to be discounted as appropriate.

- Particular reference to the impact on small business or any other disproportionately affected group;
- Concise explanation of how this proposal fits with existing and, where known, forthcoming rules and policies; and
- An indication of what account has been taken of the practicalities of implementation, including the differing benefits and costs of shorter or longer implementation periods.

This detailed assessment should form part of the external (informal and formal) consultations and should be revised at key stages in the policy making process (e.g. formal publication of a proposal, submission to the regulatory authorities, results of public consultation, etc).

The final step of RIA should be an ex post **evaluation** of the actual impact once the policy option has been implemented. This helps check the accuracy of assumptions and estimates made earlier in the process, which in turn can help improve the quality of future RIAs. This also can help throw up whether any benefits or costs were overlooked, again improving the administration's state of knowledge for the future.

Decisions that are prepared more thoroughly in this way will often result in more robust decisions that are less subject to challenge, more likely to have significant stakeholder buy-in and more likely to achieve the desired outcome on the ground. The advantages of this approach can outweigh any reduction in the pace of policy preparation.

The amount of effort that is put into the RIA for a given policy proposal needs to be proportionate. The larger the potential impact, the more effort that is justified in assessing it properly. For this reason one should apply a test of significance of the likely effects, including potential financial costs and disproportionate impacts, for example on a particular industry, social group, ecosystem or Region/Member State. To ensure that the analytical effort is proportionate, this test should also take into account the effect of carrying out a certain depth of analysis on the resources of the administration itself.

If, on the basis of the preliminary assessment, a proposal meets one or more of these tests, the more detailed assessment should be carried out. If not, then the preliminary assessment will normally suffice, though there could be the possibility for political authorities to call for a more detailed assessment where they deem it appropriate.

3.6 Common problems

There is a range of common problems encountered when seeking to implement a system of RIA. These are discussed in three main categories below – practical difficulties, cultural resistance and political pressures – though in some cases the separation is rather arbitrary.

3.6.1 Practical difficulties

The first practical difficulty to overcome is simple awareness of the need to undertake RIA amongst policy officials. This can be tackled through appropriate publicity (internal within the administration or, if appropriate, externally too) and training.

A lack of staff resources and expertise to carry out the RIAs in policy units is often cited as a key practical difficulty. This can be overcome partly through the availability of expertise and training from the better regulation structure but needs political commitment and support as well as backing at senior levels to overcome fully. The size of the public administration overall is also relevant – smaller administrations generally find it more difficult to find the resources than larger ones.

Another factor given is the paucity of good quality data on benefits and costs, including the difficulty of estimating the value of non-marketed goods (e.g. environmental degradation or damage to human health). Whilst this will indeed affect the overall quality of the assessment – which can only be as good as the inputted data – it is not a sufficient argument for not carrying out any assessment at all. Use of error estimation and ranges (rather than single figures) for benefits and costs can help, as can the input from consultation with stakeholders and intelligent use of available data, consultants and academic expertise. Seeking input from a wide range of stakeholders can help avoid the kind of bias otherwise possible from vested interests. Even where the policy is of a broader, more strategic nature RIA can be used to inform the policy development process (see for example the case study in Annex B).

3.6.2 Cultural resistance

Here, “cultural” is meant in its broadest sense. It encompasses administrative and legal arrangements that militate against easy acceptance of the more crosscutting, horizontal nature of the RIA process, which might include strong traditions or laws of independence of ministerial action and restrictions on inter-ministerial co-ordination or on external consultation.

It also includes the reaction sometimes encountered with some policy officials that they know best how to do their job and have the clearest understanding of what is best for the country or the policy area. They are therefore often reluctant to accept and make positive use of the RIA tool, resulting in a formalistic approach that sees RIA as an unnecessary bureaucratic burden to be completed as late and with as little effort as possible.

Changing this kind of cultural resistance takes time, especially if it is underpinned by legal arrangements. Standard change management tools can help in this process but it needs to be given strong political support and addressed at all levels – desk officer, middle and senior management and high level political leadership. Education as to the usefulness of the tool in assisting the policy process is vital – policy officials need to see what is “in it for them” in using the system. But there must also be a credible deterrent element – if the process is not completed properly (timing and quality), the progress of the policy can be delayed, halted completely or challenged subsequently.

3.6.3 Political pressures

Some see RIAs as an excuse to impose a business-focused, deregulatory agenda on policy makers. For a RIA done well, this is absolutely not the case. Rather, as stated elsewhere, the RIA simply sets out the information in a clear and concise way to inform – not control – the political decision. This point needs to be stressed as appropriate and real efforts need to be made to ensure that both benefits and costs are included in the assessment.

Another possible problem is the political pressure to do something – anything – now, irrespective of a proper assessment (sometimes known in its most extreme form as a “knee-jerk reaction”). It is not always possible to overcome this and it can lead those policy officials undertaking the RIA analysis to question its usefulness, but development of a good RIA system is likely to reduce the incidence of this reaction as the need for good assessment becomes commonly understood and supported. In addition, in many cases work may already have been underway in this area, so some form of assessment probably exists if RIA is already an integral part of policy development process.

A further situation can be where the main political decision has already been taken (perhaps in a government programme or party manifesto). In these cases there can be a reluctance to undertake assessment of the implementation options available. However, almost always details remain to be resolved where an assessment can play an important role in informing, in a very explicit manner, those taking the decisions on the details about the trade-offs that they are making.

Finally, there is often the perception that doing RIA takes too much time and delays the policy development process to an unacceptable degree. However, when RIA is an integrated part of the process, any delays in the earlier stages are minimised and often outweighed by time and cost savings later in the process where the greater defensibility of the policy solutions and the increased buy-in by stakeholders are important.

3.7 Recommendations

1. RIA is an ongoing, evolutionary process that informs the political choice and is not simply the production of a one-off document. A RIA should be based on coherent guidelines across all policy areas within the administration, should follow OECD guidance and should contain:
 - A clear statement of the risk or problem being addressed and of a) why action is necessary and b) why action at that level of government is appropriate;
 - A description and justification of different options considered, including alternatives to regulation;
 - For each relevant option, identification of affected parties (private and public) and a quantitative (if possible) or qualitative (as a minimum) assessment of impact on them – both advantages and disadvantages;

- A summary of who has been consulted, when and how, plus the results of such consultation (e.g. summary of or access to comments and an indication of resulting changes);
 - The estimated lifetime of the policy or options¹, plus a justification of why no review clause is proposed if that is the case;
 - Particular reference to the impact on small business or any other disproportionately affected group;
 - Concise explanation of how this proposal fits with existing and forthcoming rules and policies; and
 - An indication of what account has been taken of the practicalities of implementation, including the differing benefits and costs of shorter or longer implementation periods.
2. A preliminary assessment identifying the main risks/problems, the probable impact, the possible options and the sectors/actors affected should be produced at the earliest point in the policy development process. This can form part of early, informal consultations.
 3. A detailed assessment containing all the relevant items listed in Recommendation 1 above should be produced unless the preliminary assessment has clearly demonstrated that the proposal has no significant impact. This detailed assessment should form part of the external (informal and formal) consultations.
 4. The detailed assessment should be revised at appropriate stages as the policy development process proceeds to reflect changes and the results of consultation.
 5. Proper resources need to be allocated to carry out the RIA.

4 Consultation

4.1 Introduction

In order both to ensure high-quality regulation and to further an open transparent and democratic decision-making process it is important that groups and organisations, which will be affected by new regulation, are consulted at the appropriate stages of the regulation process. Consultation should be understood as an interaction between the bodies responsible for regulation and parties that are likely to be affected by or interested in the regulation in question.

The consultation process should be regarded as a means towards open governance. The ways to structure consultation are manifold, it is therefore not possible to identify a single model. Consultation processes could be structured for example as single source consultation or as a mix of methods (written procedures combined with conferences/committees). Whatever procedure is chosen, the aim should be to ensure that in each case all relevant parties are consulted in an adequate and appropriate way.

The possibility of participation as such can ensure better quality of regulation. At the same time consultation leads to democratic legitimacy of regulation (through the possibility of people being able to take part in the public debate) and is likely to create more confidence in the end result and in the institutions which deliver regulation. Consultation can lead to broad public support because it can explain the reasons why regulation is necessary. It can help to ensure for example a balance between rights and the need for protection or to ensure a balance between different interests (regulation as a kind of arbitration).

Major aims of the process are:

- The improvement of proposed texts (in a general sense);
- Examining the suitability of new regulation (from a technical viewpoint);
- Verifying that it can be expected to work in practice; and
- Checking that new regulation is coherent with existing regulation and that the end result is effective in the widest sense.

It is also important for the evaluation of whether the regulatory act can be considered reasonable and expedient.

Furthermore it is an independent goal to ensure that relevant parties are involved in the preparation of regulation, which has an impact on their affairs. This may further a sense of “ownership” among those consulted.

Consultation is an important instrument to reveal unintended consequences of the regulation and it can contribute to a higher level of compliance.

It is also of great value to the regulatory (legislative) bodies to know the positions of the parties affected by the proposed regulation. This may in practice advance the regulatory bodies’ discussion and adoption – or rejection – of the act later on. It can assist in developing a longer-term policy perspective. Participation in a consultation process should therefore not only be considered as a possibility to express protest but should be seen by consulted parties as an instrument to shape regulation or policies.

There are a number of possible procedures for consulting interested parties at different stages in the process of preparing new regulation. In the following, interested parties are defined broadly and may include public bodies, NGOs, such as consumer organisations, the business community including SMEs, professional associations, and interested individuals, depending on the regulation concerned.

4.1.1 Consultation procedures – different possibilities and guiding principles

It is generally best practice to submit a proposed regulatory act to a consultation procedure. In order to ensure efficiency of the decision-making process this procedure should be completed prior to the introduction of the proposal to the regulatory authorities in order to adjust the proposal in accordance with the results of the consultation.

When a proposed new act is submitted to consultation, it is generally helpful if it is completed and accompanied by some explanatory notes including information on the economic and administrative implications, etc. for business, citizens and the national administration, implications for e.g. the environment, etc. Involvement of the affected parties in the assessment of economic and administrative implications will often add value.

It is not possible generally to specify the parties to be consulted. But as a general rule, everybody who is likely to be affected by regulation on a practical level, or on a more general level as to principles or ideals, should be consulted or should have the possibility of submitting reactions. Examples might be consumer and business organisations, SMEs and local administrative bodies. In any event, it is better to consult too many rather than too few, not least since this helps avoid consultation becoming a matter only for the most resourceful lobby organisations etc.

The deadline for the consultation must be set according to the prevailing circumstances, but sufficient time should be given for the parties to give an adequate response. In this context, consideration should be given to the fact that some parties, when consulted, may need to obtain statements from subordinated institutions, which have expert knowledge etc.

Only in extraordinary and duly justified cases should it be possible to refrain from a consultation procedure prior to introduction to the regulatory authorities. However, it should be evident that such a decision has significant drawbacks.

It is generally best practice to launch a consultation on the broadest possible basis, thus enabling interested or affected parties to make comments. Internet based consultation is also recommended.

In some respects it could be desirable to have a fixed well-established consultation procedure that has to be followed independently of the subject concerned. On the other hand it is an advantage to have the possibility to choose consultation methods that are suitable for the specific act involved – for instance it may in some cases be relevant to focus the consultation on a few key issues. The important thing is to develop a structure that ensures that in each case all relevant parties are consulted in an adequate and appropriate way.

In cases where there is no real choice for the legislator as to some parts of the regulatory act, this should be made clear to those consulted.

A quick regulation procedure should not be carried out at the price of making it impossible for the interested parties to comment on the proposed regulatory act. Complying with the principles of transparency and democratic openness is an important goal in itself. Besides, an intensive consultation procedure will often imply that subsequent consideration and adoption of the act may proceed more rapidly because many questions and problems are discussed and eventually solved at an early stage of the regulation procedure.

In discussing broader or more fundamental subjects consultation may in addition to other more traditional ways be carried out as a public hearing or conference with attendance of representative organisations, experts, press etc.

In case of more extensive regulatory reforms or regulation concerning important principles, new regulation may at initial stages be prepared by preparatory committees or commissions or working groups. In these cases affected parties should be represented on the committee. A preparatory committee may furthermore invite relevant organisations or individual experts to present their views directly to the committee.

When a committee issues a report containing recommendations for new regulation, the report should be submitted to the “normal” consultation process.

It is up to the government or administration to decide on a case to case basis which approach it takes to launching the consultation procedure. This depends on the particular need and situation. The principle of proportionality applies to the way the consultation process is structured.

In Denmark, to name one example of the various procedures that exist at the national level, one way among others of assessing the administrative implications for businesses of new regulation is to consult a so-called test panel. This test panel consists of a number of businesses that are representative as to types of business, number of employees and corporate structure. The test panel is asked to assess the expected administrative implications for businesses of new regulation that is expected to have an administrative impact on businesses. The main function of a test panel is to contribute to the considerations concerning the structure of a new legislative act. The comments made by the test panel are forwarded to the regulatory authorities in connection with the introduction of the proposal.

Consultation procedures are also very useful in order to evaluate and improve existing regulation.

4.1.2 The use of consultation documents by the regulatory authorities

The comments made by the consulted parties are highly valuable to the regulatory authorities in evaluating the proposed regulatory act. These comments and/or a summary of the comments should in appropriate form be forwarded to the regulatory authorities at the same time as the introduction of the proposed act.

If amendments are made to a proposed legislative act that has already been introduced, the timeframe which applies to the reading of the proposal, will frequently constitute an obstacle to consultations. If amendments are not of far-reaching importance, omitting renewed consultation is not usually a problem. The question of consultation should however be considered in each individual case. Even though the hearing cannot be as extensive as when a hearing is conducted before the introduction of the proposed legislative act, possible ways to involve the parties, which are particularly affected by an amendment, may be considered.

4.2 Common problems

4.2.1 Problems encountered by the consulting side

Sometimes it is difficult to define the relevant parties that should be consulted in order to have a valuable targeted consultation process. It is useful that affected parties/organisations identify the subjects they want to be consulted on and notify the administration.

For the consulting party it is often not possible to identify the relevant persons within organisations, dealing with the specific topics. Organisations could name co-ordinators to be the only addressees for consultation procedures and are responsible for the distribution of information concerning consultation procedures within their bodies.

The results of consultation (i.e. the comments) are often unspecific remarks that are furthermore delivered with considerable delay. In order to have effective consultation, side letters could identify specific questions (to highlight who should comment on which subject). The consulting side should set and communicate a deadline for the consultation according to the prevailing circumstances (e.g. subject matter, urgency, etc.), but sufficient time should be given for the parties to give an adequate response. Consulted parties should deliver their opinions within the timeframe set up for consultation.

In order to be effective, consultation should be launched at an early stage. Depending on the subject matter (e.g. consultation on a policy or on regulation) the consultation process should be based, where possible, on concrete texts, thus enabling the consulted parties to give specific comments.

Sometimes administrations consider the consultation process as burdensome, lengthy and senseless, because “they know what’s best for the affected side”. From time to time, there also may be a need for administrations to bring forward regulation urgently and/or deliberately without prior consultation, thus denying affected parties time to react to new regulation in advance (for example, in the field of tax law). However, in most cases, the value in achieving “surprise” is less than the value of having proper consultation. Accordingly, it is considered that doing without consultation would only be a valid option in extremely limited cases where the consultation process can reasonably be expected to seriously undermine or compromise the effectiveness of the new regulation. A new thinking is needed, because the consultation process should be regarded as a partnership that could improve the quality of regulation and uses external know-how and expertise (professionalism of consultation).

The consulting side will often face the problem of diverging opinions as a result of consultation (e.g. SMEs have different interests in comparison to international corporations, economy/industry “against” environmental protection agencies). It is therefore important that the consulting side should be regarded as an impartial mediator between different groups of interests (objectivity of consultation).

It is of utmost importance that consultation, leaving aside exceptional and specific cases (e.g. matters of state security), is not limited to a specific group. It is up to the

consulting side to decide who should be consulted, but generally a wide range of parties (not only the “usual suspects”) should be addressed. Internet based consultation is a means to ensure the spread of information on a wide basis.

Consultation is often seen by regulatory institutions (bodies) as replacing the decision-making. This is a misunderstanding since consultation should complement and improve draft regulation but not replace decision making regulatory bodies.

It is often considered that there exists a tension between faster decisions and better, but time-consuming consultation. This tension does not necessarily pose a problem since investment in good consultation may produce better quality regulation that can be adopted more rapidly and is easier to apply and to enforce.

Guidelines should be used to ensure uniform application of rules concerning consultation.

4.2.2 Problems of consulted parties

Since consulted parties are regularly affected by a vast variety of regulations, institutions are often on a standard mailing list, thus receiving all kinds of information. Sometimes this causes an overflow of information and important consultation processes are not identified. Side letters could indicate the subject matter (and thus the importance) of a consultation process.

In order to ensure efficient consultation, consulted parties have a responsibility to respond and have to stand by their opinion issued during the consultation process. The response should be given in the set deadline.

Some consulted parties, especially representative organisations (trade unions, etc) need to obtain statements from their member or subordinated institutions. Often, deadlines for consultation are too short for them to have proper time to do so. Therefore deadlines must be set according to the prevailing circumstances, but sufficient time should be given to the parties to give an adequate response, bearing in mind that consulted parties may need to consult third parties as well.

4.3 Recommendations

Consultation is a very important instrument that may be carried out in various ways and at different stages in the regulatory procedure.

1. Consultation should be transparent and all those affected and/or interested should be involved as early as possible.
2. In addition to and/or instead of the traditional consultation process, proposed regulation should be made accessible on the Internet, thus enabling all interested parties to make comments.
3. It should be possible for the general public to get access to the comments made by the consulted parties (except in due and limited cases of commercial confidentiality).

4. The comments made by the consulted parties should be forwarded to the regulatory bodies as soon as possible and/or a summary of the comments in order for those bodies to take proper account of the views and assessments of the interested parties. This material can play an important part in the regulatory process.
5. A standard minimum consultation period should be established.
6. The actual consultation period used should be appropriate to the matter being consulted upon and the range of stakeholders being consulted.

5 Simplification

5.1 Introduction: the concept of simplification

In the last decades, regulations have enabled governments to protect a wide range of economic and social values. But as economic and social conditions are rapidly transformed – through globalisation, rapid technological change and cultural pluralism – the existing regulatory systems become increasingly obsolete and unnecessarily burdensome.

One of the greatest challenges facing our governments is, therefore, to update and simplify the modern mass of regulations in our respective legal systems.

Regulatory systems must, moreover, be periodically examined in order to be well maintained. A regular and systematic review of existing laws, rules and regulations is essential to prevent national legislative systems from becoming so complicated, onerous and outdated that they undermine the value of law itself, as well as economic performance.

This Chapter seeks to identify the problems experienced thus far, in order to set out workable suggestions for improvement, and to address proposals for a global strategy of simplification of existing regulation, to be understood as follows.

5.1.1 Simplification does not mean ignoring real-world complexities

The very complexity of our world demands rules adequate to govern it.

It is important to respect rather than deny this complexity when complexity is necessary to further a better quality of life. But we must always pursue the best solution; that is the least burdensome for those to whom the regulation is addressed.

In other words, simplifying regulation does not mean trying to make the world less elaborate and less evolved. Rather, it means making regulation more “user-friendly” and making the associated procedures easier to follow, for example through the innovative use of ICT, self-certification, etc.

Simplifying an existing regulation, in fact, generally furthers effective compliance. Overly complex regulation is harder to comply with, which can lead to less protection on the ground. If those who are regulated find it easier to comply, they are more

likely to do so and less likely to give up and avoid the regulation completely. Thus simplifying regulation can result in greater levels of compliance and therefore greater protection than would otherwise be the case.

5.1.2 Simplification does not mean deregulation

The Group's concept of simplification is not to be mistaken with deregulation. The two concepts cannot be regarded as synonyms. Deregulation simply refers to the abolition of rules in a certain sector, whereas simplification - a more advanced stage in governing regulation - is aimed at **preserving the existence of rules** in a certain sector, while making them **more effective, less burdensome, and easier to understand and to comply with**. The complexity of regulation that arises from the need to protect the interests of society and of vulnerable groups within it and is linked to the public's growing aspirations to high quality goods, services, work, living conditions and the environment is not the target of simplification. The concept of simplification intended by the Group respects these fundamental needs of our democratic and pluralistic society, requiring appropriate legislative responses.

Therefore, by simplification we refer to the process of reform of existing regulation, which seeks to streamline administrative procedures and to reduce the burden of compliance on citizens, businesses and the public sector itself, while preserving the intended (political) goals of the regulation.

5.2 Common problems and lessons learned

Many countries within and outside Europe have initiated simplification programmes in the past several years, aiming in particular at reducing the burden of government formalities and simplifying permitting procedures. Those experiences have been researched and analysed in depth by the OECD, among others, over the past two years, leading to policy conclusions and recommendations derived from the experiences and challenges faced by Member States in their drive to reform regulatory regimes.

Based on these examples and analyses, we can derive the following general conclusions:

- **Simplification cannot be a “one shot” policy.** If it is to have significant benefits, simplification must be viewed as a process, not a discrete project. It is a process because it poses a continuing challenge, and is not a one-time *ad hoc* effort to be completed next year. Regulations must be reviewed systematically against the principles of good regulation and from the point of view of the user rather than of the regulator, to ensure that they continue to meet their intended objectives efficiently and effectively;
- **A simplification program ought to be based on sustained political support.** Because of the difficulties in reforming legal rules, owing in particular to vested interests and to opposition in both public and private sectors, a general program of simplification must respect general social and political attitudes. Politicians and the public must accept the need for change and be ready to move forward in a concrete manner. A key element of simplification is

thus sustained political support. In many countries Prime Ministers themselves are personally involved with this work.

Some practical lessons can be learned from the efforts of European governments to carry out simplification programmes:

- **Broad programmes with clear objectives and frameworks for implementation.** If a general programme of simplification does not start with clear goals, it will falter along the way. Thus, it is necessary that political actors adopt broad programmes establishing clear objectives and frameworks for implementation. The question of marginal change versus radical overhaul merits serious consideration. Marginal changes that make existing regulation work better can produce substantial results. Yet it has often been difficult to make real, long-term progress. Thus, to produce real change, comprehensive review and reconstruction of entire regimes is often necessary. This is expressed by the slogan “reinventing regulation” used in the United States;
- **Importance of a multidisciplinary approach.** Simplification, or any regulatory reform for that matter, requires a multidisciplinary approach. Lawyers, economists, jurist-linguists and public managers must work together for the programme to produce results. Regulation must be viewed as a legal instrument with economic effects carried out through public institutions. This institutional dimension is critical. Simplification must be carefully constructed in light of the background legal and institutional environment, and with a respect for the relationships between different levels of government and European institutions;
- **Integration of processes for reviewing and improving both existing and new regulations.** In fact, similar kinds of reform are needed at both stages of regulation (for instance, regulatory impact analysis, public consultation and the systematic consideration of alternatives). Reviews structured along the same principles used for new regulations will close the circle, making regulatory reform a truly life-cycle activity extending from regulatory cradle to grave;
- **Measurement of results is a key issue.** It is important to establish how to measure change and the results of simplification. Measurement is important both as a management tool to keep reform on track and also as a means of communication, enabling policy officials and the public to see concrete results. Analysis of the costs and benefits of change is one possible method for assessing whether simplification is justified;
- **The need for an implementation strategy.** It is important to assess how governments go forward and at what speed. Reform must be worked out within the context of the institutional environment, taking account of the risks of each option. For the effectiveness of the implementation strategy, it is also necessary to have a structured process, with some kind of independent oversight. Positive experiences registered in many countries show the high added value derived from the creation of effective and credible mechanisms inside the government for managing and co-ordinating regulation and its reforms;

- **Transparent consultation with interested parties.** In any simplification programme, dialogue with the affected parties is important. To the greatest extent possible, all interested parties should be given the opportunity to express their views in developing reform policy, through an open, transparent consultation. Such consultations must, however, be carefully structured to avoid undue delays.

5.3 Contents of an effective simplification policy

If the process of simplification of existing regulation and associated procedures is to succeed, better regulation and simplification efforts must be pursued, independently but in a co-ordinated manner, at both European and national levels within the framework of a coherent and well co-ordinated general policy for simplification. This policy should be built upon some basic principles of regulatory quality for both existing and new regulation, for instance as recommended by the OECD in the 1995 Regulatory Reform Report.

5.3.1 Establishment of a simplification programme

This general policy should entail the **establishment of a systematic, preferably rolling and targeted programme of simplification of existing regulation in all areas**, therefore covering the regulation that impacts on citizens and on public bodies that have to implement it as well as on business. In order to gain effective results, the simplification program should be organised along the following lines:

- a) It should be a **systematic**, preferably **rolling** and **long-term** programme, made up of annual steps that are reviewed and reassessed in the following year.
- b) The first move should usually be to identify (on the basis of priorities identified as below) areas of regulation for review. This review process should lead to the setting out of **clear targets** (that is, a concrete list of existing regulations and/or procedures to be simplified within the year) and **methods** to be employed (especially the innovative use of ICT).
- c) It should **significantly involve businesses, consumers and other 'recipients'** of regulation, both in the identification of priority areas for review and in its subsequent implementation.

The identification of the regulations and the tools contained in the plan ought to arise mainly from an examination of the "critical points" as highlighted in an ex post evaluation. This identification, as far as the following implementation of the plan goes, should see an active involvement of the economic and social partners and all the various civil society players, without whose assistance no simplification policy can succeed (for further details, see Section 4).

- d) It should set out **priorities** among them and a timetable for action and should be backed up by innovative methods, budgetary funding and effective means of appraisal.
- e) It should be **supported by sufficient, well-focused resources**, targeted to reduce the burden rather than just the number of existing regulations.

- f) It should be **connected with review of existing regulation** and with **codification or other forms of consolidation** (see Section 6).

Simplification is closely associated with the process of consolidation and codification of regulation². For instance, although the two processes are different, the “codifiers” could stress the importance of or the need for simplification measures in the sector they are dealing with. For their part, the “simplifiers”, in streamlining and rewriting the discipline of a sector, could also highlight the need for consolidating it. Regulatory codification or other consolidation processes could also consider the introduction of the guillotine system³.

- g) Simplification should, in some cases, involve the **repeal of an old regulation** that for instance:
- No longer serves a useful purpose;
 - No longer complies with the general principles of the European legal system, or is no longer consistent with the main objectives of the general regulation of a sector or with the principles of EU institutional reform;
 - Currently involves costs that outweigh its benefits; or
 - Establishes a special regime for a specific area that goes beyond the relevant general requirements and is no longer justified.
- h) Simplification should always consider the **use of ICT** to re-engineer procedures.

5.3.2 A culture of simplification

Simplification should be a general policy in the behaviour of Member States and EU Institutions. In this respect, codes of conduct should be adopted by all bodies involved in legislating, ensuring that they help to promote the simplification of rules and to disseminate best practice in this area.

As far as the effectiveness of the simplification program is concerned, the Group is aware that even the best annual plans can be undermined unless the process is conducted within a **co-ordinated framework** and has a concrete time-table and an effective decision-making procedure.

As far as co-ordination is concerned, it is important that the decisions on the simplification programme involve the various Ministries (Directorates General) interested in the same regulation. The co-ordination of this process should be done by the body/structure charged with overall management of the quality of regulation (see Section 7, where the Group recommends that a primary unit within each administration should be considered, preferably at or near the centre). As far as the

² In particular, in the process of “recasting” (or “refonte”) – consolidating and amending existing legislation

³ In the 1980s Sweden established registries of all their rules, culling unnecessary ones and commenting on rules that they thought were unnecessary or outdated as they went, in effect reversing the burden of proof for maintaining old regulations. When the “guillotine rule” went into effect, “hundreds of regulations not registered...were automatically cancelled,” without further legal action.

effectiveness and the flexibility of the rule-making process is concerned, an accelerated legislative procedure for simplification of non-contentious regulation should be foreseen, according to the respective constitutional and legal framework.

5.3.3 Coherence with other tools

Simplification tools should be **coherent** with the ones for **improving the quality of new regulation** and existing regulation tested in a similar manner (see Section 3 on RIA and Section 4 on consultation).

5.3.4 Measurable results

The review of existing regulation should be done not only with a view to simplification or creating more clarity, but also regarding the effect of existing regulation on innovation, economic growth and employment. To do these kinds of reviews, it is suggested that benchmark studies take place with other trading blocks to see how they have set up their regulatory environment in a certain area or concerning a specific sector.

Moreover, any new important European regulation should provide for a procedure for assessing its results, in particular the attainment of its objectives. These assessments should be made public.

5.3.5 Simplification and new regulation

Simplification should always be considered when introducing new regulation. This means addressing the consequences of new regulation in relation to existing regulations and using the opportunity to reconsider each area of regulation every time new regulation in a specific area is proposed.

5.3.6 Monitoring, defence and consolidation of simplification

The **monitoring, protection and consolidation of the simplification process** (no “re-complication”) should be ensured. An *ex post* evaluation of the simplification strategy is crucial to fine-tune the subsequent steps. In this respect, the above mentioned tools (see Section 5.3.3) should be used also to assess the outcomes of the simplification measures already adopted.

Moreover, existing “simplified” regulation should be reviewed on a regular basis. To help the process we could think about “sunsetting” or at least about a mechanism of periodic review to be included in every significant new proposal for EU or national regulation. In this context, the use of review/sunset clauses should be considered, whenever appropriate, in new regulation adopted (see Section 2.3).

An on-going program of reviews, to be included in the annual simplification measures, will be essential to guard against unnecessary regulation and to allow for the amendment of regulations in the light of experience and changed circumstance. Assessments should be part of this program. These assessments, if carried out at the appropriate time, should provide valuable information on the working of regulation as well as opportunities for review.

5.3.7 Establishment of multi-disciplinary regulatory management

The culture of simplification and the use of its relative tools should be spread among EU and Member State civil servants. The first step in this direction should be the establishment of expertise in multi-disciplinary “regulatory management” (law, administration, linguistics, economics, statistics, ICT, etc), beginning with a **tailored programme of training for officials** (addressed to both national and European “professional regulators”). This will help promote better understanding of the meaning and the use of the better regulation principles, including those promulgated by the OECD.

5.3.8 Transparent and understandable simplification

The review and improvement of the legal stock is a priority, but the difficulties of the task mean that years would be needed to see results. To help produce early results for citizens and businesses, each Member State should investigate the creation of a single authoritative source for all applicable administrative procedures and forms (including those at EU level). This source would need to be kept up to date and made available online and might also act as a portal site, allowing online access to the procedures and forms themselves as well as the relevant legal provisions⁴. The single source of procedures and forms could significantly enhance transparency for users, increase confidence in the government/administration and reduce search costs for businesses and citizens. Setting out the procedures in this way can also increase the predictability of action by the administration and could help promote a rationalisation of the rules.

This proposal backs the recent call from the Commission⁵ to make online services available to citizens and businesses, a relevant issue also in the Group’s opinion (see Section 6.5).

5.3.9 Member State simplification

All regulators in Member States should, in parallel with the Commission, simplify their regulation (including regulation transposing European legislation) (see Section 8.2), following the above mentioned guidelines and adapting them to their respective national circumstances.

The Member States also have a key role to play in ensuring the success of the EU level simplification policy. To this end, they should:

- Formulate national measures to help further the EU level simplification policy (for example by contributing constructively to EU level simplification exercises);

⁴ Such a process could be inspired by the French CERFA (Centre d’Enregistrement et de Révision des Formulaires Administratifs) model and other Member States’ e-Government initiatives

⁵ Communication from the Commission “*Strategies for jobs in the Information Society*” of 4 February 2000 (COM(2000) 48 final)

- Create more propitious conditions for the proper functioning of mutual recognition; and
- Refrain from introducing **unnecessary** detail or **over-complex** administrative requirements when transposing European legislation.

5.4 Recommendations

1. Establishment of a systematic, targeted and preferably rolling programme of simplification of existing regulation in all areas, therefore covering the regulation that impacts on citizens and on public bodies that have to implement it as well as on business. In particular, the simplification program:
 - Should be a rolling and a long-term programme, made up of annual steps that are reviewed and reassessed in the following year;
 - Should identify priority areas of regulation for review;
 - Should set out clear, prioritised targets and the methods to be employed;
 - Should be supported by sufficient well focused resources;
 - Should significantly involve business and other 'recipients' of regulation, both in the identification of priority areas for review and in its following implementation;
 - Should be connected with the review of existing regulation and with codification or other forms of consolidation;
 - Simplification should, in some cases, involve the repeal of an old regulation; and
 - Should always consider the use of ICT to re-engineer procedures.
2. Simplification should become a general policy in the behaviour of Member States and EU Institutions. Concrete steps need to be taken to ensure that the simplification program is effective, systematic and carried out in time, e.g. through the adoption of codes of conduct and a co-ordinated and simplified decision-making procedure, according to the respective constitutional and legal frameworks.
3. Simplification tools should be coherent with the ones for improving the quality of new regulation and existing regulation should be tested in a similar manner and its results should be measurable.
4. When introducing new legislative acts, one should always take the opportunity to simplify other relevant existing regulation.
5. The monitoring, the defence and the consolidation of the simplification processes (no "re-complication") should be ensured.
6. Establishment of expertise in multi-disciplinary regulatory management, beginning with a tailored programme of training for officials.

7. Making simplification transparent and understandable to the public by, for example, investigating the possibility of establishing step by step a single source of all applicable administrative procedures and forms.
8. Regulators in Member States should, in parallel with the Commission, simplify their regulation (including regulation transposing European legislation), refrain from introducing unnecessary detail or over-complex administrative requirements and follow the above mentioned guidelines, adapting them to their respective national circumstances.

6 Access to regulation

6.1 Definitions

a) Consolidation

Consolidation means bringing together multiple texts that regulate a particular area into one, with or without minor changes to the substance. (Major changes to substance are carried out when the regulation is simplified – see Section 5.) At European level, the term is often used to describe an unofficial process undertaken by Commission officials, producing a text without legal effect but of practical benefit.

In this report, consolidation is used in its generic sense and includes both codification and recasting. The term “legally effective consolidation” means production of a consolidated text that has legal effect, through either codification or recasting.

b) Codification

At European level, the term “official codification” is used to describe the process of repealing a set of acts in one area and replacing them with a single act containing no **substantive** change to those acts. It thus produces a text with legal effect.

In some Member States (for example France), the meaning of codification is closer to the European term recasting (see below) – that is the process not only brings together multiple texts into one, but also makes changes to remove out-of-date or nonsensical provisions or correct gaps. It also has the sense of “incorporating into a code” in those countries that have such a legal structure.

In this report codification is used in the European sense unless specified otherwise by the context.

c) Recasting (Refonte)

This term is used at European level to describe a combination of (European) codification and substantive changes. It is not however wholesale repeal or, generally, major review of regulation. It is used in this sense in this report.

6.2 Introduction

The question of easy access to the law has for a long time been dealt with solely as a matter of principle (“no-one is deemed to be ignorant of the law”), without the practical demands inherent in such principles being taken into account. However, the conditions on which people may gain access to the law have changed significantly over recent years under the combined effect of two factors.

Firstly, the proliferation of pieces of regulation. This has made it impossible both for ordinary citizens and the legal profession to gain an understanding of or, in practical terms, even to get a general overview of all the rules of law which affect them.

Conversely, the development of information technology and the computerisation of bodies of regulation and case law have added an immense potential to the traditional sources, making access to them and their management easier.

Concurrently with this twofold trend in the practical conditions governing access to the law, the movement towards improved guarantees of citizens’ rights and greater transparency in the operation of democracy has strengthened demands on the part of citizens for better access to the law.

Against this background, the effort needed to facilitate access to legal information may be seen from three standpoints.

The first consists of improving the **coherence**, the **clarity** the **form** and the language of regulations: this would be based on codification or recasting (see Section 6.1 for definitions).

The second is to improve **practical access** to the rule of law and the search for legal information: this would be based on the development of the new technologies.

The third consists of the **understanding of the rule of law** by the user or the beneficiary of the regulation. This presupposes the existence of appropriate intermediaries and agencies.

6.3 Consolidation

6.3.1 Aims of legally effective consolidation

At the present time and in the world as a whole, legally effective consolidation covers very different realities. Even within Europe, there is no single model of legally effective consolidation. Each Member State and the European Union have developed their own concepts and practices for organising their regulation on a subject basis. However, these concepts need to take account of two new demands:

- The rapid growth in the production of regulations has made it particularly necessary to make an effort to bring all these texts together in an ordered fashion based on various regulatory subject headings which together make up “the law”.

- The strengthening of democratic principles demands the widest and easiest possible access for citizens to the rule of law. This demand particularly concerns those involved in the practice of the law, whether they are public administrations, the courts or the legal advisors of persons brought before the courts.

Wherever it is undertaken, the work of legally effective consolidation has two main objectives:

- **To make the body of laws and regulations more coherent** and, therefore, to facilitate reforms and simplification. One of the main aims – with a view to ensuring clarity and therefore legal security – is to identify and correct illogical elements, inconsistencies and gaps in the existing regulations and also to harmonise and, if necessary, modernise the legal language used. Another aim is to eliminate obsolete provisions from the law currently in force.
- **To make the law easier to find out about and understand for its users**, thereby increasing compliance with laws and regulations. This involves presenting the law currently in force by subject, ensuring coherence and providing a system of cross-references between subjects (and therefore between codes or other legal acts) and – through constant updating – offering an easy means of consulting the law currently in force.

6.3.2 Loose-leaf official consolidation

Some countries organise an official and on-going compilation of regulation, classified under a set of chapters previously defined by law, and matching the needs of the common user. This complement to codification, based on a loose-leaf updating mechanism, clearly reveals the (sometimes excessive) volume of regulation in a certain chapter, and therefore the need to reduce or codify it.

This method is followed in the US Federal Code. Its merits include achieving a massive clarification of the set of existing regulation in various areas of activity in a relatively short time and forcing the drafters of new regulation to integrate it in the existing chapter.

In this system, an article of each new regulation states in what chapter it belongs, thus ensuring a flexible system without the need to create a new public body to oversee the proper insertion of new regulations in the existing chapters.

6.3.3 Common problems and potential solutions

The experience of countries with long experience of a process of legally effective consolidation has revealed various kinds of difficulties that require appropriate action in order to overcome them.

6.3.3.1 Length of the process

The experience in France, which has been codifying its regulation for around fifty years, with several periods of intense activity, gives us some idea of how long the process takes: a little over half the regulations currently in force have been codified.

In order to reduce this difficulty, the work of legally effective consolidation should be conducted on the basis of an organised work programme and be monitored by a permanent body, which would include the Parliament and be supported by fast-track procedures for Parliament to approve the consolidated regulations.

6.3.3.2 *Unclear texts*

This difficulty is inherent in the application of the principle whereby the consolidated texts have a legislative value. This means that the codes or other legal acts have to be amended when new laws are adopted, making the latter less directly comprehensible.

Therefore it is desirable for new laws (or regulations) to be published both in the form in which they were adopted by the Parliament (or the statutory authority) and also in their codified version.

6.3.3.3 *Volume of regulations*

In the interests of the users of the law, legally effective consolidation should be extended to all applicable provisions and therefore not just the primary laws, but also the secondary regulations implementing them.

Legally effective consolidation of this second category of texts, which is generally much larger, should as far as possible be co-ordinated with the consolidation of the corresponding laws and be conducted within the same timeframe.

6.3.3.4 *Maintenance of codes*

This is the most serious difficulty for those countries which have consolidated regulation. New laws do not simply amend existing provisions. They also innovate which, on the consolidation side, means the introduction of new Articles or Chapters. Where they exist, codes are based on a specific plan and the provisions are divided into Articles, in theory based on a rational breakdown. Any additions should not upset the logic of the plan nor that on which the division of the Articles is based.

It is therefore necessary to ensure proper management of the consolidation, which will have repercussions at an earlier stage on the rules for the drafting of regulation. For this reason, it is necessary to provide training for the officials responsible for drafting consolidated texts. Similarly, as in some countries, it would be worth developing methods – or even IT tools – to assist in drafting in a consolidated environment.

6.4 Better access

6.4.1 Growing use of the Internet

For some years now, the States have made a particular effort to promote the use of the Internet by government and institutions. This effort must be continued. In so far as they have access to the Internet, citizens have the right to expect improvements

in the opportunities available to them for gaining access to the law – in particular information on their rights and obligations.

6.4.2 Public authorities and better access

A debate about the ways in which access to the rule of law can be provided has been going on, especially since the 60's and the 70's, both within the European States, the European Union and in the United States. This debate was reopened a few years ago with the development of computerised databases; the possibility that their use would become more widespread; and that they could be accessed via the Internet. The introduction of new information technologies leads us to consider redefining policy on access to legal information.

This debate on the dissemination of the rule of law covered the definition of the respective roles of government and the private sector. The issue here remains the delineation of the scope of a public service giving access to the law and the definition of what such a public service could consist of. Several questions were raised on this subject: what type of information should government provide compared with that provided by the private sector? What sort of added value could government provide in the dissemination of the rule of law (explanatory notes on a particular area, guidelines on the application of the law etc.)? On what terms and conditions should the private sector be allowed to exploit public information? Should a distinction be maintained between paid access to a database for professional users, using high-performance technical tools and giving access to a vast body of information, and a database to which access is free of charge, but which contains a limited amount of information?

Although it may not be possible to give a precise reply to these questions which would be applicable to all circumstances, it should be possible to provide some clarification in the form of general guidelines. The dissemination and public availability of regulation should be considered as a public service. For this reason, it should be able to provide for the largest number of people, either free or for a small fee, access to texts which are comprehensible in themselves – particularly in the case of those sections of the population who are culturally most remote from access to the law. The Internet, without excluding the use of the printed word, would seem to be the appropriate medium for this, provided of course that an adequate effort is made to give everyone access to it.

6.5 *More comprehensible regulation*

6.5.1 More readable legal language

For some twenty years, legal language has been accused of being obscure, archaic, cumbersome and excessively technical. Even if legal language cannot always be reduced to ordinary, everyday language since it has to ensure a particular level of predictability and security, the overall aim must be to make it understandable for those to whom it is addressed.

Work has been done in some countries, for example Sweden, to modernise legal language. There is also an Inter-Institutional Agreement on common guidelines for

the quality of drafting of Community legislation (1999/C73/01), which underlines the importance of clear, simple and precise drafting. According to this agreement acts should be readily understandable by the public and by economic operators. The institutions should now take implementing measures to ensure that the guidelines are properly applied. The European Union uses a number of legal/linguistic experts whose aim is, for example, to harmonise the terms used in different texts and to prepare definitions of terms. However, more action is needed in order to ensure that the structure and language of the rules will be as clear as possible.

6.5.2 Easier understanding of rights

Whilst legal texts are essential for *professionals* or all the *agencies* involved in civil life, they remain obscure to the ordinary citizen who is unable to understand or interpret them in order to find out about his rights and obligations.

Access to the information society is certainly a concern of public administrations and local authorities. But, as yet, insufficient consideration has been given to all the sectors of the population who need to be covered, the local portals providing services for residents, access to rights, the networking of public services and education. The difficulties here are not financial, but lie rather in the problem of mobilising all the players involved and bringing about a change of culture. Putting information on-line opens up the way to areas of law that are frequently inaccessible: local finance, regional development or urban planning projects or the introduction of new rights.

However, it is the duty of public administrations to overcome these difficulties, since they may also be seen as a potential obstacle preventing the most vulnerable members of society from exercising their rights.

Community-based associations can play an important role as intermediaries, especially for those members of the public experiencing difficulties (explanatory Web sites). Moreover, the Internet has very quickly become a centre of interest for legal experts. Privately sponsored sites and portals have sprung up, providing texts of laws and regulations, court decisions, legal treatises and explanations of the law in simple terms, often in the form of answers to frequently asked questions and sometimes with the aid of graphics. Initiatives of this kind should be encouraged.

6.5.3 Better understanding of the law in context

The transparency of the processes involved in law-making and efforts made to explain the law help users to gain an understanding of the law applying to them. However, any desire to make the law more readable comes up against difficulties such as the irreducibly technical nature of legal texts, the reluctance of the public authorities to simplify legal language and the presence of a pre-existing body of law (national, international and European law).

Consequently, additional efforts should be made to provide access to the law within its context, so as to provide users of the law not only with the text itself but also with the preparatory work which preceded it and also other regulation related to the particular text being sought. Thanks to the multimedia facilities now available,

placing a particular piece of regulation within its context is greatly facilitated by the use of hypertext links.

6.6 Recommendations

1. For the purposes of legally effective consolidation, every authority (Member States and the Commission) should prepare, in line with its respective legal culture and tradition, a structured work plan in consultation with its Parliament. This should include a fast-track procedure for the adoption of codified acts, provided that the Parliament's rights are clearly respected. This codification plan could form part of the broader simplification plan (see recommendations on simplification Section 5.4).
2. Training of the officials responsible for the drafting of texts, for the simplification of the language therein and for the development of methodological tools suitable for codification could be considered concurrently with the implementation of the codification plan.
3. The provision within each Member State and at European Union level of a public service (either free or for a reasonable fee) giving access to the texts of laws and regulations is one desirable response to the growing demand on the part of citizens for better access to the law.
4. Difficulties with understanding legal texts – particularly for those sectors of society with the greatest problems – should provide the public authorities with an incentive to make a special effort (in consultation with the competent agencies) to provide appropriate educational tools (on the Web for example).

7 Effective structures and a culture of better regulation

7.1 Introduction

The majority of European administrations (i.e. national governments and the European Commission) have developed an array of fairly well designed tools for better regulation, though they vary significantly across the Member States. Each administration uses a unique mix of these tools, though none uses them all. Where the same tool is in use in a variety of administrations, the degree of development and sophistication varies. The fact that we still face considerable problems almost everywhere is clearly and primarily due to severe implementation deficits. In many administrations existing tools are either applied insufficiently or without the necessary skill. Awareness of such tools and/or of their basic efficiency is clearly underdeveloped. Commitment to applying them can also be lacking, with mechanisms that formally are mandatory being practically ignored. The application of pre-defined procedures (if they are applied at all) often amounts to nothing more than a reluctant bureaucratic exercise carried out with the minimum of effort and added value. This bears the risk of a “virtual reality” where the requirement for better and simpler laws is, at best, complied with formally, but disregarded in terms of substance.

National governments and the European Commission need to make better regulation a strategic issue and a common priority, with an emphasis on the question of structure. This means fixing precise organisational and procedural structures that guarantee that the spirit of rules governing better regulation will be complied with and not just the letter. High quality of regulation is an important and central part of public welfare. It is a democratic virtue in itself and a public good, as well as conferring direct benefits, and as such needs its own champions within administrations. Achieving this requires an alliance of politicians, administration and civil society aimed at creating awareness (a new culture) of the urgent need for better regulation.

While much work has already been carried out on the tools for better regulation, in many administrations the central problem of necessary organisational structures has only recently come to the fore. But the issue of appropriate **structures** is an absolutely **crucial topic**. The success of efforts on better regulation will ultimately depend on this very issue.

Those who hold political responsibility often face enormous public pressure to initiate draft regulation of specific content within extremely brief periods of time, pressure that is hard to fend off. This inevitably entails the substantial risk of poor laws. The conditions of a media society can hardly be changed. Appropriate structures of better regulation are, however, in a good position to strike a suitable counter-balance: that is to support those politically responsible in their efforts to obtain higher quality regulation, which is also very much in the public interest. Policy-makers can refer to processes and structures by which they are bound themselves. From a systematic viewpoint, this would represent a targeted, built-in mechanism in the interest of the overall democratic system. This need not – as existing systems show – lead to serious delays in the drafting of regulations at all, but it ensures that regulatory quality as an independent public good is taken into due account.

For this reason, national governments and the European Commission should – if and insofar as they have not yet tackled these issues – seize the opportunity to approach the topic of structures as a priority, systematically and without delay, based on existing experiences and best practices.

Achieving suitable organisational structures does not require an administration to completely re-invent the wheel. There is already a very broad set of options that have been developed in other administrations, which can offer some guidance. In addition, given the sensitive nature of the field of structures, and the degree to which the best solution for a particular administration depends on many factors, it is not possible to dictate the ideal structural solution for all administrations at once. Therefore, the approach this Section takes is to identify the essential elements for effective structures, the minimum set of tasks that need to be assigned and then the array of best practice options. Each national governments and the European Commission can then choose the most appropriate and effective combination of those options for its own situation and implement it. However, it is vital that a structural solution is chosen and implemented – in this area, “do nothing” is not a viable option.

Finally, it is also important that national and European Parliaments are appropriately involved in improving the regulatory environment as described in other Sections of this report (see for example Section 4 and Part III).

7.2 Essential elements of effective structures

Based on the experience in various administrations there are four main elements that seem to be essential for the chosen structure to be effective:

- **Strong political support.** Better regulation programmes need very strong political support to produce the desired outcome;
- **Support from the centre.** The best results are often achieved with the Head of Government personally and/or at least institutionally interested and involved;
- **A horizontal approach.** Very clearly, an all-government approach is necessary; sectoral approaches limited to individual Ministries or Directorates-General will not achieve optimum results and a coherent, horizontal approach is needed; and
- **A strategic approach.** Close connection to the strategic planning of the government/administration is of real benefit.

7.3 Tasks of effective structures

In addition to these essential elements, the chosen better regulation structure should also be charged with certain fundamental tasks as a minimum:

- Development of general strategic proposals for the creation, implementation and monitoring of better regulation rules for the national government or European Commission as a whole;
- Provision of advice, guidance and training of the best possible standard for the policy officials in charge of preparing/executing regulations; and
- Supervision of the application of better regulation instruments.

These tasks would involve a range of activities. An indicative list is:

- a) **Development of methodologies and tools.** Development of new methodologies and tools and adaptation of existing ones to new circumstances, for example:
 - List alternatives to regulation and promote the use of them;
 - Development and maintenance of tools and techniques for use during the creation process of new regulation (preventive) as well as for the evaluation of existing regulation (curative);
 - Development and maintenance of common indicators to evaluate progress and performance; and
 - Techniques to map the burdens relating to administrative processes and procedures (cost/benefit analyses) for all stakeholders.
- b) **Guidance and support.** Support to integrate all these techniques into the daily activities of departments (Directorates-General) and to establish the necessary cultural change, for example:
 - Technical support as to the use and implementation of those tools;

- Guidance for important cross-departmental (cross-DG) projects; and
 - Exchange of best practices and promotion of co-operation between Ministries (Directorates-General).
- c) **Monitoring and reporting.** Central monitoring and progress reporting, including on the probability of bottlenecks, and/or on how common problems can be detected quickly (warning function) and solutions found.
- d) **Co-ordination.** Assuring co-ordination between all institutions and departments (Directorates-General) concerned:
- On a national (respectively EU) base;
 - Between national and Commission central knowledge units; and
 - In Member States, between different levels of Government States (regional administrations, local authorities, etc.).

7.4 Working methods of effective structures

The experience of most administrations is that there needs to be a balanced mix of decentralised assessment and centralised management and monitoring within an administration. The officials responsible for the policy are best placed to carry out the actual assessments and simplification work, since they have the know-how and expertise. Nevertheless, these officials must be convinced of the need to use the tools offered by a general regulatory management programme. Otherwise Ministries or Directorates-General could shirk responsibility, become uninterested in the matter and might refuse to use the developed regulatory management tools after a short period.

By contrast, overall management of the quality of regulation needs to be the responsibility of particular bodies and/or structures that are dedicated to better regulation (see Section 7.5), not least for the reasons set out in Sections 7.1 and 7.2. This body/structure must, by virtue of its qualified staff with a range of expertise, its specific position in the administration, its recognised authority and its expertise in managing regulatory quality tools, be able to ensure adherence to the process that contributes towards improving regulatory quality. At the same time this body/structure must have an appropriate level of autonomy, as well as objectiveness with regard to the policy officials who prepare regulations.

Depending on the needs and organisation of the particular administration, the body/structure might also be given a gate-keeping function whereby a dossier is only allowed to progress through the legislative process if it is accompanied by a good quality assessment. It could also be the arbiter of any “test of significance” used to establish which dossiers are assessed or reviewed and to what level of detail.

Normally it will not be a task of this body/structure to interfere with the substance of regulation.

7.5 Best practice options for effective structures

There are five main best practice options for effective structures, of which the first is recommended by OECD guidelines:

- A primary unit based at or near the centre of the administration, with or without a network of satellite units across the main Ministries or Directorates-General;
- A primary unit based in a part of the administration other than the centre (e.g. Public Administration or Economic Affairs Ministry), probably with a network of satellite units;
- An inter-ministerial co-ordination committee;
- A network of units/responsibilities across the main Ministries or Directorates-General, with or without support from a primary unit; and
- A body external to the administration (a body of such type may especially be apt to be integrated into the evaluation of the consequences of already existing regulation).

Of course, some of these options can be combined to provide the appropriate solution for a particular administration, and other specific units can be charged with executing particular discrete tasks (though the overall body/structure would need to be kept informed in order to guarantee a co-ordinated approach).

With whichever option is chosen, in Member States with a federal structure the arrangement could separately be established in both the central and regional administrations.

The issue of adequate training and a specific degree of harmonisation of training with the help of available and new methods and instruments could be the subject matter of deliberations by a special working group to be jointly established by Member States and the Commission.

7.6 Common problems

The specific problems encountered by a national government or the European Commission will vary according to its own organisation and legal context. Nonetheless, there are certain problems that are common to several:

- **Federal/regional structure.** Where competence for a particular issue is not entirely at the national level, there can be tensions if a single body/structure is envisaged. In these cases, a good solution is often to encourage the sub-national administrations to create equivalent bodies/structures and to promote co-operation between them and the national version.
- **Delineation of responsibilities.** In some administrative traditions few or no parts have the right to be involved – let alone to veto – work carried out in others. Even where this is not the case, there can often be strong resistance to what is sometimes perceived as unwarranted interference. This can be partially overcome by creating a network across all parts that is charged with

this function alongside other activities to increase acceptance of the system. Where it is feasible, placing the nucleus of the body/structure in one of the parts of the administration that does have the right to get involved can also help.

- **Insufficient resources.** To be effective, whatever structure is developed must have the appropriate level of resources for the training, guidance and monitoring functions. The size of the public administration overall is also relevant – smaller administrations generally find it more difficult to find the resources than larger ones. This is one reason why strong levels of political support are necessary.

7.7 Promoting a culture of better regulation

Given the fact that better regulation is a very important public good, there is an urgent need for a basic change of culture, for a new approach to thinking and acting in the field of better regulation. It is necessary to pave the way for relevant general awareness to grow within the population, at institutions and above all on the part of those who are specifically in charge of drafting relevant regulation.

Energetic efforts by Parliaments, governments and European institutions are necessary, focussing on the general public on the one hand and the national governments and European Commission on the other.

Above all, four things seem to be necessary:

- Targeted public and public relations measures to promote the aim envisaged. This includes conveying the conviction, in word and deed, that higher-quality and simpler regulation is possible;
- Utmost transparency with respect to an overall strategy in place, along with sufficient publicity regarding efforts made and successes achieved;
- The active involvement of civil society in these efforts (See Section 4); and
- The broad-based and competent training of staff.

Appropriately qualified staff are required both in the proposed general regulatory management body/structure and in the relevant Ministries or Directorates-General. Regulatory quality methods and tools must be made available to all persons involved in making or evaluating regulations.

The main aim of training, beyond the techniques, would be to develop a sense of responsibility and ownership within policy units so that they more automatically take into account the quality of their regulatory proposals. This would be an important step in securing the development of expertise as well as the indispensable cultural change.

The issue of adequate training and the extent to which this can be common to all administrations could be the subject matter of deliberations by a special working group to be jointly established by Member States and the Commission.

7.8 Recommendations

1. National governments and the European Commission should make better regulation a strategic issue and a common priority, putting an emphasis on the question of structures.
2. The following core tasks must be fulfilled in order to achieve fundamental change:
 - Fixing of precise organisational structures guaranteeing that the rules for better regulation will be complied with; and
 - Establishing a new culture of thinking and acting.
3. Piecemeal efforts are not promising – a strategic overall approach is necessary. One key element of such an overall strategy must be to create, with the help of political and public relations measures, a widespread awareness within administrations, among policy-makers and citizens that compliance with the rules governing better regulation is necessary to render the entire regulatory regime more transparent.
4. The field of structures is a sensitive issue. Therefore, the Commission and Member States will examine and implement these Recommendations, based on their particular individual situation. Nonetheless, sustained efforts will be absolutely necessary, both for most Member States and at EU level. In most cases there will be no excuse at all for doing nothing.
5. There should be strong political support from the whole national government or European Commission, especially from the Head of Government or Commission President.
6. There should be an overall, horizontal approach applicable to all Ministries or Directorates-General.
7. A close connection to a government's/administration's strategic planning is recommended.
8. A primary unit within each administration should be considered, preferably (in accordance with OECD guidelines) at or near the centre.
9. There should be a balanced mix of decentralised assessment and centralised management/monitoring within the administration, with the officials responsible for the policy carrying out the actual assessments and simplification work and overall management of the quality of regulation being the responsibility of the dedicated better regulation body/structure.
10. The body/structure must, by virtue of its qualified staff with a range of expertise, its specific position in the administration, its recognised authority and its expertise in managing regulatory quality tools, be able to ensure adherence to the process that contributes towards improving regulatory quality. At the same time the body/structure must have an appropriate level of autonomy, as well as objectiveness with regard to the policy officials who prepare regulations. Normally

it will not be a task of this body/structure to interfere with the substance of regulation.

11. The main tasks of the body/structure will be the development and management of strategy, tools, advice and monitoring and the co-ordination of the better regulation programme. Additionally, the body/structure might be attributed a gate-keeping function whereby a dossier is only allowed to progress through the legislative process if it is accompanied by a good quality assessment.
12. There should be broad-based and competent training of all appropriate staff.
13. Recognising their full sovereignty and aware of the fact that it is exclusively they themselves that can make a decision on this issue, Parliaments should be invited to take an interest in the process of better regulation, and to contribute to an overall system of regulatory review.

PART III EU-SPECIFIC RECOMMENDED PRACTICES

1 Introduction

Outside the areas where it has been granted exclusive competencies (such as for international trade matters), regulatory action at European level must comply with the principles of subsidiarity and proportionality. According to the former, European regulation is only justified where:

- The issue under consideration has transnational aspects which cannot be satisfactorily regulated by action by Member States;
- Actions by Member States alone, or lack of European action, would conflict with the requirements of the Treaty or would otherwise significantly damage Member States' interests; and
- Action at European level would produce clear benefits by reason of its scale or effects compared with action at the level of the Member States.

Most of the European legislative activity in shared competency matters is destined to approximate national rules in areas where the principle of mutual recognition does not properly function, thus creating obstacles to the single market. However, during the last decade, European regulation has progressively moved into new areas previously exclusively regulated by Member States. Typical examples are to be found in areas such as environment, consumer protection, social, health and safety rules where national rules either do not always exist or where the European dimension needs to be taken into account to create a level playing field.

Although under the Treaty the Commission exercises its sole role of initiative for legislative action at European level, it should be remembered that its proposals have the following origin:

- 20-25% are a follow-up to Council or European Parliament resolutions or to requests on the parts of the social partners or economic operators;
- About 30% arise from international obligations on the part of the EU;
- 10-15% relate to obligations under the treaty or secondary legislation; and
- About 20% are for updating existing European regulation.

To improve regulatory quality at EU level, a strategy is needed which addresses all relevant aspects and which includes the whole life cycle of a European act. This implies involving and committing all the players throughout the decision-making process, i.e. all European institutions and the Member States.

2 Choice of instrument: Regulation or Directive

A specific question relevant to the European level is the choice – in those cases where the Treaty allows it – between using a Regulation or a Directive to introduce new laws.

The caveat above is important – in many articles of the Treaty there is no choice; either Directives (for example Articles 94 and 96) or Regulations (for example Article 89) are specified. Even in those where the Treaty is silent (such as Article 95), there has sometimes been a political decision to favour Directives over Regulations.

In those cases where the choice remains open the protocol to the Treaty of Amsterdam on Subsidiarity and Proportionality is clear – Directives are to be preferred to Regulations, other things being equal.

One argument advanced in favour of the greater use of Regulations is that this speeds up the legislative process by eliminating the need for Member States to transpose the agreed regulation into their national law. However, this is only part of the issue – in very many cases the negotiation phase will be longer for a Regulation than for a Directive. This is precisely because Member States will not have the possibility of transposing it into their national regulation, making it all the more important to them that full account is taken of national specificities.

A further complication arises when the Regulation is agreed. Again, as Member States have not had the opportunity to transpose the regulation into their national law, the unintended and potentially quite serious consequences on the rest of the national legal order are much harder to mitigate. For example, will a Regulation specify for each of the Member States exactly what sanctions should apply to a breach? If so, the consequences could be very wide-ranging, and if not, how can the Regulation bite?

In conclusion then, the Group is **not** convinced that the case for generally preferring Regulations to Directives is a strong one. However, the Group does agree that more attention needs to be paid, on a case-by-case basis, to the choice of which instrument is most suited. Some Regulations are unnecessarily cumbersome and complex, when they could better attain their goal by means of a more general Directive. On the other hand, the very freedom which Directives leave Member States to introduce or retain national provisions may create unnecessary disharmony between Member States, when the use of a uniformly applied Regulation would have simplified them under terms that would have been acceptable for all the parties concerned.

3 Applying RIA to the EU level

This section describes one possible **RIA process** for European proposals, taking into account the roles and responsibilities of the Parliament, Commission, Council and Member States in preparing European regulation⁶. Of course, many aspects of the best practice described in this report are already in place or being developed at EU level (see for example the Commission's White Paper on European Governance). In these cases it is more a case of extending and consolidating existing good practice than of the introduction of brand new processes and requirements.

⁶ This system should also apply, adapted accordingly, to proposals that the Commission makes based on processes such as the social dialogue.

The early part of the policy formulation phase at EU level takes place within the Commission, as it exercises its sole right of initiative under the Treaty. It is crucial that even at the earliest stages of this initial work, a **preliminary assessment** is carried out (see Section 3.5), not least since a decision by the Commission to propose regulation will almost always lead eventually to regulation at the Member State level too. This assessment would be the start of a process accompanying and integral to the policy development process. For example, it could be a requirement that such a preliminary assessment be carried out and made public before an item could be included in the Commission's Annual Work Programme. Where the proposal in question is a development of an existing one, the assessment might be carried out as part of the review process and used to inform any new proposals.

Very often, the first attempt at a preliminary assessment will be as useful for the gaps in knowledge it highlights as for the information it actually contains. As the policymaking process continues within the Commission the internal and external expertise and information available can be used to **fill these gaps progressively**. Where the preliminary assessment meets the test of significance (see Section 3.5), there will be a need for more work to prepare a **detailed assessment** (see Section 3.5). An early draft of this detailed assessment would form a key part of the informal and formal consultations the Commission undertakes. All stakeholders, and Member States in particular, would have a responsibility to assist in providing the necessary information. When the dossier is submitted to Commissioners for adoption, the final version of the detailed assessment would be available alongside and would be published no later than when the proposal is published.

Since the proposal's effectiveness (benefits) and costs are influenced quite strongly by the way in which it is implemented and enforced, the detailed assessment would also need to contain an indication of what account has been taken of the **practicalities of implementation**. This would usefully include the benefits and costs of different implementation periods as these can have a great impact and would have to be heavily informed by Member State contributions.

The next phase of the process is discussion in the **European Parliament** and in the **Council**. Both Institutions would need to commit themselves to not considering proposals unless accompanied by the Commission's detailed assessment described above (or, if appropriate, the preliminary assessment demonstrating there is no need for a detailed assessment), except in cases of urgency.

Amendments to the Commission's proposal by MEPs or Member States can have very significant impacts and ideally, to maintain the integrity of the process, the Council and the European Parliament should have an assessment of the impact of significant and substantial proposed amendments before it to inform its decision making. For these significant and substantial amendments, where possible the person or body making the proposal should indicate the likely broad impacts, where appropriate in co-operation with the Commission. In this model, such an assessment would cover at least the same ground as the preliminary assessment described above and would be available to MEPs or Ministers before they voted on the amendments. If necessary, and in accordance with the Treaty, the Commission may request a temporary halt to discussions until it can undertake a more detailed assessment.

As part of its opinions on the Common Position and the Parliament's amendments, the Commission could also include a revision of key elements of its original detailed assessment. In addition to providing the other Institutions with this valuable information, this would also provide the Commission with an opportunity to reflect whether its original proposal had been so far changed that it should be withdrawn, in line with the Commission's commitment in the Governance White Paper.

3.1 Additional recommendations

1. The Commission should continue to move rapidly towards a new, comprehensive and suitably resourced impact assessment system covering its proposals with possible regulatory effects. This system should be based on the recommendations in this report, including an initial screening process followed by a more detailed, proportionate assessment in appropriate cases.
2. The Parliament, Council and Member States should take this assessment into account in the development of the proposal. The practical functioning of this could be set out in an agreement between them and the Commission.
3. The relevant Commission policy officials should prepare RIAs primarily, with training, guidance and support from a centre of expertise, use of economic advice and scientific research as appropriate and input from business and other stakeholders.
4. Commission services should produce and make public a preliminary assessment before a proposal is included in the Annual Work Programme.
5. Commission services should produce a detailed assessment before adoption of a policy proposal unless the preliminary assessment has clearly demonstrated that the proposal has no significant impact.
6. In the interests of transparency and accountability, the Commission should publish the detailed assessment no later than the formal adoption by the College of the policy proposal.
7. The Council and European Parliament should not consider proposals unless they are accompanied by a detailed regulatory impact assessment (or, if appropriate, the preliminary assessment demonstrating there is no need for a detailed assessment), except in cases of urgency. This should be set out formally by each institution and be part of the overall agreement on better regulation.
8. To maintain the integrity of the process, the Council and the European Parliament should have an assessment of the impact of significant and substantial proposed amendments before it to inform its decision making. For these significant and substantial amendments, where possible the person or body making the proposal should indicate the likely broad impacts, where appropriate in co-operation with the Commission. If necessary, and in accordance with the Treaty, the Commission may request a temporary halt to discussions until it can undertake a more detailed assessment.

9. As part of its opinions on the Common Position and the Parliament's amendments, the Commission could also include a revision of key elements of its original detailed assessment.
10. Member States and the Commission should promote the exchange of best practice in this field between themselves and with other administrations.
11. The EU should, in line with the Cardiff process, develop robust indicators of better regulation.
12. The EU should consider actively fostering the interest of academia and European think tanks in RIAs and the methodologies used to increase the knowledge base and potential input.

4 Consultation in the EU

The views in Section 4 apply both to the regulatory process at the European level and to the national regulative process.

Consultation at European level is an important element in the regulatory process, cf. also Protocol no. 30 to the Amsterdam Treaty. As part of the general guidelines for the regulative process the Commission makes use of various instruments. The annual work programme of the European Commission sets out the political priorities and indicates the areas where the Commission intends to proceed with consultations.

The Commission also organises seminars and consultations with special consultative committees and groups of independent experts as well as the consultations with the social partners. A key element is the green- and white papers and work programmes, which may form the basis for substantiated reactions from affected parties. An early, broad and systematic consultation and dialogue involving all affected parties is of key importance to the regulatory process at the European level and should form a central part of it.

The European Parliament and its committees regularly seek public and expert views through consultation and public hearings. Some Member States systematically consult at a national level on proposals tabled in the Council.

European citizens and national parliaments (for example through their specialised European affairs committees) should be encouraged to play a more active role in the European consultation process.

There is currently a lack of clarity about how consultations are run and to whom the Institutions listen. The Commission for example runs nearly 700 ad hoc consultation bodies in a wide range of policies. The increase in the volume of international negotiations generates further ad hoc consultation. This unwieldy system needs to be rationalised, to make it more effective and accountable both for those consulted and those receiving the advice.

New legal rules on consultation are not necessarily needed. Instead we recommend a code of conduct (maybe in the form of an Inter-Institutional Agreement to cover all

European Institutions) taking on board various elements of already proved best practices in Member States that sets uniform minimum standards, focusing on what to consult on, when, whom and how to consult. Those standards could reduce the well known risks of policy-makers just listening to one side of the argument or of particular groups getting privileged access on the basis of sectoral interests or nationality, which is a clear weakness with the current method of ad hoc consultations both with the Commission and the European Parliament. These standards should improve the representativity and structure the debate with and within the institutions.

In some policy sectors the Commission could develop more extensive partnership arrangements. On the Commission's part, this would entail a commitment for additional consultations compared to the minimum standards. In return, the arrangements would prompt consulted organisations to tighten up their internal structures, furnish guarantees of openness and representativity, and prove their capacity to relay information or lead debates in the Member States.

4.1 Additional Recommendations

The Commission should of course act upon the already approved guidelines for its conduct, e.g. as stated in Protocol 30 to the Amsterdam Treaty. (Except in cases of particular urgency or confidentiality a wide consultation process has to take place before regulation is proposed, and consultation documents have to be published wherever appropriate.)

Bearing the above viewpoints in mind, it is further recommended that the European Institutions seek to find appropriate ways of observing the following measures.

1. A strengthened dialogue at an early stage between the Commission and the interested parties and Member States in order to ensure transparency and democratic openness. More specifically, this should ensure that the consequences of a regulatory instrument – including the economic consequences – are established before the regulatory bodies formally consider the proposal.
2. Before formal introduction of the proposal to the regulatory bodies (i.e. Council and Parliament) the Commission should, within its sphere of competence, present a specific, yet still preliminary text for the interested parties, including the regulatory bodies. The proposed text should whenever possible be accompanied by extensive explanatory remarks (Section 3 on Regulatory Impact Assessment and particularly Recommendation 1).
3. Uniform minimum standards for consultation (for example minimum time periods) should be established.
4. A web-based register of all ongoing EU consultations.
5. Networks for specific consultation processes should be built up.

5 European simplification programme

Numerous initiatives have been introduced in recent years by the European Institutions with a view to taking European action on simplification (see Annex B). Nonetheless, however commendable their aims and the methods involved, they have not had a sufficient enough impact to dispel the general feeling that too little has been achieved in this field.

As to the SLIM initiative, in particular, the overall conclusion is that SLIM is a useful exercise and the Group welcomes the key action points arising from the Commission's review of SLIM, aimed at increasing accountability and improving co-ordination between the various players. The Group also welcomes the recommendations in the European Parliament's Opinion. However, the Group believes that this simplification exercise is still affected by several limitations.

Firstly, SLIM has a limited scope, as it deals only with Internal Market regulation that has an impact on business. Secondly, it is based on focused initiatives and lacks a strategic vision. Finally, it has proven difficult to achieve implementation of the resulting proposals, extremely few of which have so far been adopted by the Council and the European Parliament.

The internal market area was no doubt the first and the main one to need a simplification strategy. But simplification is a more general issue and it needs to be dealt at a more general level and addressed to other regulatory fields not necessarily linked with the internal market.

Furthermore, a simplification strategy can no longer disregard the effects of regulation on non-business recipients, and ought therefore to cover the regulation that impacts on citizens and on public bodies that have to implement it.

In other words, we should move from a "SLIM-approach" to a more global approach, extending simplification methods and tools to the entire EU regulation and to its entire range of recipients – a "SimpReg Programme" (SRP).

Broadening the scope of the simplification programme may not be sufficient unless set in the context of a strategic vision. As stressed above, "if it is to have significant benefits, simplification must be viewed as a process, not a project".

This broader vision should also incorporate the lessons of the SLIM experience on the need for stronger political support, for more effective co-ordination and for a streamlined decision-making procedure to introduce the resulting changes.

5.1 *The SimpReg Programme*

Given the arguments set out above, the Group proposes establishment of a new, rolling, targeted programme of simplification for all European regulation – "SimpReg Programme" (SRP). Drawing on EU and national experience, this programme should be a rolling and long-term process, well resourced and with **clear targets and priorities**, the identification of which ought to rise from the significant involvement of the Member States, businesses, consumers and other recipients of regulation (see also Section 4).

Moreover, it should be made up of **annual steps**, with a review the following year submitted to the European Parliament and Council as part of the annual report on improving the quality of regulation.

The long-term plan should also contain the concrete measures to be taken – and should list the regulations to be simplified – for the first year and the guidelines for the following ones.

Finally, concrete steps need to be taken to ensure that the simplification programme is effective, systematic and carried out in good time. Among these, an agreement between EU institutions should speed up the decision making process, by setting out the conditions under which proposals from the SRP will be fast-tracked through the codecision process according to existing Treaty provisions for agreement after First Reading.

5.2 Additional Recommendations

1. Establishment of a rolling and targeted programme of simplification (SimpReg Programme or SRP) of all existing European regulation (i.e. including regulation that impacts on business, citizens and public bodies).
2. EU institutions should reach an agreement setting out the conditions under which proposals resulting from the SRP will be fast-tracked through the codecision process according to existing Treaty provisions for agreement after First Reading.
3. EU institutions should adopt an Inter-Institutional Agreement on recasting.

6 Access to European regulation

The functions that legally effective consolidation of European law may be asked to fulfil are broadly the same as those demanded at national level. The main issue here is the clarity of the law, to ensure that it can be understood and that information about it is widely disseminated so that it can be applied effectively. This applies even though the citizens of Member States will have less direct interest in it than they have in national law (with the exception of Regulations and Directives for which the transposition deadline has passed). On the other hand, European codification could become a factor in the regulation of national legislative activity for two reasons.

6.1 Codification and internal law

Recent years have provided some gross examples of conflicts between laws in these two categories. Such conflicts of laws are not without their effects on the finances of the Member States (proceedings for infringement of European regulation) and on the consistency of action by national authorities who are also involved in originating European policies.

Codification – a tool for gaining knowledge of the law – would seem to be a means of ensuring compliance with European regulations, the disregard of which still all too frequently results in penalties being imposed by the courts.

Secondly, codification, considered as an instrument for clarifying the current state of the law and its content, should help governments to organise their work programmes so that Directives can be incorporated into their internal legal systems by the required deadlines.

6.2 Codification and enlargement

Codification of the entire body of European Union laws and regulations should facilitate the entry of new members as far as regulation is concerned.

If the governments of the new Member States were provided with the texts of regulation organised by major legal subject areas, this would facilitate the necessary transposition of Directives into their internal legal systems. It would also help to familiarise them both with how the European Union institutions work (this applies particularly to the courts in the countries concerned) and with European law itself.

This form of assistance is also necessary if we consider that the transposition and incorporation of European law into the national law of the countries concerned – depending on whether it was codified or not – would involve three times as much work (and administrative costs). (The proposed codification programme would aim to reduce existing European law from around 80,000 pages to around 30,000 pages and the overall number of acts by around 40%.)

For these two reasons, the efforts needed to implement the programme for the codification of European Union law between now and 2004 should be made as a matter of priority.

6.3 Additional Recommendation

1. The implementation of a plan for the codification of European law before the EU is enlarged by the accession of new members is a matter of priority.

7 Effective structures and better European regulation

National governments and the EU, jointly, should make better regulation a strategic issue and a common priority, with an emphasis on the question of structure. This might be supported by a formal agreement between the relevant bodies, setting out their common understanding of the issues and, where appropriate, their agreement on how to tackle them.

7.1 Institutional obstacles and weaknesses

As well as the general arguments set out above (Section 7), at the EU level there are some specific obstacles to improving the quality of regulation related to institutional arrangements and organisation.

Many of the reasons for the complexity of regulation are intrinsic institutional obstacles that could be remedied only by revision of the treaty, should the Member States think that to be necessary.

Among those, the obstacle most specifically affecting the complexity and the growth of EU regulation rests in what has been defined as the “political asymmetry of the European political system”. At national level there is a political mechanism - the collegiate action of government - that brings a plurality of interests inside the policy formation process. At the European level, even if the proposals have to come from the Commission, which, operating in collegiate fashion, seeks to weigh the various demands and interests, the competent Council is composed of just the sectoral ministers, who are in charge of the final decision. This asymmetry leads to a systematic tendency towards the growth of regulation.

Apart from these intrinsic institutional obstacles, there are some regulatory issues that can be confronted from within the current institutional structure.

Complicated regulation arises in large part from current practice of the Commission, by which regulation is drafted primarily by more than 20 Directorates-General, with an imperfect degree of co-ordination among them. This does not optimise collegiate action and often forsakes the benefits that could be gained by a more deliberative form of decision-making. On this crucial topic, it has been widely observed that different DGs draw up draft directives in themselves perfectly compatible with the objectives and administrative culture of a particular DG, but compatibility with general EU interests is weakly ensured.

Furthermore, policy-makers and technical experts generally draft regulation, while better regulation experts, who could contribute to clearer and simpler regulation, have thus far played a relatively limited role.

The above-mentioned factors may be aggravated by the lack of a systematic and reasoned appraisal of the cost of having such complex rules at the European level. While the EU has carried out a number of ad hoc measures, these have been of limited effect in the absence of a general political framework for promoting simplification.

A greater degree of co-ordination in the decision-making process should therefore be pursued within the Commission, the Council and the European Parliament (see also the Commission’s White Paper on Governance).

7.2 Additional recommendations

1. Member States and EU Institutions should make better regulation a strategic issue and a common priority, with an emphasis on the question of structure. This might be supported by a formal agreement between the relevant bodies, setting out their common understanding of the issues and, where appropriate, their agreement on how to tackle them.
2. All Commissioners must be seen to be behind the drive for better regulation, and especially the President.
3. The Commission should establish an effective, well-resourced structure to promote and support its better regulation activities. If possible, this structure should have strong links to the Secretariat-General’s strategic planning function.

4. The Commission and the Member States should consider establishing special working groups to examine:
 - The issue of joint training;
 - Possible recommendations regarding model structures (organisation and procedures); these may also be structures applied outside EU Member States; and
 - The problems of deepened co-operation between the legislative and the executive in the field of better regulation at EU level.

Discussions on these points, especially the last one, should also include the European Parliament.

5. A network of better regulation contacts across all Member States and the Commission (and, where possible, other EU institutions) should be established, to help share best practice and expertise.
6. Within their respective responsibilities, the Commission, European Parliament and Council should take further practical steps to ensure their internal co-ordination and the coherence between European regulatory policies.
7. The European Parliament should take note of the actions being undertaken by the other Institutions and pay the same level of attention in its own work and internal co-ordination.

8 Implementation of European regulation

8.1 Introduction

This Section focuses on the implementation of European regulation – that is its incorporation into national law (known as transposition for Directives), compliance and enforcement. During the process of implementing European legislation Member States can face various problems such as those relating to integrating European legislation into their national systems and to unclear definitions or meanings. As a result Member States can also experience problems in complying with the European requirements or in enforcing the national legislation.

In addition to the experience of the Group, this part of the Report also draws on Member States' answers to the Commission Questionnaire on the Application of Community Law.

Section 8.2 identifies the problems relating to the incorporation process and gives some explanations for these problems. Section 8.3 discusses the effects of these problems on compliance and enforcement and Section 8.4 sets out recommendations on both areas.

8.2 Incorporation into national law

8.2.1 Conditions for incorporation

Member States are obliged to incorporate European legislation into their domestic legislation within a certain time period. When the legislation in question is a Directive, this is called transposition. Regulations and Decisions enter into force directly without need for transposition and without any national policy freedom, but often will need changes to national legislation to give effect to them. Most of this section applies to transposition of Directives – where wider matters are concerned; the term “incorporation” is used.

There are several preconditions for transposing European legislation into national legislation. In its case law the European Court of Justice has developed a number of requirements concerning this, aimed in particular at ensuring the effectiveness of the directives and guaranteeing legal certainty. These requirements can be seen as conditions when transposing European legislation. The Court of Justice has:

- Set out specifications about the character of the transposing regulations. National authorities must (1) choose the most effective form of measures, (2) use legally binding measures and (3) ensure publicity for implementing measures;
- Stated that transposition measures must ensure the actual and full application of EC legislation in a specific and clear way;
- Determined that where a directive is aimed at creating rights for individuals these should be able to ascertain the full extent of these rights from the national provisions and be able to invoke them before the national courts;
- Required that transposing measures use the same form of instrument for transposing directives as used for the same issue in that Member State.

8.2.2 Transposition problems

In spite of these preconditions, Member States still face problems during their transposition process. This section focuses on problems relating to correct transposition, timely transposition and gold plating (that is going beyond the European requirements). The problems are primarily a result of the content and quality of the European legislation and of the incorporation into national administrative structures and legal systems that have developed over time.

8.2.2.1 Correct transposition

Correct transposition means that the national transposing legislation is in accordance with the European legislation. The freedom of national authorities to choose form and method has decreased because of the content of European legislation. Constraints on Member States result from the fact that:

- The conditional right of individuals to invoke directives against the state in national courts has decreased the differences between directives and regulations; and

- The directives have become more technically and detailed.

This second constraint means Member States can face problems when transposing a Directive. In addition, the lack of simplicity, clarity and accessibility also leads to problems in transposing Directives. The common guidelines for the quality of European legislation as laid down in the Inter-institutional Agreement of 1998 may be helpful in tackling these problems.

This problem may be caused by compromises in the Council, resulting in the different positions of negotiators being reflected in the legislation. But sometimes, European legislation also introduces new legal concepts and terms which are unknown in the Member States and which could be in contradiction with the national structures or legal systems.

Of course the content and quality of European legislation is not the only factor in transposition problems or differences. Differences are also the result of national practices, national legal differences and different cultures. When the national administrative structure of a Member State is out of alignment with the objectives of European legislation problems and differences can rise.

There are two main approaches when it comes to transposition: centralised and decentralised approach. Of course all kind of variations in approach exist. It is not the intention to express preference for one of these approaches nor is it possible to make specific recommendations for each approach. Therefore recommendations useful for both approaches are given in Section 8.4.

Although the approaches are very different there are several factors that can explain these differences. For example:

- The existence of central co-ordination of the activities during the negotiating and transposition processes in a Member State;
- The choice of the national legislative instrument by a Member State;
- The nature of the administrative structure of a Member State (centralised or decentralised);
- The administrative and political culture in a Member State;
- The mobility of government officials between departments. Their expertise is not directly accessible for others; and
- The daily workload of the officials (which increases when they are involved in both the negotiation and transposition process).

In particular, fragmentation (and concurrent powers) can have a negative influence on transposition and appears in both federal and centralised states.

8.2.2.2 *Timely transposition*

Transposition of European legislation into national legislation must be done within a certain time period. This time period differs from one Directive to another.

When a Directive is transposed Member States need to inform the European Commission (notification). Notification is a formal obligation, but all it does is inform the Commission when a Member State considers transposition complete according to the latter's subjective opinion. It does not give any information as to the quality of the transposition; nor does it take account of the Commission's opinion on the matter.

The Commission's regular Single Market Scoreboard reports on the transposition rates as notified by the Member States and shows they differ sharply. However, as explained above these figures should be treated with caution.

Timely transposition is very important for the Member State itself but also for other Member States. The lack of coherence and transposition in some Member States risks further distortion of the internal market. The quality of the European legislation can be improved: transposing it incorrectly, late or not at all causes additional problems.

It is not always easy for Member States to transpose on time. Problems with the content and quality of the European legislation or problems relating to the incorporation into the national system can lead to delays. Some Member States feel that when asking the European Commission for help during their transposition, that help is not forthcoming. An important reason for the Commission not giving feedback is that Member States can use these answers as the means to justify choices that are not compatible with the spirit or the letter of the Directive. Member States feel that they don't have any certainty whether they transposed a Directive correctly and fully.

As a result of dialogue during the transposition process, the Commission can often have insight into the current state of play in each Member State on a certain Directive. This information is not accessible for third parties like Member States. Therefore it is not easy for Member States to learn from each other and from common experience.

8.2.2.3 Introduction of extra requirements

Quite frequently Member States in transposing a Directive decide to adopt rules which are stricter than those provided for by the Directive. This phenomenon, which is sometimes known as "gold plating", usually occurs where a Directive provides for minimum harmonisation or where the Treaties contain an explicit legal base for stricter national measures⁷. Such stricter national measures inevitably lead to new barriers to trade and the freedom to provide services and therefore need to be justified in the light of the Treaty provisions on free movement of goods and services. This is the case if the Member State concerned can demonstrate that these stricter national measures are necessary on grounds of general interest recognised in the Treaties or in the case law of the Court of Justice and that they are proportional to that aim.

⁷ Examples include the field of the internal market (Article 95(4) and (5) EC), consumer protection Article 129(5) EC and the protection of the environment (Article 176 EC).

To the extent that stricter national measures than provided for by a Directive are indeed justified, barriers to trade and the provision of services within the internal market remain intact. In view of these effects Member States should consider their position very carefully before introducing extra requirements in the legislative measures they adopt in transposing a Directive.

It should also be pointed out that stricter national measures in many cases may be considered to be “technical regulations” within the meaning of Directive 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations. In that case these measures should be notified in draft to the Commission, who sends the draft on to the other Member States, so that during the ensuing stand-still period of three months they can be screened as to their effects on intra-Community trade. This procedure can therefore be useful in detecting and remedying problems at an early stage. It should be noted in this context that failure to comply with the obligation to notify such measures renders them inapplicable and unenforceable against companies and individuals⁸.

8.3 Compliance and Enforcement

8.3.1 Conditions for compliance and enforcement

The second part of implementing European legislation is its application and enforcement to ensure compliance in practice. This is necessary to realise the *effet utile* of European legislation and will involve national authorities preventing violations and taking action against infringements. Compliance and enforcement – both the organisation and the realisation thereof – are the responsibility of Member States. In this respect the competent authorities within each Member State have their own responsibility for acting in conformity with European law. Compliance and enforcement are closely connected with the form of government, national systems and traditions and the identity of the competent authority or authorities depends on the national administrative structure.

Problems and difficulties that rise in the implementation process regarding European legislation are often reflected in the way transposed European legislation is complied with and enforced in the Member States. In the following section some practical problems and their causes are described.

8.3.2 Compliance and Enforcement problems

It is not always easy to apply, comply with and enforce the national legislation by which European legislation is transposed. An important reason for this is the quality of the higher European legislation, which affects the national legislation. In practice the quality of European legislation might lead to unclearness, poor applicability, compliance and enforcement problems and inefficiency. This undermines the effectiveness of European legislation and the competitive position of businesses.

⁸ Judgment of the Court of Justice in the *CIA Security Case*: Case 194/94, (1996) ECR 2201

8.3.2.1 *Content and quality of European legislation*

The OECD has set up criteria for the quality of legislation in general. These criteria are lawfulness, administrability and enforceability, effectiveness and efficiency, subsidiarity and proportionality, mutual harmonisation, simplicity, clarity and accessibility. When looking at these OECD criteria for quality of legislation a relationship is visible between the content and quality of European provisions and the impact on the application, compliance and enforcement of those regulations within the Member States.

The lack of simplicity, clarity and accessibility of European provisions – such as unclear, confusing terminology, incomplete or inconsistent regulations or use of vague terms – constitute significant problems.

Many of the problems relating to the accessibility of European provisions are caused by the fact that there are various different legislative cultures within the Commission, each with their own tradition. The technical aspects of European legislation related to accessibility are not high on the list of priorities of the parties involved in the preparation of European provisions. The low priority also means that any comments regarding the technical aspects of legislation have little status during the preparations of European provisions. Bridging these differences by way of a compromise often does not lead to clarity but is an integral part of the European process of “negotiated law”.

Insufficient mutual co-ordination between pieces of European legislation also exists. Legislation sometimes includes conflicting requirements relating to the same subject. The main cause for this insufficient internal harmonisation is the fact that the Commission DGs focus on their own legislation. As a result of this Member States face problems when complying and enforcing this legislation when incorporated into national law. When facing such problems, dialogue with the Commission is often difficult.

8.3.2.2 *Early attention to compliance and enforcement*

When European legislation is clear and in conformity with other European legislation there still can be problems relating to the administrability and enforceability. The problems in this field have different causes. The most important are:

- In the preparation of European legislation, insufficient attention is drawn to the application, compliance and enforcement of the European legislation itself, and/or the implementing measures required on the basis thereof. Also administrative and enforcing institutions are not systematically involved in the preparation of European provisions. Foreseeable problems are therefore not signalled or signalled too late, not resolved at an early stage; and
- Institutions responsible for administering and enforcing are sometimes incapable of or unable to apply European legislation. This problem is not always caused by the problems related to the quality of the European rules themselves or the quality of their preparation. However, in combination with the few direct possibilities of feedback of the experiences to the Commission and difficulties to

communicate problems it causes the stagnation of the compliance with and enforcement of a (transposed) European directive.

Of relevance to this is also the choice of legislative instrument (Regulation or Directive). This is discussed in more detail in Section 2 of Part III.

8.4 Recommendations

Implementation is both a national concern and, in its role as guardian of the Treaties, an important point for the European Commission. Because the content and quality of European legislation has a big influence on the implementation process, this section of the Report contains recommendations addressed both to the Member States and to the European Commission, whilst respecting Member States' responsibilities in this area. It is not easy to provide general recommendations that are fully applicable for all Member States.

1. The incorporation of European legislation into national law should be seen as an extension of the negotiation process and vice versa, not kept distinct. Cultural aspects, such as informal procedures, are an important aspect during negotiation and incorporation processes.
2. All parties should pay more attention to the precision, clarity and coherence of European legislation during the negotiating process.
3. During the negotiating process all parties should pay more attention to a better balance between detailed and technical legislation on the one hand and national freedom in choice and form on the other hand.
4. Member States should start considering incorporation early. This means for example involving lawmaking specialists early and paying more and/or better attention to administrative structures during the negotiating process.
5. Member States should pay increased attention to more formal procedures to facilitate incorporation of European legislation. For example creating more central co-ordination and/or units with lawmaking specialists to facilitate the transposition process or publishing guidelines/checklists on the procedure and content of incorporation.
6. Member State officials need to be aware of the importance of the negotiating process. This means, for example, early involvement of lawmaking specialists and responsibility for negotiating in Brussels and incorporation in the Member State resting with the same officials within the lead department.
7. Member States need to give higher priority to the incorporation of European legislation.
8. The transposition periods for transposing European legislation must be sufficient.
9. Member States should be provided with more certainty as to whether they have transposed a European Directive correctly and fully, for example by sending an interpretative declaration by the Commission to confirm the transposition and/or

arranging meetings during the transposition process to exchange experiences between Member States. (Such an approach already exists for Consumer policy.)

10. The Commission should facilitate mutual learning and sharing of best practices between Member States.
11. The Commission should create a free of charge online database of legislation requiring implementation and the current state of play in each Member State.
12. The relevant bodies should develop a system for online notification by Member States.
13. When transposing a Directive, Member States should consider their position very carefully before introducing extra requirements in the legislative measures that they adopt.
14. Improving the quality of European legislation can make a contribution to better application, compliance and enforcement. In particular, there should be better preparation of European legislation through:
 - Better consultation between (administrative and enforcing institutions in) the Member States and the Commission; and
 - Inclusion in regulatory impact assessments of systematic and early consideration of administrative and enforcement effects.
15. National actors (businesses, NGOs, administrative and enforcing institutions) should be involved early and efficiently in the implementation process.
16. Member States should provide for sufficient administrative and enforcing structures and means.
17. Review of European legislation should include specific consideration of its administrability and enforceability.
18. The dialogue between Member States and the Commission should be intensified by way of informal (systematic and ad hoc) contacts regarding compliance and enforcement problems, with the aim of finding practical solutions.

ANNEXES

Annex A

OECD Reference Checklist for Regulatory Decision-making 1995

Question No. 1 – Is the problem correctly defined?

The problem to be solved should be precisely stated, giving clear evidence of its nature and magnitude, and explaining why it has arisen (identifying the incentives of affected entities).

Question No. 2 – Is government action justified?

Government intervention should be based on clear evidence that government action is justified, given the nature of the problem, the likely benefits and costs of action (based on a realistic assessment of government effectiveness), and alternative mechanisms for addressing the problem.

Question No. 3 – Is regulation the best form of government action?

Regulators should carry out, early in the regulatory process, an informed comparison of a variety of regulatory and non-regulatory policy instruments, considering relevant issues such as costs, benefits, distributional effects, and administrative requirements.

Question No. 4 – Is there a legal basis for regulation?

Regulatory processes should be structured so that all regulatory decisions rigorously respect the "rule of law"; that is, responsibility should be explicit for ensuring that all regulations are authorised by higher-level regulations and consistent with treaty obligations, and comply with relevant legal principles such as certainty, proportionality, and applicable procedural requirements.

Question No. 5 – What is the appropriate level (or levels) of government for this action?

Regulators should choose the most appropriate level of government to take action, or, if multiple levels are involved, should design effective systems of co-ordination between levels of government.

Question No. 6 – Do the benefits of regulation justify the costs?

Regulators should estimate the total expected costs and benefits of each regulatory proposal and of feasible alternatives, and should make the estimates available in accessible format to decision-makers. The costs of government action should be justified by its benefits before action is taken.

Question No. 7 – Is the distribution of effects across society transparent?

To the extent that distributive and equity values are affected by government intervention, regulators should make transparent the distribution of regulatory costs and benefits across social groups.

Question No. 8 – Is the regulation clear, consistent, comprehensible, and accessible to users?

Regulators should assess whether rules will be understood by likely users, and to that end should take steps to ensure that the text and structure of rules are as clear as possible.

Question No. 9 – Have all interested parties had the opportunity to present their views?

Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses and trade unions, other interest groups, or other levels of government.

Question No. 10 – How will compliance be achieved?

Regulators should assess the incentives and institutions through which the regulation will take effect, and should design responsive implementation strategies that make the best use of them.

Annex B
Simplification Initiatives At EU Level

Since 1995, the intense EU debate on the need for simplification activities has led to distinct lines of simplification, the most relevant ones being specific simplification initiatives, the SLIM programme and the Business Environment Simplification Task Force.

The SLIM (Simpler Legislation for the Internal Market) pilot project - Of the *ad hoc* initiatives introduced by the Commission, particular mention must be made of its SLIM programme, a pilot project introduced in 1996 as an initiative for improving the quality of Internal Market legislation, for counteracting superfluous legislation and for limiting the costs associated with implementing legislation.

Motivated by business calls to lower regulatory burdens, as expressed for instance in the UNICE and Molitor Reports, SLIM attempts to focus attention on specific issues and is not meant to advocate deregulation: recognising that complicated regulations can reduce the competitiveness of business, and especially small businesses, SLIM aims at analysing the state of regulation in a number of areas and coming up with proposals for simplification.

The working method is based on the co-optation of “users” (that is business and the Member States) and the limitation to small groups (teams of five business experts and five national experts are typical, plus Commission officials), in order to facilitate a co-operative working method among experts and thus avoid mere inter-governmental committees with the fifteen states fully represented. The work is extremely targeted, in order to be run in a limited period of time, and focused on making precise recommendations.

It should be stressed that the European institutions have agreed that simplification ought not to encroach on the so-called *acquis communautaire*. In essence, simplification is to be prevented from acting as a passkey to calling in question again harmonisation reached in sectors like health protection, worker and consumer protection, environmental policy and free trade. Simplification - this is the idea - should become a resource for completing the internal market, not for dismantling it.

The BEST (Business Environment Simplification Task Force) - In 1997 the Commission also set up the Business Environment Simplification Task Force (BEST) with the aid of representatives of socio-economic interest groups and universities. This task force submitted a report containing 19 recommendations in 1998. These focused on the business environments in the Member States in a wide variety of fields (administrative procedures, education and training systems, labour flexibility, access to research and technology, relations with credit and finance, taxation and innovation).

The Action Plan for the Single Market - The Commission launched 1997 an Action Plan for the Single Market, listing four strategic objectives: making the rules more effective, dealing with market distortions, removing barriers to market integration, and finally ensuring an internal market that benefits all citizens of the Union.

Alongside specific initiatives on simplification, the action plan has also brought in the 'scoreboard' for member states' degree of compliance with the internal market, a measure strongly advocated by Commissioner Monti to help make Member States more responsible in this area.

The "state of the art" on simplification in the "better law-making" reports - Each year, since 1995, the Commission publishes a report on "better lawmaking" in which it reports also on the contribution it has made to simplifying EU rules. The most recent report, published in November 2000, outlined the progress of a number of recent simplification measures and drew attention also to the work being carried out to codify, recast and consolidate EU rules, avoiding overlaps and deleting outdated provisions.

The Inter-Institutional Agreement on drafting quality - An Inter-Institutional Agreement on drafting quality was published in March 1999, following on from the Treaty of Amsterdam; this agreement is not binding upon the Commission, the Council and the European Parliament but is a political commitment. It is as yet too early to assess the impact of this agreement.

The Unit for regulatory policy co-ordination in DG Enterprise - As part of the internal administrative reforms which the Commission set in train in the autumn of 1999, a "Unit for regulatory policy co-ordination" was established in DG Enterprise. Though this is a welcome step forward, the Economic and Social Committee has already considered that the action taken by this unit will remain limited as it is not directly attached to the General Secretariat since simplification has to become a requirement for all the DGs and other departments of the Commission.

Annex C
Member State Context and Experience

During the last decade a multitude of reports, published by the OECD and the European Institutions, indicated that the existing stock of regulation in Member States represents a heavy burden on citizens and businesses as well as on public authorities. The responses to a questionnaire on better regulation issued in January 2001 show that all Member States have now recognised the importance of addressing the accumulated regulations, procedures and formalities that have built up over many years. Most Member States however have only recently begun to turn this recognition into concrete action along the lines recommended by the EU and, more particularly, the OECD, which mainly explains the reason why progress has not yet been evaluated.

Based on the responses to that questionnaire, this Annex gives an overview of the different approaches used by Member States, the tools that are used and the way in which stakeholders are involved in the process of improving the quality of regulation.

Frameworks and principles

There seem to be two main frameworks used for work on better regulation in the Member States. One of these is modernisation of public administration, such as better quality and more responsive public services, easier access to information and forms by using new information and communication technology (ICT) and a greater sense of commitment to complying with the law. The other is economic reform – removing barriers to entrepreneurship, innovation and employment and improving the competitiveness of business. Of course, these two frameworks are not mutually exclusive, and many responses referred to both. However, ten responses had a greater accent on the former and four on the latter.

Irrespective of the main framework chosen, a number of principles are used across the EU to guide this work. Accessibility, accountability, consistency, effectiveness, enforceability, necessity, proportionality, simplicity, targeting and transparency are among those quoted in the responses.

Structures and driving forces

The different emphasis placed on the two frameworks described above is also reflected in the structures chosen in each Member State, which in turn is often linked to who is the political force behind the better regulation programme. Those Member States with a greater emphasis on economic reform are more likely to have administrative or institutional arrangements based in the Economics Ministry and the political impetus coming from business and/or the Economics Minister. Those taking more of a “modernisation” approach tend to organise themselves around the Ministry of Public Administration or Premier’s office and to have the political impetus from the concerns of citizens as well as business, often with the Premier personally interested.

Whichever framework applies most in a given country, in general the responses indicated an awareness of the need for support from the whole government in order

for the better regulation programme to succeed. One fairly common mechanism to secure this is the use of inter-ministerial committees or structures.

Several Member States also seek to involve business and other stakeholders in the process through Task Forces, test panels and representation on steering committees.

In addition, in most Member States the Ministry of Justice, Court of Auditors or Council of State also has a role in checking the consistency and/or quality of legislation, but the exact arrangements vary greatly depending on the constitutional and administrative organisation of the country concerned.

Approaches and tools

Within the overall framework chosen the different approaches that are used to reduce administrative and regulatory burdens can be divided into two groups:

- Improving the quality of new and existing regulation; and
- Making compliance easier (ICT/e-Government, making access to information easier, integrated service provision).

Most Member States use one approach more than the other, though most use elements of both.

To carry out these approaches Member States use a range of tools:

- Ex-ante assessment (RIAs);
- Improving the linguistic, legal and technical quality of texts (using handbooks, guidelines, training etc);
- Consultation on draft proposals or existing laws (business test panel, task forces or steering committees, hearings, etc);
- Measurement or assessment of existing burdens (quantitatively or qualitatively) to identify problem areas;
- Reduction of burdens on business or citizens through greater use of ICT, simplification of procedures and forms, etc;
- One-Stop Shops (physical or virtual); and
- Information provision (accompanying regulations).

Each Member State uses a unique mix of these tools, though none uses them all. Where the same tool is in use in one or more Member States the degree of development and sophistication also varies.

Review of existing regulation

All Member States review their existing regulation, although not always systematically. Many follow an ad hoc approach, initiated by a variety of sources: internal (individual Ministers, ministries) and external (business organisations, trade unions, civil society and consumer groups).

Where there is a systematic approach it is often result oriented, with clearly identified targets, timetables for their review and benefits from formal Ministerial approval. Such an approach makes the process of review transparent and those responsible for it accountable.

In some Member States, the bodies responsible for better regulation, initiate and coordinate, the process and support and offer guidance to those carrying it out. In three Member States, external bodies can also propose areas for review and make recommendations for change.

The majority of Member States mentioned simplification and codification as goals of review, though only a few have a strategy for achieving them. Those which do, sometimes have a “framework” law, which makes it easier to simplify or codify existing legislation. In some Member States the responsibility for the simplification programme is given to an inter-Ministerial Committee, which defines the procedures, monitors the process and proposes legislative changes. In Member States, which have a codification programme a similar procedure is used. Codification programmes also usually define both what areas of legislation are to be codified and how.

Assessment of new legislation

Most Member States assess the impact of new regulation before a legislative proposal is submitted to Council of Ministers or Parliament, in three Member States this assessment is made even before a text is drafted. These assessments are mandatory and are in most cases attached to the parliamentary documents and thus public information.

However, the extent of the assessments varies: in some Member States the assessment is limited to a qualitative description, others follow a more scientific approach and assess both macro and micro economic factors. Other issues considered include objectives and expected results, the financial and time costs of compliance, results of consultation, etc. Five Member States also consider alternatives to regulation in their assessments. Amongst the alternatives used, economic instruments, self-regulation, voluntary agreements and improved information were mentioned most.

All Member States provide information to accompany new regulations to aid compliance when it is considered necessary, but there is very rarely a systematic approach.

Consultation

Although all Member States consult stakeholders, the channels used to do so differ however on both the subject and the formal (advisory bodies, committees, etc) or informal character (hearings, meetings, etc). Where stakeholders are involved in simplification and codification programmes, it is usually through the same channels. Internet consultation is not yet a widespread practice although a few Member States recently launched some experiments. In almost all Member States stakeholders are consulted on the content of the legislative proposal, but only a few also consult on execution aspects.

In some cases consultation documents are published, six Member States even do so systematically. These are usually paper documents but nine countries now also use the Internet to publish them. Three Member States have a specific fixed period of consultation, which differs from 15 working days to 12 weeks, in other countries the period depends on the policy area and issue. In five Member States, those who have been consulted receive feedback, and in three of the five this is mandatory. In most Member States written justification is required for new regulations and takes the form of an explanatory memorandum that accompanies the text of the regulation. In Member States where impact assessments are mandatory, these include an explanation of why the regulation is necessary.

Concerns for future European action

Responses in this section of the questionnaire mostly noted the need for a cohesive and comprehensive European strategy for all aspects of better regulation that would improve the performance of the single market and bring the EU closer to its citizens. This strategy should, in the view of most respondents, include improved co-ordination between Member States and the Commission, a system of impact assessment for new regulations and a rolling programme of simplification and codification of existing regulations.

Conclusions

The answers from the Member States to the questionnaire clearly indicate that improving the quality of regulation and making compliance easier is a continuous process. Many Member States have elaborated ambitious regulatory reform and/or simplification programmes and have developed a wide range of tools, based on EU and OECD guidelines or on successful experiences from other countries.

The responses also show these programmes cannot produce the expected results without a strong political support, clearly defined targets within a strict timetable, commitment of public authorities, efficient communication and co-ordination, involvement of stakeholders, continuous evaluation and the use of a mix of tools aiming at all these aspects.

Annex D

Glossary of terms used in this Report

Term	Meaning in this Report
<i>Alternatives to regulation</i>	Strictly, alternatives to pure, traditional, legislation-based regulation such as self-regulation, co-regulation, and so on.
<i>Better regulation</i>	The policy of seeking to improve and simplify the regulatory environment. Regulation should be used only when necessary and be appropriate and proportionate to the task. It should be transparent and accessible to all and as simple as possible. It should be enforceable and at European level should obey the principle of subsidiarity.
<i>Codification</i>	<p>At European level, the term “official codification” is used to describe the process of repealing a set of acts in one area and replacing them with a single act containing no substantive change to those acts. It thus produces a text with legal effect.</p> <p>In some Member States (for example France), the meaning of codification is closer to the European term recasting – that is the process not only brings together multiple texts into one, but also makes changes to remove out-of-date or nonsensical provisions or correct gaps. It also has the sense of “incorporating into a code” in those countries that have such a legal structure.</p> <p>In this report codification is used in the European sense unless specified otherwise by the context.</p>
<i>Compliance</i>	The extent to which regulation is obeyed on the ground.
<i>Consolidation</i>	<p>Bringing together multiple texts that regulate a particular area into one, with or without minor changes to the substance. (Major changes to substance are carried out when the regulation is simplified.) At European level, the term is often used to describe an unofficial process undertaken by Commission officials, producing a text without legal effect but of practical benefit.</p> <p>In this report, consolidation is used in its generic sense and includes both codification and recasting.</p>
<i>Consultation</i>	An interaction between the bodies responsible for regulation and parties that are likely to be affected by or interested in the regulation in question to permit the latter to contribute their views, experience and expertise.
<i>Co-regulation</i>	Control of activities by a combination of action from private parties and public authorities.
<i>Enforcement</i>	Applying regulation on the ground.

Term	Meaning in this Report
<i>Evaluation</i>	The process of examining the effectiveness of regulation and regulatory processes. There are two main types – ex ante evaluation where tools such as regulatory impact assessment and consultation are used and the regulatory process examined to ensure all appropriate steps have been undertaken and ex post, where the effectiveness of the regulation concerned is examined, often against a checklist.
<i>Gold plating</i>	Over-implementation of a European directive by the creation of extra national requirements going beyond those in the directive.
<i>Implementation</i>	The process of incorporating any European legislation (that is, Decisions, Regulations and Directives) into the national legal framework and ensuring its application.
<i>Incorporation</i>	The incorporation of European regulation into national law. In the case of Directives, this is usually known as transposition, but it also includes the legal changes necessary to support something that is directly applicable such as a Decision or Regulation.
<i>Legally effective consolidation</i>	In this report the term “legally effective consolidation” means production of a consolidated text that has legal effect, through either codification or recasting.
<i>Legislation</i>	Primary or secondary law passed by legislative or executive bodies.
<i>Recasting</i>	This term is used at European level to describe a combination of (European) codification and substantive changes. It is not however wholesale repeal or, generally, major review of regulation. It is used in this sense in this report.
<i>Regulation</i>	Legislation and other forms of binding action by public authorities to implement public policy.
<i>Regulatory authorities</i>	The body or bodies involved in producing and agreeing regulation, that is Parliaments and, at European level, the Council.
<i>Regulatory impact assessment (RIA)</i>	A structured framework for informing the consideration of the range of options available for handling policy problems and the advantages and disadvantages associated with each. A good RIA should consider all kinds of impact.
<i>Review</i>	The process of examining existing regulation to determine what changes, if any, to make to it.
<i>Review clause</i>	This is a provision in regulation that requires a review to be conducted within a certain period, but where the outcome (status quo, revision or repeal) is not pre-

Term	Meaning in this Report
	determined.
<i>Self-regulation</i>	Control of activities by the private parties concerned without the direct involvement of public authorities.
<i>Simplification</i>	Making existing regulation clearer to understand, easier to apply and to comply with by taking away unnecessary, outdated or over-burdensome provisions whilst maintaining the original purpose and protection of the regulation.
<i>Sunset clause</i>	This is a provision in regulation that sets a time limit on a new piece of regulation such that it actually expires, in whole or in part, after a fixed period.
<i>Transposition</i>	The process of incorporating a European Directive into national law.

Annex E
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