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**COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

Enhancing the Implementation of the New Approach Directives

EXECUTIVE SUMMARY

The Commission is determined to strengthen the foundations of the system of free movement of goods in anticipation of an enlarged European Union.

The New Approach (complemented by the Global Approach) is a legislative technique used in the area of the free movement of goods, widely recognised¹ as highly efficient and successful. For almost 15 years, the directives based on it have played a central role in the effort to ensure free movement of goods in the single market. Economic integration and trade facilitation has increased steadily since the initiative was taken to develop these instruments. Over the years, as part of a continuous assessing process, the tools have been successfully revised and significantly improved. However, no general review on its important horizontal aspects has been made yet. This paper is a part of that process, designed to further strengthen a successful tool.

With the purpose of detecting areas which could be further improved, the Commission prepared a consultation document which identified some key elements of the New and Global Approach, accompanied by a detailed inter-active questionnaire. The intention of this exercise was to involve those most directly implicated in the current system by asking them to put forward their views of its operating deficiencies and strengths. The input received in response to this questionnaire has provided valuable insight to some of the issues identified as key elements that could be further improved. In particular, answers received indicated that stakeholders wish to continue with this system and to make it more effective.

The analysis of replies to this open consultation also revealed points of weakness in the fields of co-operation both within and between the relevant authorities in the Member States and with the Commission in the designation and notification procedures for conformity assessment bodies. Systems for the administrative exchange of information, in the implementation of provisions and in their execution require strengthening. Improving understanding of the CE marking and a significant increase of the level of consistency of legal requirements were also identified as important goals to be achieved in the future.

Long experience in dealing with the individual New Approach directives both in Member States and the European Commission, supported by considerable input from the Senior Officials Group on Standardisation and Conformity Assessment (SOGS) and the working groups established under the directives, together with the assessment of results of the open consultation, form the basis of this Communication.

The Communication is addressed to the European Parliament and the Council. It contains recommendations aimed at further improving the operational efficiency of the Internal Market, thereby reinforcing the competitiveness of European industry with cost effective, targeted measures proposed by many of the stakeholders themselves.

¹ Most in the Council conclusions of 28 October 1999 OJ C 2000 141/01 on the role of standardisation in Europe.

1. INTRODUCTION

1.1. Opportunities offered by this Review

Making the free movement of goods work better in a European Union of 25 Member States is a key part of the Commission's new strategy for the internal market for the period 2003-2006. This Communication on the New Approach is therefore the first in a number of important proposals in this area which the Commission intends to table. Important work is also in preparation to improve the free movement of goods in the non harmonised area.

Finding effective and efficient solutions to ensure that the free movement of goods functions well after enlargement is essential. The Commission will therefore seek high quality feedback to its ideas and then move rapidly towards making concrete proposals for action.

The principles of the New Approach have been the basis of a growing number of directives. More than 20 directives are based on the New Approach, and a number of other directives rely on principles of the New or Global Approach.

Although the number of directives is low, the products covered by them represent a large proportion of products that are placed on the market (see annex II, table 1b). It is estimated that the trade of products covered only by the major sectors regulated by the New Approach directives largely exceeds the volume of € 1500 billion per year.

The Commission and national authorities have accumulated nearly 15 years of practical experience concerning the implementation of these directives, during which many of them have been revised. Experience has shown, that the New Approach has been a successful tool for the development of the Internal Market. However, experience, supported by evidence given at subsequent consultations, has also demonstrated that implementation of these directives can be further improved in a number of ways.

At the beginning of 2002, a detailed questionnaire² developed by the Commission was put on the web-site of the Enterprise Directorate General, inviting comments. Stakeholders across a wide spectrum of civil society responded to the questionnaire. Replies were received from manufacturers, conformity assessment bodies, accreditation bodies, designating authorities from almost all Member States, and companies that can be considered to be "global players" based in and outside the European Union. In addition, small and medium size enterprises (SMEs), organisations representing manufacturers or commercial businesses, national ministries from Member States and other Commission services also replied. Annex 1 summarises the key trends of the input received. The need to review the elements highlighted in the questionnaire was considered by all stakeholders as necessary if the New and Global Approach is to work with increased effectiveness. However, the measures proposed by this communication do not modify the basic principles of the New Approach, which have proved to be effective.

The Commission published in 1999 a revised and expanded edition of the "Guide to the implementation of directives based on the New Approach and the Global Approach"³, the

² "Working document on the review of the New Approach", closed 31 March 2002.

³ Office for Official Publications of the European Communities, reference C-22-99-014-EN-C. The guide can also be downloaded from the Europa web site in all 11 official languages of the European Community. See <http://europa.eu.int/enterprise/newapproach/legislation/guide/legislation.htm>

objective of which is to provide guidance to all relevant actors in understanding the New Approach. While this guide is widely used as a reference it cannot, by itself, reinforce the areas that need to be strengthened.

Two additional elements underpin this review:

- the New Approach now has an important international dimension. A more consistent implementation of the New Approach within the European Union will support the pursuit of the objective of promoting the adoption by third countries of standards and regulatory approaches based on, or compatible with, the EU regulatory framework. This applies within the context of the expansion of the internal market with Candidate Countries through the negotiation of PECAs (Protocols on Conformity Assessment and Acceptance of Industrial Products). The New Approach also gives a solid basis to negotiate with third countries a variety of measures to reduce technical barriers to trade.
- this review is also integral to the process of Better Regulation. The needs of small and medium size enterprises (SMEs) for a simple and transparent legal framework are particularly important in this respect. Furthermore the EU needs to be in a position to ensure that existing internal market instruments are applied in a coherent and consistent manner so as to achieve uniform implementation and a good level of compliance with Community legislation.

1.2. Legal Background

On 7 May 1985, the Council adopted a Resolution on *A New Approach to technical harmonisation and standards*, providing a new framework for the harmonisation of national regulations for industrial products.⁴ The New Approach was devised to facilitate the achievement of the Internal Market and to develop flexible and technology-neutral legislation by moving from detailed product specific technical requirements to defining the essential requirements for types of products, thus promoting innovation and competitiveness.⁵

This was complemented in 1989 by the Council Resolution on a *Global Approach to conformity assessment*, followed by two other Council Decisions⁶ setting out more detailed specifications on testing and certification procedures and providing guidelines for the use of the CE marking, which are intended to be used in the harmonisation directives. There are provisions for the Commission to “report periodically whether conformity assessment and CE marking procedures are working satisfactorily or need to be modified.”

Some New Approach directives include procedures that diverge from those used in “standard” New Approach directives, such as the notification procedure in the Toys Directive, the safeguard clause procedure in the Low Voltage Directive 73/23/EEC or the conformity assessment procedures in the Construction Products Directive. The use of modules to assess conformity with individual directives has posed some problems that were also highlighted by

⁴ OJ C 136/1, 4.6.1985.

⁵ The Agreement on the European Economic Area extends the Internal Market to Iceland, Liechtenstein and Norway. Consequently, all New Approach Directives apply in these countries as they do in the EU Member States. References to the Internal Market in this working document should be interpreted accordingly.

⁶ Council Decision 90/683/EEC of 13 December 1990 OJ L 380/13, 31.12.1990 replaced by Council Decision 93/465/EEC of 22 July 1993 OJ L 220/23, 30.08.1993.

the consultation results. Conformity assessment according to the modules is based on the intervention of the manufacturer (first party) or of a notified body (third party) in the design and/or the production phase. Some of these aspects are sector specific and will need to be addressed on a sector specific basis.

1.3. The main elements of the New Approach

The main elements of the New Approach have been defined in the Council Resolution on a New Approach to technical harmonisation and standardisation⁷:

- The definition of mandatory essential requirements to ensure a high level of protection of the public interest at issue, such as health, safety, consumer protection or the protection of the environment. Essential requirements must be worded in terms that can be uniformly enforced by Member States. Furthermore, they must enable conformity assessment bodies to evaluate conformity of products with essential requirements and standardisation bodies to develop standards that ensure, partly or completely, the fulfilment of those essential requirements.
- Manufacturers are free to choose any appropriate technical solution that meets the essential requirements. Products that comply with harmonised standards, references to which have been published in the Official Journal of the European Communities, are presumed to meet the corresponding essential requirements. Harmonised standards are produced by the European standardisation bodies⁸ on the basis of mandates from the Commission.
- The definition of appropriate conformity assessment procedures, taking into account, among other things, the type of risk related to the products. Where appropriate, these procedures require the intervention of third party conformity assessment bodies, known as notified bodies. Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive(s).
- The introduction of the CE marking, which declares the fact that the manufacturer has verified that the product conforms to all the harmonisation provisions that apply to it and that the product has been the subject of the applicable conformity assessment procedures.
- The obligation on Member States to take all appropriate enforcement measures, including market surveillance, to ensure that non-conforming products are withdrawn from the market.

The Commission has previously addressed the role of standardisation in its report on the *Efficiency and Accountability in European Standardisation under the New Approach*.⁹ This report was the basis of two resolutions adopted by the European Parliament¹⁰ and by the Council¹¹. Additionally, the Commission adopted a report describing actions that have been taken following those resolutions¹². A further set of conclusions of the Council has been

⁷ Council Resolution of 7 May 1985 OJ C 136, 4.06.1985.

⁸ European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC) and European Telecommunication Standards Institute (ETSI).

⁹ COM(1998) 291 final of 13.5.1998.

¹⁰ Resolution of 12 February 1999 on the report from the Commission, OJ C 150, 28.5.1999.

¹¹ Resolution of 28 October 1999 on the role of standardisation in Europe, OJ C 141, 19.5.2000.

¹² COM(2001) 527 final of 26.9.2001.

recently published¹³. This is the reason why the aspects of the New Approach related to standardisation are not dealt with in the present communication.

2. STRENGTHENING THE IMPLEMENTATION OF NEW APPROACH DIRECTIVES

2.1. Introduction

New Approach directives provide controls of products (depending on the subject and risk covered) for both pre-market (conformity assessment modules) and post-market (market surveillance). These controls should be considered as part of a spectrum whose common aim is to ensure a high level of safety of products on the market.

The appropriate balance between pre- and post-market controls varies from one sector to another – some items are relatively easy to check and trace once in use or in circulation (industrial machinery), others are not (toys, electrical appliances, etc.). In some sectors, experience shows that an adjustment of the balance may be required. This will need to be addressed in the context of individual revision of relevant directives.

2.2. Notified Bodies

2.2.1. Introduction

The conformity assessment procedures included in the directives are based on conformity assessment modules. Most of the modules foreseen in New Approach directives require the intervention of a third-party conformity assessment body known as a notified body and, as a general rule, are used for higher risk products. It is therefore essential that these notified bodies operate with a proven high level of competence, integrity and professionalism. Approximately 1000 bodies had been notified to the Commission by the end of 2002 (see Tables 1a and 1b in annex II).

Notification of conformity assessment bodies is an obligation under New Approach directives and the requirements that those bodies must meet can be found in the annexes to the respective directives. Member States are responsible for the designation, notification and the application of the defined criteria, when assessing the ability of the body to carry out the conformity assessment procedures in question.

2.2.2. Notification procedure

Notification plays a crucial role in the functioning of the system. Most directives state that the notification should be sent to the Commission and to the other Member States. Member States authorities are, in principle, obliged to accept certificates issued by bodies for which they have received a notification. In order to facilitate this procedure, the Commission has produced a guidance document and developed standard forms for the use of notifying authorities. Nevertheless, the procedures are not always fully observed by the notifying authorities, especially the obligation to send the notification to all other Member States. This may lead to problems concerning the recognition of notified bodies in other Member States and, ultimately, may result in restrictions to the free movement of goods.

¹³ Council conclusions of 1st March 2002 on standardisation, O.J. 2002/C 66/01.

The Commission calls on Member States to ensure that their notifying authorities are made fully aware of their obligations concerning the notification procedure and that efforts are made towards shortening the period of time that elapses between the decision to notify a body and the completion of the notification procedure.

The New Approach directives require the Commission to publish the lists of notified bodies for each directive in the *Official Journal of the European Communities*. However, these lists are published for information only and have no legal effect. Since a significant period of time can elapse between the notification of a body and the next publication of the corresponding list, it would be impractical to rely on the lists as the sole information mechanism concerning the status of notified bodies.

The Commission is already taking steps to make available an on-line database on the Europa web site containing the list of notified bodies designated by EU, EEA and candidate countries and proposes the development of an on-line notification system to replace the existing paper-based system. This will considerably reduce the processing time and enable notified bodies to act with virtually no delay. Further, the Commission believes that the publication of the relevant lists in the Official Journal of the European Communities should be abolished once the on-line publication on the Internet is achieved.

This database will also contain information about the Conformity Assessment Bodies (CABs) designated by the third-countries with which the Community has concluded Mutual Recognition Agreements (MRAs) and the bodies designated by those candidate countries with which the Community has concluded Protocols on Conformity Assessment (PECAs). This will also allow the information concerning notified bodies to be publicly available in “real time” and enable notifying authorities to update information more easily. The Interchange of Data between Administrations (IDA) programme already in place¹⁴, or its successor, could be used as a platform to implement the measure.

2.2.3. The legal framework for the designation of notified bodies

It is the responsibility of Member States to notify those bodies under their jurisdiction which meet the requirements of the directives and have been designated to carry out specific tasks. Council Decision 93/465/EEC sets out some general guidelines concerning notified bodies. However, it is the individual directives which provide the legal basis for notification and contain the legally binding criteria that Member States must apply when assessing notified bodies. Nevertheless, the directives do not include detailed provisions on how these principles should be implemented. This situation reflects a political decision that the designation of bodies should remain a national competence, i.e. the assessment and designation of notified bodies is governed by the principle of subsidiarity and the acceptance of these bodies is based on the principle of mutual recognition.

Since the inception of New Approach directives, with few exceptions, there has been no systematic exchange of information between Member States concerning the criteria and procedures applied at national level for the assessment and surveillance of notified bodies. This lack of transparency has encouraged suspicions about uneven levels of implementation which, in turn, undermine the confidence that is essential if the mutual recognition and acceptance of certificates issued by notified bodies is to function smoothly. Ensuring greater

¹⁴ Decision No. 1719/1999/EC of the European Parliament and of the Council of 12 July 1999, O.J. L 203/1.

transparency about the implementation of the directives' requirements concerning notified bodies, and improving the implementation of those requirements, is one of the key challenges for the functioning of New Approach directives.

Certain differences between the systems leading to notification of conformity assessment bodies, and the possibility to demonstrate the abilities of those bodies by other means, have led to a lack of confidence among some stakeholders.

Therefore, in order to increase the levels of confidence and trust, joint working groups of Member States' officials have been established. Efforts of Member States and the Commission towards reaching a homogeneous designation system must be intensified.

This is important for several reasons:

- to ensure the safety of products and to avoid restrictions on the free movement of goods that could arise due to shortcomings in relation to the competence, impartiality, etc. of notified bodies;
- to allow notified bodies to compete on a level playing field, while ensuring that competition does not lead to a reduction in the quality of the service they offer;
- to demonstrate to third countries with which the Community has concluded trade agreements that there is a consistent approach to the implementation of EU legislation across the Community.

Council Decision 93/465/EEC specifies conditions regarding, for example, subcontracted work (competence of the establishment operating as subcontractor, ability of the notified body to exercise effective responsibility for the work carried out by the subcontractor), the establishment of co-operation among notified bodies, and the transfer of files when a notified body ceases its activities. These conditions are not normally reflected in the directives. However, some directives, due to the specificity of the sector, include similar requirements using different wording or specify additional requirements which are absent from other New Approach directives. This may result in legal uncertainty and in diverging approaches by different designating authorities. This situation could be remedied if all the requirements concerning notified bodies were to be consolidated by means of a single legal text.

The Commission considers it necessary to consolidate the requirements notified bodies have to fulfil. This could be covered either as part of a horizontal directive or as a standard article to be included in the respective directives. These requirements should take into consideration differences in the wording and the option to add, if necessary, complementary requirements.

2.2.4. The role of accreditation

The Global Approach gave an important role to accreditation of conformity assessment bodies. Accordingly, Council Decision 93/465/EEC states that bodies that “can prove their conformity with harmonised standards (EN 45000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives.” Similarly, New Approach directives state that bodies which meet the criteria of the relevant harmonised standards are presumed to meet the corresponding minimum criteria of the directives. In practice most designating authorities now rely, to various degrees, on their national accreditation bodies to assess and oversee the bodies they designate.

The problems signalled by the replies to the consultation concern the extent to which accreditation bodies integrate directive-specific requirements in their assessments of notified bodies. The same question occurs even where accreditation is not used. In either case, the assessment of the body must comprise an evaluation of its competence, in accordance with the relevant annex of the directive, in order to assess the conformity of products with the essential requirements of the directives. Competence to assess the conformity of products with the applicable harmonised standards is not sufficient to be designated as a notified body.

The solutions adopted by Member States rely, in most cases, on the use of accreditation. Therefore the use of EN 45000 series standards has proved to be useful. However, it must also be recognised that the EN 45000 series does not cover all criteria that need to be considered for notification. Furthermore, these standards, despite their direct reference in Community legislation, have since been superseded by international standards which need to be formally evaluated for their conformity with the criteria imposed by the New Approach directives and/or their completeness.

A number of designating authorities, generally in co-operation with their national accreditation body, have developed directive-specific accreditation programmes to cover the requirements of the directives. These programmes are designed to expand on the generic competence requirements contained in the EN 45000 standards although some additional criteria are required for certain directives (e.g. medical devices). However, due to the nature of the legal framework governing the designation of notified bodies, the different national programmes have developed in an uncoordinated fashion.

The Commission considers that in order to improve this situation, more comprehensive guidance for the use of accreditation should be developed with the aim of increasing coherence and structure for accreditation services within the Community, especially regarding the independence of accreditation bodies from commercial activities and competition between different bodies, whilst leaving the final responsibility to the Member States. Basic elements of such guidance could be part of the common legal provisions referred to in 2.2.3.

Performing accreditation in a similar manner in all Member States requires clear guidance for these bodies. Such guidance can be provided either by setting common rules of conduct or by accreditation bodies agreeing on a common policy. The flexibility of national systems should not be the target of this guidance; it is the accountability of the systems that needs to be improved. The more national authorities, and also authorities of other Member States, can rely on a high level of credibility of results of the accreditation system, the more the differences will disappear.

Progress is necessary in co-ordinating the actions of designating authorities and accreditation bodies in the Member States in relation to the assessment, designation and surveillance of notified bodies. Within the current legal framework, the Commission's ability to steer developments depends on the co-operation of national authorities. The responsibility to achieve further progress, therefore, falls mainly upon the national authorities.

The Commission intends to establish a permanent forum of Member States' authorities responsible for designation, in order to facilitate the exchange of best practices for the assessment, designation and surveillance of notified bodies. This forum could formulate recommendations to be followed on a voluntary basis.

2.2.5. *Surveillance of notified bodies*

Member States have an obligation to ensure that notified bodies continue to have the technical qualifications required by the directives. In addition, New Approach directives require that a Member State must withdraw a body's notification if the latter no longer complies with the requirements of the directive. These legal requirements *de facto* imply a procedure through which designating authorities regularly verify that notified bodies continue to meet the applicable requirements of the directives. Accreditation offers one way of doing this, as all accreditation bodies carry out regular surveillance and re-assessments of their accredited bodies. National authorities should not confine themselves to verifying *ex ante* that notified bodies meet the requisite criteria, e.g. technical competence, staff, equipment, etc. They must also verify *ex post* that notified bodies carry out their duties correctly. In other words, national authorities need to apply the criteria contained in the directives as imposing an obligation of results on notified bodies. Therefore, Member States must ensure that notified bodies that issue incorrect certificates, or other conformity assessment decisions, either undertake corrective action or have their notification suspended or withdrawn. Additionally, procedures to be followed for transferring the technical files of notified bodies that have been subject to suspension or withdrawal of their notification, or have voluntarily ceased to be notified, need to be found and consistently applied. However, the designating authority retains the responsibility for the designation and surveillance of notified bodies.

The exchange of experience of notified bodies is, at the present time, not built on a legally binding basis. The successful work of these notified bodies groups should be continued and put on a legal basis.

The Commission intends to propose introducing the exchange of experience of notified bodies as a requirement of New Approach directives. Future proposals to revise New Approach directives will introduce requirements concerning actions to be taken when notified bodies fail to perform their duties accordingly or cease to provide such services. Alternatively, this kind of co-operation could be foreseen in the legal requirement referred to in 2.2.3.

2.2.6. *Cross-border activities of notified bodies*

The designation of a notified body is based on a decision of the respective Member State. These bodies automatically (by means of the mutual recognition principle) have as their potential market the entire internal market (even beyond its limits, where the CE Marking is accepted) and can offer their services everywhere in the European Union. Conversely, some notified bodies are subsidiaries of organisations established outside the Member State designating it, including countries outside the EU. In some cases it is the latter that carries out most technical activities on behalf of the notified body.

However, designating authorities do not always have the tools to assess and control the activities of the notified bodies they have designated, but which operate in countries outside their jurisdiction. This may impede them from taking appropriate measures if the bodies' activities do not conform to the applicable legal requirements set out in the directives.

In order to ensure that notified bodies may offer their services without restriction in the Internal Market and to facilitate the implementation of mutual recognition, the Commission intends to support the establishment of an information exchange procedure between authorities and/or accreditation bodies in the "host" country and the designating authority in the "home" country of notified bodies, as part of reinforced administrative co-operation. The

Commission believes that this would require a legal basis to be introduced either in a common base or in individual New Approach directives.

This will allow Member States to alert each other about possible problems concerning the activities of notified bodies outside their country of designation and encourage the resolution of problems through bilateral contacts.

2.2.7. Recognition of Notified bodies in non-EU countries

The New and Global Approaches were, and continue to be, essential building blocks for the creation of the Single Market. They have also provided an essential element for the conclusion of Mutual Recognition Agreements (MRAs) with a number of countries in the sectors covered by New Approach directives. The EU continues to receive requests, from our trading partners around the world, to negotiate further MRAs. One of the problems with MRAs is the difficulty to assess the benefits of such agreements in relation to the costs, which are substantial in terms of negotiation and implementation. Political and commercial interests have mainly dictated our MRA priorities. Conditions under which non-European Economic Area (EEA) conformity assessment bodies can be active under the same conditions as the notified bodies under the jurisdiction of EEA States have been subject to negotiation. One alternative to MRAs could be the contractual relations that some notified bodies have already established with conformity assessment bodies in countries outside the EU aiming at reducing the costs of testing and certification for products. In addition, a recent Commission staff Working Paper¹⁵ has highlighted a number of other means to facilitate international trade by the removal of technical barriers to trade.

The conclusion of PECAs¹⁶ with candidate countries is a good example on how viable solutions can be found. Further efforts need to be undertaken by the Commission to establish a structured framework to allow conformity assessment bodies from other countries to perform tasks corresponding to notified bodies activities under New Approach directives. Such a framework should also establish the conditions under which a reciprocal arrangement could be negotiated with a third country.

Testing and certification procedures are elements that play a major role in ensuring that the efficiency of the system is consistent. Multilateral Agreements (MLAs) on accreditation, certification, testing laboratories and inspection bodies can be considered to be other elements that can be applied. The conditions under which MLAs function need to be set out in accordance with present legislation and the objectives the European Commission currently pursues.

2.2.8. Separation of regulated and non-regulated area

One of the important features of the New Approach at the time of its conception was the fact that structures used (i.e. standardisation, accreditation, conformity assessment etc.) for the non-regulated area could be used also for the purposes of regulation. Over the years, mainly due to the non-existence of a legal basis for the non-regulated area, a separation from this principle has developed and it has created, in some cases, a dichotomy in the activities of the relevant bodies despite the fact that most of them (accreditation bodies, conformity

¹⁵ Implementing Policy for External Trade in the Fields of Standards and Conformity Assessment: A Toolbox of Instruments, SEC(2001) 1570 of 28.9.2001.

¹⁶ Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products

assessment bodies) are active in both the regulated and the non-regulated area in their respective domains.¹⁷

The Commission considers that there are important public interests at stake in the area of non-regulated conformity assessment, as for example the assurance of trust to the users of relevant services in the single market.

The Commission considers that in preparing future actions (of legislative or non-legislative nature) in the field of conformity assessment no distinction should be made between the regulated and non-regulated areas, taking into account the necessary freedom to be left to operators in the non-regulated areas.

2.2.9. Co-operation and exchange of information between notified bodies

Some New Approach directives require notified bodies to have an active exchange of information on denied or withdrawn certificates. This is considered to be a most useful tool in order to prevent manufacturers from applying more than once for a certificate for the same (non-compliant) product. Some national authorities have included in the terms of contracts they conclude with conformity assessment bodies, once they wish to be notified, provisions for an active exchange of experience, not only useful for detecting problematic cases requiring interpretation, but also to ensure a uniform level at which notified bodies in the respective country work. However, exchange of information, as described above, does not prevent manufacturers from applying for certificates for non-compliant products at notified bodies in another Member State, with possibly a different result.

It is important to exchange information on denied or withdrawn certificates in order to ensure a uniform implementation of community legislation and to prevent deficient products from being submitted for testing or certification several times. Information transmitted by notified bodies to their colleagues in other notified bodies need only refer to the type of product and to the reasons for denial or withdrawal, thus not covering the whole product and possibly making public confidential information or technical details subject to secrecy imposed in contractual terms between the applicant and the notified body. The activities of Notified Bodies' Groups should be encouraged with the aim of ensuring a level playing field for all.

The Commission intends to propose introducing in all New Approach directives provisions for notified bodies to exchange information on non-compliant products submitted for testing or certification and to support future activities of Notified Bodies Groups in order to promote the exchange of experience among all bodies notified under the respective directive.

2.3. Conformity assessment procedures

The consultation results show that there is no reason to question the effectiveness of the modules¹⁸. However, manufacturers may face problems related to product evaluation because of a limited choice of modules available in the directives in cases where a product is covered by more than one directive. On the one hand, all applicable directives may not share a common module, thus obliging manufacturers to apply different modules for different risk categories. On the other hand, even when the same module can be used for all the applicable directives, there is not always a single notified body available, designated under all the

¹⁷ See also further in chapter 2.4.

¹⁸ Modules for conformity assessment as defined in Council Decision of 22 July 1993 (93/465/EEC).

applicable directives. Manufacturers must, therefore, either call upon several notified bodies to assess the conformity of their products or agree with specific work being subcontracted by the notified body. As each notified body should restrict its assessments to the requirements of the directives for which it has been designated, the intervention of several notified bodies inevitably increases costs.

Modules H, E and D (declaration of conformity using quality systems) allow manufacturers to produce and market their products with less frequent involvement of a notified body, which carries out an assessment of the management system and of the product-related issues foreseen by the modules. Quality assurance systems are product oriented and allow for the necessary flexibility to take into account different types of risks presented by a product covered by several directives. It is, therefore, considered that conformity assessment procedures based upon the implementation of an appropriate quality system may ease certification of those products.

The Commission will propose to introduce modules H, E or D in existing and future New Approach directives where this is appropriate and to further ensure their proper application.

Some practical problems related to the concepts of placing on the market and putting into service have also been raised, including the need for harmonised definitions of the manufacturer, of his representative, and of placing on the market, as well as differences between consumer products and products for professional use.

The Commission will prepare a proposal, to be applicable on a horizontal basis, clarifying the definitions to be applied in conformity assessment procedures.

2.4. The CE conformity marking

The CE marking, being an indication that all requirements of each applicable directive have been fulfilled, is addressed to, and is protected by, the authorities of the Member States. The legal status of the CE marking is established by the directives and is not a commercial quality mark but should be seen as a declaration by the manufacturer, or his authorised representative, that the product conforms to all applicable harmonised provisions. Although this distinction is quite clear to authorities, it is not so to the public which, while it increasingly recognises the mark, often mistakes its meaning. In particular, there is a tendency to add elements to the understanding of this marking that were never the intention of the directives.

There is a strong need for Member States and the Commission to clarify the meaning of the CE mark and to promote its accurate representation to consumers. An information campaign can help achieve this. Such a campaign should be extended beyond the borders of the European Union, because the intention and meaning of CE marking is still not sufficiently well known to third country manufacturers of products intended to be placed on the Internal Market.

Furthermore, in several sectors, products frequently carry voluntary marks in addition to the CE marking. Some of these marks existed long before New Approach directives were introduced, while others appeared afterwards in response to market pressures. Although they are not legally obligatory, various economic actors such as wholesalers, distributors, installers or insurance companies often rely upon them. Additional voluntary marks are not, *per se*, in contradiction with CE marking as long as they do not cause confusion or overlap in meaning or purpose with it and offer a value-added to those being addressed (i.e. consumers, users,

public authorities etc.). It is the duty of Member States to ensure that the integrity of the CE mark is not violated and that it is protected accordingly.

In order to strengthen the role of CE marking, the Commission intends to take the necessary steps to clarify and promote the meaning of the CE marking, to introduce enforcement and protection measures, including sanctions and clarify its relation to voluntary product marks.

In addition, the Commission proposes that the whole issue of the unduly affixed CE mark to be further discussed and the most important factors identified. The Commission intends to launch an information campaign to be initiated in close co-operation with Member States.

On the basis of experience gained, the Commission does not exclude the possibility to propose a clearer legal text in order to exclude ambiguities and to strengthen the position of the CE-marking.

2.5. Enforcement and market surveillance

2.5.1. Enforcement measures

Appropriate enforcement measures, including market surveillance, are essential to ensure that New Approach directives are correctly applied, allowing citizens to benefit from a high level of protection and enterprises to operate on a level playing field throughout the Internal Market. However, there is no assurance that levels of enforcement do not vary throughout the Union. This undermines the credibility of the New Approach and could lead to a *de facto* re-fragmentation of the Internal Market.

Monitoring the products to be placed¹⁹, or already placed, on the national market falls under the responsibility of the national market surveillance authorities. They are also the ones to take necessary action if products that do not meet the provisions of national law transposing the respective New Approach directive are found on the market.

Different needs and geographical or market particularities in the Member States have led to solutions that do not always ensure strict separation between designating authorities, accreditation bodies, conformity assessment bodies and market surveillance authorities. Those potential sources of conflict of interests need to be eliminated.

Although experience varies from one directive to another, the recent Mutual Joint Visit Programme (MJVP)²⁰ between national market surveillance experts highlighted the existence of different approaches and levels of market surveillance in Member States. Some Member States have a “proactive” approach to market surveillance, while others adopt a “reactive” strategy. A reactive strategy covers activities such as response to complaints, safeguard clause notifications of other Member States and basic customs checks. A proactive approach suggests targeted campaigns, use of risk assessment tools, co-operation with other authorities.

The issue of limited resources features in every Member State for every directive. In some Member States, severe financial restrictions mean the effectiveness of market surveillance is

¹⁹ This is the case when products are displayed on trade fairs, commercial exhibitions, etc.

²⁰ The MJVP was a Commission-funded initiative covering five sectors: toys, electromagnetic compatibility, low voltage equipment, machinery, and personal protective equipment. Experts from national enforcement authorities in all Member States plus Norway visited their counterparts in other countries and reported on the content and conclusions of their visits.

limited. Effective market surveillance is, however, a part of the New Approach system and resources, both human and financial, need to be ensured. The MJVP programme identified a number of means by which enforcement can be strengthened and made more consistent: application of a common set of minimum criteria for surveillance, including product safety checks at external borders; reinforced administrative co-operation; and revision of the Safeguard Clause procedure for notification of national measures restricting the free movement of CE marked products.

Proposals for additional measures to achieve these objectives are set out in the following subchapters.

2.5.2. *A common level of market surveillance throughout the Union*

Member States can achieve a common level of market surveillance based on the following criteria:

- Infrastructures and human and financial resources must be sufficient to ensure that all products within the scope of a Directive are subject to surveillance and that a range of controls can be applied, as appropriate, to each product group. In some cases where, for example, the market size does not permit viable surveillance systems or expertise is not available, Member States could combine their efforts through relevant co-operation agreements.
- Accident data analysis is to be used to develop a strategic market surveillance programme, and, whenever useful, should be conducted in co-operation with other Member States.
- Taking into account cultural or practical differences between Member States, the sanctions or penalties applied to non-compliant products must not only be proportionate to the degree of non-compliance identified, but also sufficiently effective to have a dissuasive effect. Transparency concerning surveillance campaigns and enforcement measures will serve to reassure end-users that effective action is being taken, and signal to industry that products are subject to post-market controls.
- Member States need to ensure effective communication and co-ordination at national level between their market surveillance authorities and their other authorities which work in the field of product safety such as occupational health and safety authorities and customs. For example, one essential element of effective enforcement is co-operation between customs officers and market surveillance authorities. Checks for conformity with the rules on product safety in the case of products imported from third countries²¹ are a common base for this co-operation and Member States have to ensure that regulations are being correctly applied.
- Risk analysis and risk management measures envisaged by market surveillance authorities should be correlated with actions taken by customs authorities.
- Additional implementation efforts may be required to ensure that both the resources and the communication mechanisms exist to allow customs officers and product

²¹ Checks for conformity with the rules on product safety for products imported from third countries are foreseen in Regulation 339/93/EC.

safety officers to work together as foreseen by the Regulation. Within the Customs 2002 Programme, the Commission is supporting Member State co-operation to provide practical guidance for customs authorities when examining safety aspects of imported products.

- National authorities are called to fully participate in administrative co-operation with their counterparts in other Member States. This particularly implies an exchange of information on (potentially) non-compliant products, test results, enforcement actions taken, control priorities and the resulting campaigns.

The Commission calls on Member States to ensure a common level of market surveillance and to support clear action towards this goal. Defining basic rules with which Member States will be obliged to comply (e.g. sanctions, information exchange provisions) require a revision of the legal framework either by means of a horizontal directive or by including these rules in the individual directives.

Information campaigns and recall measures made public will help market surveillance authorities increase the effectiveness of their activity.

Deterrent measures like strong sanctions against persons or companies repeatedly misusing the freedoms offered by the New Approach system, product recall actions or information campaigns are appropriate actions to help reduce the number of deficient products on the Internal Market.

2.5.3. Reinforced administrative co-operation

Market surveillance must be accompanied by effective cross-border administrative co-operation. Two Council Resolutions²² have clearly underlined the importance of this co-operation in promoting effective enforcement of Internal Market legislation, and invited the Member States and the Commission to intensify their efforts in this area. Several measures for reinforcing existing administrative co-operation on enforcement issues can be identified:

- The competent authorities of the Member States have an obligation, resulting from Article 10 of the Treaty and specified in some Directives, to assist each other in the fulfilment of market surveillance activities and, in particular, by exchanging information concerning product examination and its results. Enforcement authorities frequently benefit from cross-border assistance in tracing a non-compliant product back to the certifying Notified Body, to the manufacturer or to his authorised representative. This mutual assistance has to take place on an EU-wide level, or between only those authorities concerned with a specific issue.
- One forum in which co-operation takes place is that of Administrative Co-operation Groups of Member States' market surveillance experts, which currently meet informally and only under some directives²³. A clearer definition of the status and

²² Council Resolution of 16 June 1994 on the development of administrative co-operation in the implementation and enforcement of Community legislation in the internal market (Official Journal C 179, 1 July 1994); Council Resolution of 8 July 1996 on co-operation between administrations for the enforcement of legislation on the internal market (Official Journal C 224, 1 August 1996).

²³ Directive 73/23/EEC on low voltage electrical equipment; 89/336/EEC on electromagnetic compatibility; 98/37/EC on machinery; 89/686/EEC on personal protective equipment; 94/25/EC on

objectives of Administrative Co-operation groups and their legal basis should be established, in order to provide firmer operational basis.

- Information about non-complying products, especially those that are subject to frequent complaints, need to be passed from one national authority to all other national market surveillance authorities faster than the products can be moved from one national market to the other. This is the objective to be reached by the authorities in their co-operation, if the market surveillance is to be considered efficient. The efficient use of the Interchange of Data between Administrations (IDA) programme could help accomplish this goal. However, this needs a clear legal basis to be realised.
- Mutual assistance is particularly important to the effective exchange of information. Protection of professional secrecy and different legal provisions concerning the status of information to be considered public should not prevent the sharing of relevant information with other surveillance authorities, since this type of information can be essential for the protection of health and safety.
- Information relating to dangerous products is to be made available to the public; this is particularly important concerning product identification, the nature of the risk, and the measures taken. Detailed reflection on the modalities of information exchange is required in order to avoid overlap of systems and duplication of effort. Information is only to be shared when it clearly offers added value to surveillance activities.
- The Commission encourages cross-border control campaigns and has provided grant financing for some clearly-defined projects undertaking practical co-operation on market surveillance. These projects promoted contacts and supported Member States to spread best practices in the medium-term. Such co-operation, supported by the means of e-administration, must become a standard element of co-operation.
- European administrations are currently using with great success the Interchange of Data between Administrations (IDA) programme in a variety of fields such as employment, health, agriculture, fisheries, statistics and competition. Inter-institutional communication is going to be helpful also in the area of administrative co-operation of authorities in Member States dealing with New Approach directives by providing the advantages of new technological opportunities.

The Commission intends to propose introducing a legal basis for administrative co-operation among Member States in the New Approach directives that do not yet foresee this in addition to continuing practical and financial support.

As market needs do not always require the existence of bodies notified for all directives in the different Member States, and as the market for a certain type of certification service is too small, often co-operation among Member States has proven to be a practicable solution. The Commission encourages Member States authorities to conclude bi- or multilateral agreements regarding mutual assistance and the sharing of infrastructure (including technical knowledge, testing facilities, training opportunities for the relevant staff) for market surveillance activities. The benefits of such agreements became evident during negotiations for the conclusion of PECAs with candidate countries.

recreational craft; 95/16/EC on lifts; 99/5/EC on radio equipment and telecommunications terminal equipment, 88/378/EEC on toys.

In order to avoid areas of activities not being covered by market surveillance authorities, Member States are encouraged to conclude bi- or multilateral agreements for mutual assistance.

2.5.4. The Safeguard Clause in the New Approach directives

Member States are obliged to take restrictive measures against products, covered by the scope of a New Approach directive, which are found to be unsafe. Action may be taken at different stages: before the product is to be put on the market, if it is already on the market, before being put into service and even if found in service. The mere fact that a product should be, but is not, CE-marked is one criterion to enable a market surveillance authority to identify that the product is non-compliant. Real hazards on a systematic basis must be demonstrated – therefore the authority must have the necessary skills, equipment and procedures to demonstrate systematic non-compliance. This is a costly and sometimes burdensome requirement needing skilled personnel. Nevertheless such action has to be taken, as it is the legal obligation of the Member States to protect their own population against dangerous products.

Actions, such as restrictions, bans, withdrawal of products, are to be notified by the Member State immediately to the European Commission because free circulation is hindered. The safeguard clause procedure foreseen in New Approach directives allows the Commission to verify the justification of national measures, which restrict the free movement of CE marked products. However, the current procedure is lengthy and difficult to apply in practice. Lengthy procedures also create problems to the industry (and especially SMEs) since they entail long periods of legal uncertainty.

Therefore, the Commission is confronted with difficulty in managing the safeguard clause procedure of the safeguard clauses as currently designed in most of the New Approach directives. The Commission is given the task to of managing highly complex, technical cases, on the basis of decisions taken at national level by technically specialised authorities or agencies, and (in certain cases) to perform a risk analysis. Due to the technical nature of such cases, specialised technical expertise, rarely available within the administration, is required. To procure specialised expertise makes the procedures longer and compromises their effectiveness in terms of free circulation.

In the case of the Low Voltage Directive, the currently applied procedure is simpler and faster and focuses on the most problematic cases. A further advantage relates to the fact that the Commission, in the case of the Low Voltage Directive, can make use of the technical expertise available at the level of Member States. Therefore, whilst maintaining the concept of the safeguard clause in accordance with Article 95(10) of the Treaty, there is a potential to simplify the safeguard clause procedure in the New Approach directives and to render it more effective in view of the functioning of the Internal Market.

The Commission will propose to modify the safeguard clause procedure in the New Approach directives in order to ensure a more uniform approach throughout the New Approach directives, to simplify and shorten the process and to render it more effective to ensure the functioning of the Internal Market.. This proposal would require a revision of the legal framework.

Involvement of Member States not directly concerned by the notified national measure in the analysis of technical files justifying the safeguard clause could be considered. This would provide the opportunity for authorities to transmit relevant information from past controls and

tests. In addition, there is a need to be certain that other Member States take appropriate actions on their national markets once the Commission finds that a notified action is justified. Only in this way can legislation be uniformly enforced across the EU.

Notifications or, in some cases, the information exchange preceding them, should take place within the framework of a systematic confidential exchange of information related to potentially dangerous products through a telematics-based system. This system would allow a comprehensive information exchange concerning enforcement measures taken or envisaged by national authorities. Such information should be available to competent authorities in the Member States and not to the public. Should one of the aforementioned authorities consider it appropriate, it can release confidential information, also to the public e.g. for recall actions, on the basis of national legal provisions.

2.5.5. Relationship with the Directive on General Product Safety

The recent revision of the General Product Safety Directive (GPSD)²⁴ has important implications for consumer products covered by New Approach legislation. The GPSD functions as a safety net, meaning that its safety requirements apply to consumer products for which other Community law does not contain provisions on safety and risks. Since New Approach directives regulate all aspects of safety and categories of risk relating to the products to which they apply, the safety requirements of the General Product Safety Directive do not apply to those products.

However, New Approach directives do not contain detailed provisions regarding means of enforcement. Therefore, the relevant enforcement provisions of the revised General Product Safety Directive apply to consumer products covered by New Approach legislation. Such provisions include, for example the requirement for Member States to define the organisation and tasks of their surveillance authorities, the RAPEX procedure and imposing the obligation on manufacturers to order the recall of dangerous products. This situation will mean that industrial and consumer products covered by the same New Approach directive could, in practice, be subject to different market surveillance provisions.

The RAPEX procedure requires notification of measures taken against a product or product batch which presents a serious and immediate risk to the health and safety of consumers. It applies to consumer products covered by New Approach directives, such as toys and low voltage electrical equipment, for which the directives do *not* provide an equivalent procedure. RAPEX is quite distinct from the Safeguard Clause procedure and it does not exempt a Member State from applying the Safeguard Clause procedure if the conditions for its use are fulfilled.

The Commission intends to propose introducing provisions in New Approach directives for an information exchange concerning industrial products which present a serious and immediate risk to users. This information exchange will involve authorities in all Member States and the Commission services.

²⁴ 2001/95/EC, OJ L 11, 15.01.2002.

2.6. Consistent and effective implementation of New Approach directives

2.6.1. Revision of the legal framework

A number of weaknesses that can best be addressed by revising the legal framework have been identified. The need for a more coherent approach to the assessment, designation and surveillance of notified bodies, the revision of the safeguard clause procedure and the need to strengthen enforcement measures, including market surveillance are core issues to be addressed. There are a number of options to achieve this. One possibility is to introduce the appropriate requirements in all sectoral directives. This was the approach taken when the CE marking provisions were introduced through directive 93/68/EEC. This would allow the needs of each sector to be taken into account. However, it is a lengthy process and does not allow the problems to be addressed in a horizontal manner.

As products may be governed by more than one New Approach directive, since different hazards may be dealt with under different directives, the simultaneous application of several directives can create problems:

- unintentional differences can be found in sectoral New Approach directives. For example, in relation to notified bodies, the relationship between the minimum requirements set out in the relevant annex of directives and harmonised standards is phrased differently in each directive. The differences are sometimes subtle, but can have important legal or practical implications. In some cases, the consequences are not fully appreciated by all the parties concerned. This can reduce legal certainty;
- products falling under more than one directive may create confusion on the meaning, operation and procedures (including conformity assessment procedures) if these are different in the directives concerned;
- the original intention of the New Approach was to provide a common doctrine concerning key concepts that would be used in all directives. However, in practice, specific definitions have been introduced in some directives and even new types of modules have been created in New Approach directives going beyond the placing on the market and having thus in service provisions for the products they deal with. This can lead to problems if these definitions are incompatible with definitions or with prevailing interpretations in other directives applying to the same product;
- solutions have been found in some sectors which could be equally useful in others. For example, Article 17 of directive 97/23/EC on pressure equipment provides a legal basis for administrative co-operation, missing from other directives. However, the need for effective administrative co-operation is common to all directives. It is therefore useful to create a single legal basis that applies to all sectors.

It is considered to be more efficient, and will ensure consistency, if the Commission were to establish a working group to develop the wording of “standard articles” dealing with elements common to all New Approach directives, as well as any additional provisions clarifying the procedures to be followed in the implementation and application of the revised directives. This would enable the preparation of the “all-in-one” solution of a *common base directive*, as being a simple means of reducing legislative work in the longer term.

A common base directive would avoid many of the problems identified above and simplify the legislative process, as each sectoral directive would then contain only the provisions

specific to the sector concerned, mainly the definition of essential requirements and the appropriate conformity assessment modules. Still, the question needs to be assessed carefully, because:

- the adoption of a common base directive implies the revision of all New Approach directives. A common base directive is only justified if it also introduces new substantive requirements. This requires a decision to move ahead with at least some of the proposals set out in this communication;
- the adoption of a common base directive will not solve all problems. For example in the case of conformity assessment procedures to be applied, where more than one directive applies to a product, where product specific approaches when dealing with issues like potential to harm, manufacturing conditions or surveillance measures are to be taken into account, close consultation with all stakeholders and Commission services and co-operation will be necessary when elaborating the solutions. Some of these issues could be addressed directly, when revising the respective directives.

The Commission proposes to start examining the benefits and disadvantages of a common base directive and of the inclusion of standard articles on horizontal issues in New Approach directives in order to detect the best solution and the largest extent of such horizontal issues to be taken into consideration. The Commission believes that a common base directive will be the better solution because of reduction of legislative work in future directives and the more homogeneous handling of identical or similar issues in New Approach directives.

2.6.2. Outsourcing to support implementation

The implementation of New Approach directives places a significant administrative burden not only on the Member States but also on the Commission, in particular in relation to the technical analysis relating to the application of safeguard clauses. Annex III sets out some statistics on the number of notifications received. This indicates a growing trend, attributable in part to a more active enforcement policy by national authorities in relation to a number of directives. Nevertheless, experience indicates that many measures are still not notified. The Commission expects the number of safeguard clause notifications to continue growing, a trend that will be reinforced by the enlargement of the Community.

If the current trend is maintained, the question of appropriate financial and human resources might arise. The revision of the safeguard clause procedure considered above will offer one means to reduce the administrative burden faced by the Commission. Even the limited number of notifications received at the moment place a considerable strain on available resources, which inevitably lengthens the time required to issue the Commission's Opinion. Moreover, the Commission services often work at the limits of their possibilities due to the multiplicity of areas when analysing notifications which they, on a case by case basis, also contract to external consultants. Finding consultants who have both the necessary degree of expertise and of independence from the parties concerned can be difficult.

Another option would be to outsource certain operations to a body staffed by technically competent experts in the fields covered by New Approach directives, thus allowing a speedier analysis of safeguard clauses. Such specialisation would enable the building of a comprehensive picture of problems relating to non-conformities encountered and to identify emerging trends, thus providing the Commission and Member States with a better basis to judge the effectiveness of the directives. It could also be entrusted with other logistical tasks, such as the management of the information exchange mechanism, designation of notified

bodies related issues and of the database of notified bodies, co-ordination of notified bodies groups, information to the public, etc. Such a body could, depending on its organisational structure and degree of dependence from the Commission, create a “pooling” of the expertise already available at Member States level in a way similar to that of the European Medicines Evaluation Agency (EMA).

The Commission, in conjunction with the Member States, will examine all options available and will make the appropriate proposals in due time..

3. CONCLUSIONS

The benefits of increasing the level of uniformity in the New Approach directives and of their implementation and application are evident. Synchronising the efforts of all Member States and the European Commission to have a better regulation, and thus reducing the cost to a minimum, is a considerable incentive.

A high quality, efficient system is the goal. The benefits are obvious – better products in terms of safety, at a lesser cost, will make them even more competitive. Clearer rules of application of the New Approach directives make them easier to understand to the authorities in the accession candidate countries and, thus speed up the process of adopting the *acquis communautaire* by these countries.

Finally, trade partners, manufacturers and authorities in third countries would perceive the qualities of the European legislative framework, of its reliability in practice, of the added value of conformity assessment under the European system. A growing number of third countries are interested in the New Approach as they are convinced of the reliability of the system, leading to growing success in promoting the New Approach to other economic areas, simplifying the exchange of goods and eliminating barriers to trade.

Proposals have been elaborated with the aim of increasing the efficacy of the system, to improve its transparency, as well as its smoother functioning, for the benefit of all involved partners – manufacturers, conformity assessment bodies, authorities and, above all, product users.

With this in mind, the Commission intends to support Member States' efforts to increase transparency and to strengthen where necessary the system at the level of implementation. The recommendations of the Commission are given in the text of the present Communication in the form of text boxes. For facilitation of the reading they are recapitulated in Annex IV.

Therefore, the Commission invites the European Parliament and the Council to:

- take note of the proposed improvements to be made in the application of New Approach directives and to support the proposals of the Commission outlined above;
- lend its support to initiatives aiming to strengthen the system by legislative and administrative means for the benefits of product safety and public health;
- invite the Member States to take all necessary measures and support all action targeted to ensure a better application of the New Approach and of the respective directives;
- call on Member States to ensure that their designating, notifying, and market surveillance authorities are fully aware of their obligations and continue to do so;

- to join in the reflection on the appropriate approach for guaranteeing the required financial and human resources.

Annex I: Analysis of the Results of the Online Consultation

As part of the preparation of this Communication to review certain aspects of the implementation of the New Approach, the Enterprise Directorate General produced, towards the end of 2001, a Consultation Document concerning the functioning of the New Approach directives. This was published on the Commission's Europa internet web site in January 2002, along with an interactive questionnaire based on a set of questions derived from the content of the Consultation Document. The document and questionnaire remained open online for contributions for a period of three months. The purpose of the consultation was to elicit a broad range of assessment and feedback from stakeholders, especially enterprises, so that more detailed proposals could be elaborated and eventually put forward in the Communication. The following is a résumé of the results of the consultation by interactive questionnaire, based on an analysis of the numerical results.²⁵ A total number of 135 contributions were made in response to the online consultation.

Input by country and sector

Of the EU Member States, there were responses from all except Denmark and Luxembourg. The greatest number of contributions came from Germany (27), UK (23) and Belgium (19). The EEA countries from which there were replies were Iceland (2), and Switzerland (6). No responses came from Liechtenstein or Norway. Of the Candidate Countries, only Bulgaria and the Czech Republic responded, with one contribution from each. There were no other European contributions; five came from North America and one from Asia/Pacific, but none from either Africa or South/Central America.

All the sectors indicated in NACE responded, with the exception of Recycling & Waste Management, Wholesale, Retail and Post & Telecommunication. The highest number of contributions was from Public Administration/Other Organisations (56), and Electrical & Electronic Equipment (34). The lowest number of contributions was from the Food Industry, Textiles, Clothing & Leather, Wood, Paper, Publishing & Printing, and Chemicals, Rubber & Plastics (1 each).

Reaction to the proposals put forward in the Consultation Document

The following is a summary of the feedback received, both positive and negative, in relation to the principal themes of the Consultation Document.

1. CONFORMITY ASSESSMENT PROCEDURES AND NOTIFIED BODIES

There was positive support for the conformity assessment modules as defined in Council Decision 93/465/EEC. A majority of the respondents considered them to be efficient for their intended purpose, but thought it would be useful to reduce the choice of modules in New Approach directives. Most agreed that linking specific modules with the use by the manufacturer of harmonised standards would simplify the procedures. In terms of negative responses, a majority of respondents disagreed with the idea that a more systematic recourse

²⁵ The results analysed here are those which were contributed online via the Internet interactive questionnaire. Some additional contributions were sent to the drafting service by mail and e-mail, and while these have been taken into consideration in the drafting of the final text, they have not been included in this separate résumé.

to module H (full quality assurance) or one of its variants would increase coherence in conformity assessment.

With regard to notified bodies, there was positive support for the suggestion that if the Commission were to publish a database of notified bodies on the Internet, the publication of lists of notified bodies in the Official Journal could be discontinued. A significant majority was in favour of the proposal that the procedure for notification of conformity assessment bodies could be streamlined, and thought that an electronic notification procedure would be the appropriate solution. Of the measures considered most appropriate to increase the effectiveness of the notification system, the one thought to be most effective was that of including in all New Approach directives a requirement to withdraw or suspend notification from a body that has repeatedly issued incorrect certificates or otherwise misapplied the provision of the directive. Measures also thought to be effective were the establishment of a forum bringing together designating authorities to exchange experience and information, and of a horizontal guidance document on best practices, on the assessment, designation and surveillance of notified bodies.

2. CE MARKING

A majority of the respondents had encountered problems related to voluntary quality marks for products covered by a New Approach directive, and thought that the meaning of the CE marking and its relationship to voluntary quality product marks should be clarified. Most were against the establishment of a code of conduct for voluntary quality marks that would address transparency, impartiality, openness.

3. ENFORCEMENT AND MARKET SURVEILLANCE

Most of the respondents thought that criteria for enforcement, including market surveillance, should be defined, and agreed with the proposal to introduce in New Approach directives a legal basis for administrative co-operation. There was also very positive support for the proposals to simplify and improve the safeguard clause procedure, and for the proposal to introduce a rapid information exchange mechanism for industrial products covered by New Approach directives. A majority expressed dissatisfaction with the current management of the safeguard clause procedure.

Of the market surveillance approaches described in paragraph 2.5 of the consultation document, those considered most appropriate to ensure a cost-effective implementation of New Approach directives were, in descending order of preference:

- - co-operation between authorities (pro-active)
- - targeted campaign (pro-active)
- - rapid exchange of information (reactive)
- - response to complaints (reactive)
- - risk assessment tools (pro-active)
- - safeguard clauses (reactive).

4. IMPLEMENTATION OF THE NEW APPROACH

A majority of respondents thought that more consistency is needed in the legal requirements covering equivalent elements in all sectoral New Approach directives, and that the Commission should examine further application of New Approach principles as a means of improving and simplifying legislation. There was positive support for the idea that a common base directive covering elements common to all or most New Approach directives would be appropriate to increase consistency. Of those who did not support this idea, a majority thought that a revision of all sectoral directives would be justified, *inter alia* to improve their consistency and to adopt some of the proposals identified in the consultation document.

Annex II: Notified bodies

Table 1a: Notified bodies per country*

EU 15		EEA-EFTA	
Country	N° bodies	Country	N° bodies
Austria	37	Iceland	2
Belgium	31	Liechtenstein	0
Denmark	22	Norway	16
Finland	15	EEA-EFTA Total	18
France	81		
Germany	185		
Greece	14		
Ireland	4		
Italy	227		
Luxembourg	5		
Netherlands	29		
Portugal	22		
Spain	54		
Sweden	47		
United Kingdom	224		
EU 15 Total	997		

Note: Information up to 30.10.2002

Table 1b: Notified bodies per directive

Directive	N° bodies	Directive	N° bodies
87/404/EEC Simple pressure vessels	79	94/25/EC Recreational craft	22
88/378/EEC Toys	56	94/9/EC Potentially explosive atmospheres	31
89/106/EEC Construction products	183	95/16/EC Lifts	156
89/336/EEC Electromagnetic compatibility	40	96/48/EC High-speed rail systems	20
89/686/EEC Personal protective equipment	103	96/98/EC Marine equipment	28
90/384/EEC Non-automatic weighing instruments	320	97/23/EC Pressure equipment	88
90/385/EEC Active implantable medical devices	18	98/37/EC Machinery	146
90/396/EEC Gas appliances	37	98/79/EC <i>In vitro</i> diagnostic medical devices	17
92/42/EEC Hot water boilers	39	99/36/EC Transportable pressure equipment	92
93/15/EEC Civil explosives	6	99/5/EC Radio and telecommunications terminal equipment	54
		2000/9/EC Cableway installations designed to carry persons	2
93/42/EEC Medical devices	60	2000/14/EC Noise from equipment for outdoor use	41

Note: Information up to 30.10.2002. Some bodies are notified under more than one directive. The total number of bodies in Table 1a (listed by Member State) is therefore lower than the total number of bodies in Table 1b (listed by directives).

Annex III: Safeguard clauses

This annex provides a summary of available statistics concerning safeguard clauses received by the Commission.

Table 1: Safeguard clause notifications received in 2001.

Directive	N°	Directive	N°
Low voltage equipment (73/23/EEC, amendment 93/68/EEC)	428	Civil explosives (93/15/EEC)	0
Simple pressure vessels (87/404/EEC, amendments 90/488/EEC and 93/68/EEC)	0	Medical devices (93/42/EEC, amendment 98/79/EC)	2
Toys (88/378/EEC, amendment 93/68/EEC)	1	Potentially explosive atmospheres (94/9/EC)	0
Construction Products (89/106/EEC, amendment 93/68/EEC)	0	Recreational craft (94/25/EC)	0
Electromagnetic compatibility (89/336/EEC, amendments 92/31/EEC and 93/68/EEC)	73	Lifts (95/16/EC)	0
Machinery (98/37/EC, amendment 98/79/EC)	15	Pressure equipment (97/23/EC)	0
Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)	3	In vitro diagnostic medical devices (98/79/EC)	0
Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)	0	Radio and telecommunications terminal equipment (99/5/EC)	0
Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)	0	Cableway installations designed to carry passengers (2000/9/EC)	0
Gas appliances (90/396/EEC, amendment 93/68/EEC)	7		
		Total:	530

Figure 1: Safeguard clause notifications - low voltage directive (73/23/EEC)

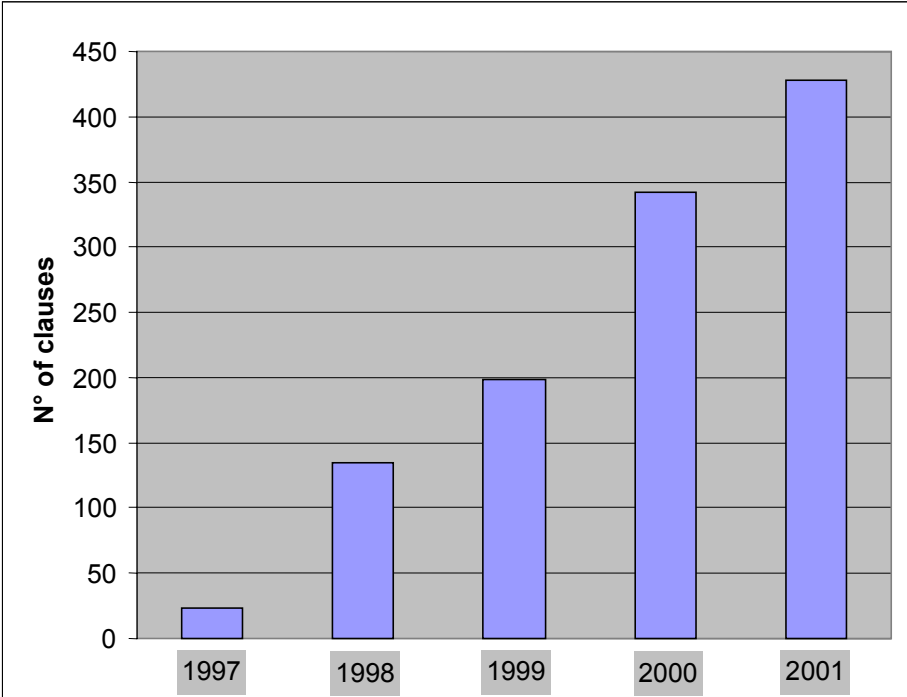
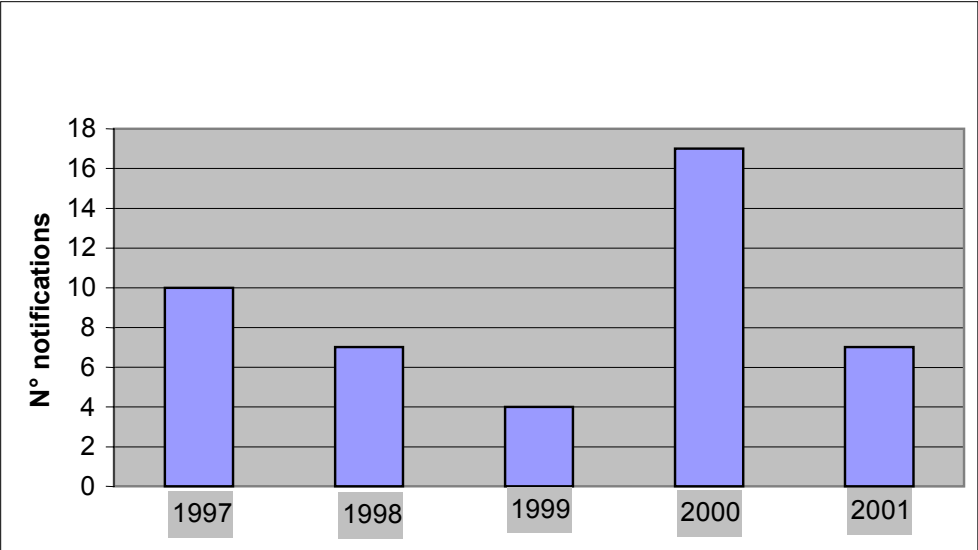


Figure 2: Safeguard clause notifications – gas appliances directive (90/396/EEC)



Annex IV: Recapitulation of recommendations of the Commission

Regarding the notification procedure the Commission

- calls on Member States to ensure that their notifying authorities are made fully aware of their obligations concerning the notification procedure and that efforts are made towards shortening the period of time that elapses between the decision to notify a body and the completion of the notification procedure;
- is already taking steps to make available an on-line database on the Europa web site containing the list of notified bodies designated by EU, EEA and candidate countries and proposes the development of an on-line notification system to replace the existing paper-based system. This will considerably reduce the processing time and enable notified bodies to act with virtually no delay. Further, the Commission believes that the publication of the relevant lists in the Official Journal of the European Communities should be abolished once the on-line publication on the Internet is achieved;

Regarding the legal framework for the designation of notified bodies the Commission

- proposes to intensify the efforts of Member States and the Commission towards reaching a homogeneous designation system by supporting the activities of already established joint working groups of Member States' officials;
- considers it necessary to consolidate the requirements notified bodies have to fulfil. This could be covered either as part of a horizontal directive or as a standard article to be included in the respective directives. These requirements should take into consideration differences in the wording and the option to add, if necessary, complementary requirements;

Regarding the role of accreditation the Commission

- considers that in order to improve this situation, more comprehensive guidance for the use of accreditation should be developed with the aim of increasing coherence and structure for accreditation services within the Community, especially regarding the independence of accreditation bodies from commercial activities and competition between different bodies, whilst leaving the final responsibility to the Member States. Basic elements of such guidance could be part of the common legal provisions referred to in 2.2.3.
- intends to establish a permanent forum of Member States' authorities, responsible for designation, in order to facilitate the exchange of best practices for the assessment, designation and surveillance of notified bodies. This forum could formulate recommendations to be followed on a voluntary basis.

Regarding the surveillance of notified bodies the Commission

- intends to propose to introduce the exchange of experience of notified bodies as a requirement of New Approach directives. Future proposals to revise New Approach directives will introduce requirements concerning actions to be taken when notified bodies fail to perform their duties accordingly or cease to provide such services. Alternatively, this kind of co-operation could be foreseen in the legal requirement referred to in 2.2.3.

Regarding cross-border activities of notified bodies the Commission

- intends to support the establishment of an information exchange procedure between authorities and/or accreditation bodies in the “host” country and the designating authority in the “home” country of notified bodies, as part of the reinforced administrative co-operation. The Commission believes that this would require a legal basis to be introduced either in a common base or in individual New Approach directives;

Regarding the relationship between the regulated and non-regulated area the Commission

- considers that in preparing future actions (of legislative or non-legislative nature) in the field of conformity assessment no distinction should be made between the regulated and non-regulated areas, taking into account the necessary freedom to be left to operators in the non-regulated areas;

Regarding the co-operation and exchange of information between notified bodies the Commission

- intends to propose introducing in all New Approach directives provisions for notified bodies to exchange information on non-compliant products submitted for testing or certification and to support future activities of Notified Bodies Groups in order to promote the exchange of experience among all bodies notified under the respective directive;

Regarding the conformity assessment procedures the Commission

- will propose to introduce module H or a variant in future New Approach directives where this is considered useful and to further ensure its proper application;
- will prepare a proposal, to be applicable on a horizontal basis, clarifying the definitions to be applied in conformity assessment procedures as far as possible;

Regarding the CE conformity marking the Commission

- intends to take the necessary steps to promote the meaning of the CE-marking, to introduce enforcement and protection measures, including sanctions and clarify its relation to voluntary product marks in order to strengthen the role of CE-marking;

- proposes that the whole issue of the unduly affixed CE-mark to be further discussed and the most important factors identified. The Commission intends to launch a publicity campaign to be initiated in close co-operation with Member States and, on the basis of experience gained, does not exclude the possibility to propose a clearer legal text in order to exclude ambiguities and to strengthen the position of the CE marking;

Regarding the enforcement and market surveillance the Commission

- calls on Member States to ensure a common level of market surveillance and to support clear action towards this goal. Defining basic rules with which Member States will be obliged to comply (e.g. sanctions, information exchange provisions) require a revision of the legal framework either by means of a common base directive or by including these rules in the individual directives;

Regarding the reinforced administrative co-operation the Commission

- intends to propose introducing a legal basis for administrative co-operation among Member States in the New Approach directives that do not yet foresee this in addition to continuing practical and financial support;
- encourages the conclusion of bi- or multilateral agreements for mutual assistance among Member States in order to avoid areas of activities not being covered by market surveillance authorities;

Regarding the Safeguard clauses in the New Approach directives the Commission

- will propose to modify the safeguard clause procedure in the New Approach directives with the aim of ensuring a more uniform approach throughout the New Approach directives, to simplify and shorten the process and to render it more effective to ensure the good functioning of the Internal Market. This proposal would require a revision of the legal framework;

Regarding the Relationship with the Directive on General Product Safety and the exchange of information concerning dangerous products the Commission

- intends to propose introducing provisions in New Approach directives for an information exchange concerning industrial products which present a serious and immediate risk to users. This information exchange will involve authorities in all Member States and the Commission services;

Regarding the revision of the legal framework the Commission

- proposes to start examining the benefits and disadvantages of a common base directive and of the inclusion of standard articles on horizontal issues of New Approach directives in order to detect the best solution and the largest extent of such horizontal issues to be taken into consideration. The Commission believes that a common base directive will be the better solution because of reduction of legislative work in future

directives and the more homogeneous handling of identical or similar issues in New Approach directives;

Regarding the possibility of outsourcing to support implementation the Commission

- believes that outsourcing, wholly or partly, some activities will speed up the process. Activities that could be outsourced include:
 - the technical preparation of the safeguard clause procedures for products (depending on the sensitivity of the matter),
 - the management of the information exchange mechanisms,
 - issues related to designation and notification of notified bodies,
 - the management of the database of notified bodies,
 - the co-ordination of notified bodies groups, and of information campaigns,
 - technical and legal analysis and objections against harmonised standards,
 - elaboration of technical documents related to questions of the interpretation of the essential requirements of directives,
 - mandates to standardisation bodies
 - co-ordination of co-operation activities of national authorities.
- This would leave the Commission services the freedom to use existing capacities for other fields. The “pooling” of expertise already available in Member States should be one of the major tasks of the body, in order to attain the highest level of expertise with the lowest administrative effort.