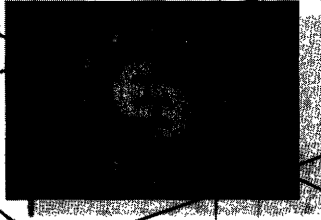


**ECONOMIC AND SOCIAL
CONSULTATIVE ASSEMBLY**

1999-2000



Standardisation and the removal of technical barriers to trade

*EUROPEAN
COMMUNITIES*



*ECONOMIC AND
SOCIAL COMMITTEE*

Brussels 1991

ECONOMIC AND SOCIAL
CONSULTATIVE ASSEMBLY

***BUILDING A SINGLE MARKET
IN THE EUROPEAN COMMUNITY***

INFORMATION PROCEDURES AND HARMONISATION MEASURES
FOR REMOVING TECHNICAL BARRIERS TO TRADE

***EUROPEAN
COMMUNITIES***

***ECONOMIC AND
SOCIAL COMMITTEE***

Brussels, April 1991

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CONTENTS

	Page
FOREWORD	5
INTRODUCTION. Background to the harmonization of Technical Standards and Regulations	7
I. OPINION on the Commission Green Paper on: <i>The Development of European Standardization: Action for Faster Technological Integration in Europe</i>	11
II. OPINION on the Communication from the Commission to the Council on: <i>A Global Approach to Certification and Testing — Proposal for a Council Decision concerning the modules for the various phases of the Conformity Assessment Procedures which are intended to be used in the Technical Harmonization Directives</i>	19
III. OPINION on <i>The Report on the operation of Directive 83/189/EEC, laying down a procedure for the provision of information in the field of Technical Standards and Regulations 1984-1987</i>	33
IV. Composition of Study Groups	43
V. COUNCIL RESOLUTION of 7 May 1985 on a New Approach to Technical Harmonization and Standards	47

FOREWORD

The impending completion of the European Community Single Market by the end of 1992 requires the approximation of laws, regulations or administrative action in Member States governing technical standards and quality assessment procedures for products placed in free circulation on the market. This process must respect the permanent need to ensure the protection of the health and safety of all citizens, in whatever walk of life.

Consultation of the Economic and Social Consultative Assembly (Economic and Social Committee - ECOSOC) is mandatory for all proposals from the Commission to the Council based on Article 100A (which covers the measures for the above-mentioned approximation).

ECOSOC, by virtue of its prerogatives and composition, maintains a close watch on the evolution of measures for the creation of the internal market from the viewpoint of the social partners - employers and employees - and of the consumers and other interested professional parties. It stresses particularly the need for cohesion throughout the Community, the future involvement of the EFTA States where applicable, and the need for full consultation with all interested parties.

It bases the Reports and the Opinions which it provides for the Council and the Commission on the consensus view of employers, employees and consumers, giving special regard to the practicability of the Commission proposals, the need to provide for a minimum regulatory framework while simplifying administration and the effectiveness and smooth-working of established procedures.

ECOSOC has put together a simple background report on developments in the approach to alignment of legislation and other relevant provisions in this field. The process involved is long and highly sophisticated involving the EC Court of Justice, the European Parliament and many interested parties, as well as the EC Council of Ministers, the EC Commission and ECOSOC itself. ECOSOC has also included in this publication its Opinion on the Commission Green Paper (of 8 October 1990) on the Development of European Standardisation, together with its Opinion on the Global Approach to Conformity Assessment and the modules for the conformity assessment procedures.

ECOSOC also reprints in this publication its review of the operation of the relevant Directives (83/189/EEC and 88/182) governing the notification of Member State regulations in this field and the provision of information by National Standards Institutions.

Last but not least, as an indispensable source of reference, it appends the Council Resolution on the New Approach to the Technical Harmonization process.

It hopes these documents, together with the essential references enclosed, will contribute to improved understanding and appreciation of a vital but frequently underestimated aspect of the process of completion of the 1992 Single Market.

INTRODUCTION

Background to the Harmonization of Technical Standards and Regulations.

1. Article 30 of the Treaty provides for goods legally placed on the market of one Member State to be permitted to be placed on the market in all others. This has been confirmed by the Court in the Cassis de Dijon and other cases.
2. As the exception to this general rule, Article 36 of the Treaty provides for the prohibition by a Member State of a good placed on the market of another Member State on grounds which include the protection of health of humans, animals or plants.
3. Article 100 (a) of the E.E.C. Treaty empowers the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

Article 100 (a) 3 enjoins the Commission in making its proposals to take as a base a high level of protection for health, safety, environmental protection and consumer protection.

Article 100 (a) 4 introduces a procedure for national exceptions to harmonization measures agreed by qualified majority in the Council (as provided for in Article 100 (a) 1). This procedure allows Member States to introduce national provisions on grounds justified by Article 36 (see above paragraph 2), or for the protection of the environment or the working environment. Recourse to such provisions is however subject to control by the Commission and appeal to the Court of Justice.
4. Each Member State has its specific regulations for industrial products depending upon its assessment of the risks which they involve. These regulations may call up standards prepared by standards bodies of the State, by a European standards body or by ISO/IEC (International Standards Organization/International Electrotechnical Commission).
5. A proportion of the industrial market of the Community is made up of goods for which one or more Member State has assessed risks which require regulations. These regulations differ between Member States and could constitute a barrier to trade. Directives 83/189 and 88/182 require Member States to notify regulations to the Commission. These are then circulated to all other Member States. There is a standstill system to deal with objections. This is the regulated sector of the Community market.
6. For this regulated sector the Community originally followed the Traditional Approach to protection under which the legislation laid down all necessary conditions to be met by the products and hence ensured harmonization.
7. This approach suffered from a number of drawbacks and has now been replaced in many sectors by the New Approach in which legislation lays down "essential requirements" only and leaves the remainder to be covered by standards. The adoption of a New Approach Directive involves each Member State in modifying its regulations to meet the essential requirements.
8. The Commission will restrict the issue of the New Approach Directives to those groups of products where regulatory differences between Member States could create barriers to trade.
9. Goods covered by the Directives may not be placed on the market in any Member State unless they satisfy the requirements of the Old Approach or the essential requirements of the New Approach.
10. If goods meet such essential requirements in the case of New Approach Directives, they will be marked with the CE mark. Furthermore the Commission will mandate the European standards organisations to write harmonised European standards which embrace the essential requirements. Goods meeting these standards will be assumed to conform to the essential requirements and may be placed on the market in all Member States.
11. The use of the CE mark involves those who place a product on the market in declaration that the product conforms to the essential requirements.
12. Each New Approach Directive to date has laid down various means or "modules" to achieve requirements for attestation of conformity, the severity of which rise in proportion to the risk of the product.

13. Some modules will involve certification and testing by the manufacturer alone, some will involve type testing and some, for products with relatively greater risk, will involve third party certification and testing.
14. Testing and certification by the Member State of origin is valueless unless there is a harmonization of test methods, with conformity of testing organizations and certification bodies to an agreed standard.
15. The Commission envisages that test methods will be harmonized by the European standards organizations; that the testing organizations and certification bodies may be accredited to a common standard (CEN/CENELEC standard EN 45 000 series) and notified to the Commission by Member States.
16. By these measures the Commission intends to reduce to a minimum the use of Article 36 by Member States and the number of referrals to the Court of Justice.
17. The Commission believes that this regulatory sector covers only a minor proportion of the Community trade.
18. The major part of trade is concerned with products whose level of risk does not justify regulations in any Member State. This is the non-regulatory (private) sector. The products are subject to Article 30, the Cassis de Dijon ruling and Article 36 and also certain rules of general applicability (e.g. producer liability). National and regional variations, tradition, custom and consumer requirements can constitute effective barriers to trade.
19. The non-regulated sector responds entirely to consumer choice which may or may not call for standards subject only to any arrangements which individual Member States may make to protect their consumers in general from unsafe or defective products. Consumer choice involves a choice of quality as well as depending on price and supply.
20. Quality is assessed in many Member States by reference to standards. Two Member States have sophisticated quality control and accreditation networks, four more are developing theirs while the remainder have yet to develop them.
21. A quality control mechanism involves standard-making bodies, testing bodies and quality assurance bodies with certification procedures. The testing and certification bodies need to be accredited to a common standard by a Member State accreditation body.
22. The Communication on the Global Approach (Section II, page 19 below) seeks to encourage a European approach to derive a Community Quality Assurance network based on mutual recognition and trust.
23. Standards may constitute a barrier to trade and the Community has therefore introduced two procedures.
24. Directives 83/189⁽¹⁾ and 88/182⁽²⁾ require the Member State national standards bodies to submit their standard making programmes to the Commission, which then passes these to the European Standards Organisations CEN and CENELEC. This procedure is not yet working as effectively as it should.
25. The other procedure has been introduced as part of the New Approach whereby such Directives empower the Commission to mandate CEN and CENELEC to prepare harmonized European standards incorporating the essential requirements. Reference to these standards where and when they exist is then mandatory under the Public Supply and Public Procurement Directives.
26. The Commission has seen fit to reinforce consumer protection by three further pieces of adopted or proposed legislation.

(1) OJ No. L 109, 26.04.1983, page 8.

(2) OJ No. L 81, 26.03.1988, page 75.

27. Legislation mainly designed for the protection of workers lays down "minimal requirements" according to Article 118A and/or regulations in that area.
28. Legislation on Product Liability has been adopted but remains to be put into practice in a number of Member States.
29. The Commission is proposing to the Council to complement Product Liability legislation by a general requirement on "manufacturers", importers and traders to produce and market only safe products (COM(89) 162 final, 7 June 1989)⁽³⁾. The ESC produced its Opinion on this proposal on 31 January 1990 (CES 85/90)⁽⁴⁾.

* * * *

(3) OJ No. C 193, 31.07.1989, page 1.

(4) OJ No. C 75, 26.03.1990.

OPINION
of the
Economic and Social Committee
on the
Commission Green Paper on the Development of European Standardization:
Action for Faster Technological Integration in Europe
(COM(90) 456 final)

On 8 November 1990 the Commission decided to consult the Economic and Social Committee, under Article 198 of the Treaty establishing the European Economic Community, on the

Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe (COM(90) 456 final).

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 8 March 1991. The Rapporteur was Mr DE KNEGT.

At its 285th Plenary Session (meeting of 20 March 1991), the Economic and Social Committee adopted the following Opinion by a majority. There were seven votes against and 12 abstentions.

* * *

1. Introduction

- 1.1. Standardization is of great importance for realizing the Single Market through the abolition of technical barriers to trade and makes possible higher productivity, a more competitive economy and a wider choice for the consumer. Related to this are also improvements in product safety and workers' health protection.
- 1.2. Standardization offers economic advantages through the avoidance of costs involved in having to produce differing series of products for different markets. These costs were too opaque to be assessed in the Cecchini Report, but they are undoubtedly high.
- 1.3. The EEC Treaty establishes the legal authority of the Council and the Commission to regulate, inter alia, the free movement of goods in the internal market.
- 1.4. The so-called "old approach" to the removal of technical barriers to trade contained detailed specifications to harmonize the provisions of Member States. This concentration on detail was dropped with the "new approach"⁽¹⁾, which lays down only "essential requirements". These are incorporated into the laws of the Member States via Community Directives.
 - 1.4.1. Standards, whether national or "harmonized", help ensure that products respect those essential requirements: reference to a "harmonized" standard provides presumption of conformity with the essential requirements.
 - 1.4.2. Standards which are shown not to conform with the essential requirements need to be withdrawn and replaced.
- 1.5. Standards based on the essential requirements of the "new approach" Directives, which cover a wide range of products, are drawn up at European level by CEN/CENELEC/ETSI under mandates from the EC Commission.
- 1.6. The lack of European standards does not necessarily mean the absence of rules. But some standards are so directly linked to considerations of safety and health that in practice trade in products of this kind for which no harmonized standards have been laid down could be difficult and even dangerous.
- 1.7. For this reason, European (and if possible international) standards for the improvement of health, safety and environment are important for the success of the internal market. The present situation with regard to the laying down of European standards, although improved, is unsatisfactory in terms of realizing the Single Market.
- 1.8. Since 1985, as foreseen by the White Paper on Completion of the Single Market, several significant Directives have been adopted by the Council (e.g. for machines, toys, pressure vessels, personal protective equipment).

(1) Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards - OJ No. C 136 of 4 June 1985.

- 1.9. These Directives underpin the need to draw up standards, e.g. on the design of products, in order to achieve the high level of protection of health, safety and environment required by the Single European Act. Standards, however, are voluntary, unless made mandatory through specific binding measures. The Committee stresses the need for further voluntary standardization in the "non-regulatory sector". These standards are necessary for better productivity, proper development of the economy and a wider choice for the consumer.

2. The Commission's initiative

- 2.1. Over the last few years, the Commission and the Economic and Social Committee have emphasized:
- support for the new approach as a factor for the development and realization of a Community market;
 - the need for a balanced representation of the interests of producers and users of products (including final consumers and workers), undoubtedly a requirement for removing trade barriers and a guarantee of a high level of safety.
- 2.2. In its Opinion ⁽²⁾ (27 September 1989) covering the report on the implementation of Directive 83/189 ⁽³⁾, the Committee said it was expecting a communication from the Commission taking account of progress in the field of standardization in the internal market and relations between the Commission and the European standardization organizations.
- 2.3. The Economic and Social Committee therefore welcomes the Commission's initiative to promote a debate in Europe on the development of European standardization. Indeed, five years after the adoption of the Council Resolution on standardization, and on the basis of the "new approach", the time is now ripe to review at European and national levels the role and work of the standardization organizations, the decision-making procedure on standards and the role of the parties involved in that procedure. It is also time to make a closer assessment of the current financial and working relationships between the Commission and the standardization organizations.
- 2.4. This initiative appears even more important in the light of the practical implementation of the Directives adopted on the basis of Article 100A in the context of the Council Resolution on the "new approach".
- 2.5. These Directives start from the assumption that European standards are in keeping with the EEC Treaty; these standards are of the utmost importance for the optimal realization of the Internal Market.
- 2.6. Directives and European standards provide the framework for product development and product safety, without which standards might be of a lower level or Member States could develop their own standards, which would not always correspond to the desired development at the European level.
- 2.7. The Green Paper expresses the wish that all "future European standards should exist **in their own right** and should not have to be transposed at national level before they can be used" (point 83). This is legitimate. However, countries should still be able, within the limits of the Treaty, to lay down standards concerning safety, the protection of workers and consumer and environmental protection which are stricter than those in force at European level, provided that such standards do not bring about unfair competition.
- 2.8. It is important that standardization be organized primarily at an international level. This would prevent countries protecting themselves artificially from international competition, as abusive standardization practised at national level may lead to protectionism. It is also at international level that one must establish where justifiable standardization ends and protectionism begins.

3. Assessment of the existing situation

- 3.1. The ESC endorses the Commission's assessment of the activities developed by CEN and CENELEC, which are described by the Commission as insufficiently flexible. In the Committee's view, in order to create as soon as possible the standards called for by the Commission, CEN/CENELEC must be given the chance to work more efficiently.

(2) OJ No. C 298 of 27 November 1989.

(3) OJ No. L 109 of 26 April 1983

- 3.2. National authorities expect openness from national standardization organizations, and expect agreement on this among all the parties concerned.
- 3.3. The Committee takes the view that these requirements must also apply at the European level, (where openness in the formulation of European standards is at present insufficient), bearing in mind the fundamental role which European standards play in implementing European legislation. It should also be noted that a number of areas which will be covered by standards in the future are at present regulated in a number of Member States by laws or by joint bodies, representing employers and workers.
- 3.4. In addition, the Committee refers to Article 100A, which requires the Commission to take as a base a high level of protection, providing for high quality standards, which would guarantee a progressive level of safety for workers and consumers - in other words, standards which ensure progress.

4. Coordination and reporting

- 4.1. In view of the lack of an integrated documentation system and of coordinated progress reporting, it is at present impossible for any interested party to have an overall view of the work of the European standardization bodies.
- 4.2. There should therefore be an effort to coordinate the work programmes of CEN, CENELEC and ETSI in the short term, in order to avoid duplication and incompatible standards. The available instruments could be improved in order to speed up the adoption of standards.
- 4.3. In this context it can be important to set up a European standardization data bank, including for example an index of available sources, bibliographical data on national and European standards and surveys of current standardization activities. It is to be recommended that the data bank use a standard "user-friendly" language for interrogation or search. The content of the data bank should as a general rule be available in all Community working languages.

5. Participation in drawing up standards

- 5.1. In view of the need for agreement on standards, the Committee feels that the Community should call on the standardization committees to reach an agreement among all parties involved in standardization (including consumers and the social partners), based on effective participation.
- 5.2. This need for the participation of the social partners is emphasized in a number of EC Directives adopted by the Council.
- 5.3. In this connection the Committee is seriously concerned about the almost total absence of the social partners from the process, the lack of consumer representation in the large majority of Member States, and the current impossibility for the standardization bodies to involve all interested parties in their work. The Committee therefore urges the Commission and the Member States to devote more attention to strengthening the role of all interested parties, thus counteracting any possible one-sided influence and helping to achieve the right balance in standardization work.
- 5.4. In view of the above, the Committee feels there is an urgent need to draw up standards, but stresses that they must be of good quality and (as mentioned above) must provide a progressive level of protection. It therefore regards the participation of all interested parties as a necessary priority, and stresses the starting-point of complete transparency, to make it possible for all parties to participate.
- 5.5. The principle of "openness" should be applied to the standardization procedure. The Committee therefore thinks that before the results of the work of the European standardization organizations are published in the Official Journal of the EC, the Commission and the Member States should ascertain whether the standards are in line with the protection aims of the EC Directives.

The drawing up of European standards in order to achieve the aims of protection laid down in the EC Directives is a task of public importance carried out by standardization organizations under Commission mandates, which arise from the Commission's political responsibility for this matter. As a matter of principle, the publication of the results of standardization cannot therefore be protected

by copyright. However, this does not mean that standards in the public domain can be freely used by all and sundry. In this respect the holder of the industrial property right for a product or process covered by a standard has a right to protection.

6. Commission proposals

- 6.1. The Committee supports the aim of those Commission proposals which seek to speed up the procedure for European standards. However, it would draw attention to the fact that shortening the timescale for public consultation should not be done at the expense of the quality of standards or without all interested parties being able to take an effective part in the process.
- 6.2. In addition, the Committee takes the view that the general application of the qualified majority rule at all stages of the process, and particularly at the level of the working group and the technical committee, should obstruct consensus as little as possible.
- 6.3. The Committee has sympathy for the Commission's proposals to strengthen the role of European industry in the European standardization process. However, in the present situation, where experts come generally only from industry and government, the participation of workers and consumers at an early stage is important in the development of standards.
- 6.4. It is important for standards to be in the language of the country concerned. It is not only of great importance for enterprises but also for workers and consumers, so that there can be no ambiguity as to interpretation of the standards. The translation of standards can only be done by specialists, who can however only be found through the national standardization organizations. The Committee realizes that this is not an easy problem to solve, bearing in mind also that the EFTA countries are involved, but wishes at least to raise the subject.
- 6.5. Health and safety measures are not just a matter of establishing standards. It is important for workers and consumers to be consulted at the time when the Commission is drawing up the essential safety provisions. Workers in particular must be invited to make a greater contribution than hitherto through existing bodies. Regarding consumers the Economic and Social Committee is therefore thinking in terms of the setting up of a specific consumer body for standardization, where problems of standardization in general can be discussed and from which the representatives in the CEN can be designated. In this respect the Committee endorses the proposals submitted to the Commission by the CCC (Consumers Consultative Council) in its Opinion on the Green Paper on European Standardization.
- 6.6. The Green Paper does not give enough details on the process of checking compliance of products on the market with standardization rules. It would be useful in particular to provide a procedure for the distribution of reports on compliance with product standardization rules.

7. Adequacy of standards

- 7.1. The Committee feels that it would be fair if the Commission, in proper consultation with the Member States, were to make proposals on the future role of the standardization bodies in relation to the adequacy of standards. The standardization bodies should inform the Commission and the Member States of the progress of work and the adequacy of the standards which have been and are being developed.
- 7.2. As regards changing the procedure for drawing up standards, the Committee sympathises with the Commission's call for the use of the qualified majority rule at all stages to speed up the process, but would regret it if this were to push the important principle of "consensus on standards" into the background.
- 7.3. In this context, the Committee has noted that up to now hundreds of standards have been requested from the European standardization bodies with a view to implementing the Internal Market. But the development and adoption of standards will not cease on 1 January 1993, since it is an ongoing process.

8. Testing and certification

- 8.1. The Committee approves in principle a separation between standardization (including specification of testing methods where appropriate) and testing and certification.

The setting up of a European Organization for Testing and Certification (EOTC) is a first step in this direction and is welcomed by the Committee.

Besides the transfer of certification agreements from CEN/CENELEC to the EOTC and the strengthening of this organization, the Community should release sufficient funds from the budget to help those Member States whose certification and testing structures lag furthest behind (as indeed is proposed in the Commission Communication COM(89) 209 on a Global Approach to Certification and Testing).

- 8.2. The Member States should ensure a guarantee of quality linked with the use of the European mark. The Committee points out the basic role of the national governments here, since, if this is not undertaken properly, the success of the whole European standardization process would be undermined.
- 8.3. Time will tell to what extent a European certification procedure can ensure that producers conform to the requirements, and show the ultimate value of such a procedure for the final consumer.

9. No increase in the number of full members

- 9.1. The Committee also sympathizes with the Commission's view that a rapid increase in the number of full members of the European standardization bodies could obstruct the aim of developing European standards rapidly.
- 9.2. Nonetheless, the Committee urges the Commission to ensure that central and eastern European countries remain or become closely involved in the development of European standards. This is important not only for those countries themselves but also for possible economic growth in the Member States of the Community. Therefore the Committee welcomes and supports all efforts to achieve the objectives of the European standardization process in European countries outside the EC and EFTA. The Commission is urged to reinforce its efforts in this context.
- 9.3. In addition, the Committee calls for attention to be given to the worldwide standardization which takes place in the ISO framework. The Committee therefore proposes that ISO standards and European standards be harmonized as far as possible with a view to avoiding (technical) trade barriers vis-à-vis non-Community countries. This could also remove the current apprehension in non-Member countries about the development of a "Fortress Europe" in the standardization sphere.

10. Future structures

- 10.1. The Committee welcomes the idea of an organization such as the European Standardization Council proposed by the Commission to improve coordination and coherence, propose priorities and encourage participation and transparency in the field of European standardization, including the national level. This in no way means that the Committee also endorses the composition of the Council as indicated in the Green Paper.
- 10.2. The Committee stresses the need for a balanced representation of the European organizations concerned; in this context, it must be assumed that the national structure plays a crucial role in the application and future development of the standards.
- 10.3. As to the future role of the national bodies, the Committee reiterates that the national level must be in the forefront in enabling all interest groups to participate.
- 10.4. The Committee feels that the proposal to strengthen the role of the ASBs ⁽⁴⁾ may lead to a different approach, for example in the sphere of safety; not all interested parties may be involved in the standardization process. The Committee is worried that this could lead to more red tape.

(4) ASBs = Associated Standardization Bodies.

- 10.5. Taken together with the direct financing by industry, this proposal could endanger the necessary balance between producers and consumers as the latter would no longer be involved.
- 10.6. The Committee urges the Commission and the Member States to do their utmost to support the participation of all parties, and especially that of trade unions and consumer organizations.
- 10.7. In this connection the Committee welcomes the support given by the Commission to the trade union movement's technical committee on safety and health, responsible for providing information and technical assistance to trade union representatives in European standardization work.
- 10.8. Account must also be taken, in the context of further discussions, of the proposed creation of a tripartite standardization committee under the auspices of the Advisory Committee on Safety, Hygiene and Health Protection at Work.

11. The need for a signal from the Council of Ministers

- 11.1. The Committee supports the idea of strengthening the links within the European standardization system through a clear Decision of the Council of Ministers. Such a Decision would indeed have political significance.
- 11.2. On the Commission's idea of following this up with a promise of financial support from the Community, no position can yet be taken. The Committee would first like to be better informed on the basis for the financing, which should benefit not only industry but also all bodies within the Community which are involved in standardization.

12. Final comments

- 12.1. The Committee would ask the Commission to follow the technical work of the European standardization bodies closely, particularly at the crucial stages, and to give them the necessary technical and legal information to enable them to concentrate the scope of their work on the essential requirements for implementing the basic safety provisions of the Directives.
- 12.2. The Committee calls on the Commission to provide, where applicable, interpretations of the essential requirements more quickly, as, until this is done, the standard setting process cannot begin.
- 12.3. Bearing in mind, then, that in the field of protection of citizens' health it is the role of governmental bodies to lay down, for example, maximum exposure levels to dangerous substances, the Committee would ask the Commission, once the relevant decisions have been taken, to supply the European standardization bodies with the relevant values and to inform them that the laying down of such values falls outside the Commission's terms of reference.
- 12.4. The Committee agrees with the Commission's view that it can be of great importance in the context of European standardization for industrial sectors to second experts for standardization work. Medium and small-sized firms, particularly in specific sectors, usually do not have this possibility, although they undoubtedly have the interest and expertise to make a contribution. The Committee therefore urges the Commission and public authorities in general to give small and medium-sized enterprises such support as will enable them to make their own contribution to standardization work.

Done at Brussels, 20 March 1991

The Chairman
of the
Economic and Social Committee

François STAEDLIN

The Secretary-General
of the
Economic and Social Committee

Jacques MOREAU

OPINION
of the Economic and Social Committee
on the
Communication from the Commission to the Council on
A Global Approach to Certification and Testing -
Proposal for a Council Decision concerning the modules
for the various phases of the conformity assessment procedures
which are intended to be used in the technical harmonization directives
(COM (89) 209 final - SYN 208)

On 14 August 1989, the Council decided, in accordance with Article 100a of the Treaty establishing the European Economic Community, to consult the Economic and Social Committee on

A Global Approach to Certification and Testing -

Proposal for a Council Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives

(COM(89) 209 final - SYN 208).

The Section for Industry, Commerce, Crafts and Services was instructed to prepare the work on this topic and adopted its Opinion and Report on 9 February 1990. Rapporteur: Mr de NORMANN.

The Economic and Social Committee, at its 274th Plenary Session, meeting on 28 February 1990, adopted the following Opinion by a majority with 1 abstention.

* * * *

1. Summary Conclusions

- 1.1. The Committee supports the overall objectives of the Commission Communication - A Global Approach to Certification and Testing - Quality Measures for Industrial Products - (COM(89) 209 final, 24 July 1989), together with the proposal for a Council Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in technical harmonization directives.
- 1.2. In particular the Committee:
 - 1.2.1. Supports the modular approach to testing and certification in the form of standard procedures for selection for use in future New Approach Directives and in the revision of existing New Approach Directives adopted by the Council in the regulated sector of the Internal Market.
 - 1.2.2. Endorses the emphasis on transparency and the creation of confidence in the regulated sector through the use of the new CEN/CENELEC standards (EN 45000 series) as a means for Member States to ensure equivalence and independence in their nomination of laboratories and certification bodies. Bodies meeting the new EN 45000 series of standards of competence should be regarded as satisfying the technical requirements for Member State government nomination to carry out certification and testing under directives.
 - 1.2.3. Encourages the promotion of quality assessment through the use of the CEN/CENELEC (EN 29000 series) standards.
 - 1.2.4. Supports the emphasis on mutual recognition of products legally placed on the market in the different Member States whereby different national standards can coexist as available criteria to be freely invoked voluntarily anywhere in Europe. This applies to the non-regulated sector.
 - 1.2.5. Approves the intention of the Commission in the non-regulated sector to build on systems which are in place at the national level either by broadening their scope or by developing understanding between existing schemes, rather than creating from scratch a centralized European system. The European Organisation for Testing and Certification (EOTC) envisaged will act as a forum to enable those with an interest in developing mutual recognition agreements to come together and reach an understanding, drawing upon the experience and resources of the European standards bodies CEN and CENELEC.
 - 1.2.6. Supports the concept of the global approach which requires an infrastructure for certification and testing to be put in place which will inspire trust and confidence and guarantee access to the market under similar conditions. The Committee recognizes the need for positive measures (e.g. know-how transfers) and budgetary support to help build up these structures in those countries of the Community where it is needed.
 - 1.2.7. Underlines the necessity to provide for the co-involvement of social forces (industry, workers, consumers) in both the regulated and non-regulated sectors.

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The Committee wishes to bring attention to certain aspects concerning the detail of the proposed policy and its implementation by the Commission, especially with regard to the coordination with existing Directives and the need for further work in some areas.

2. Preamble

2.1. The Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards stated that this should be accompanied by a policy on the assessment of conformity.

2.2. In response the Commission have made a proposal for a Global Approach in this area with the aim of creating the conditions which will enable the principle of mutual recognition of proofs of conformity to operate in both the regulated and the non-regulated spheres.

2.3. On 21 December 1989 the Council approved a Resolution submitted by the Presidency. This approves the basic lines of that approach and adopts the following guiding principles for a European policy on conformity assessment:

— A consistent approach in Community legislation should be ensured by devising modules for the various phases of conformity assessment procedures and by laying down criteria for their use in those procedures, for the designation and notification of bodies under those procedures and for the use of the CE mark;

— Generalized use of European standards relating to quality assurance (EN 29000) and to the requirements to be fulfilled by the bodies mentioned above (EN 45000), the setting up of accreditation systems and the use of techniques of intercomparison should be promoted in all Member States as well as at Community level;

— The promotion of mutual recognition agreements on certification and testing between bodies operating in the non-regulatory sphere is essential to completion of the internal market; the setting up of a flexible, minimally bureaucratic testing and certification organisation at European level with the basic role of promoting such agreements and of providing a prime forum within which to frame them should contribute significantly to the furtherance of that objective;

— Possible differences in levels of development in the Community and in industrial sectors with regard to quality infrastructures (especially calibration and metrology systems, testing laboratories, certification and inspection bodies and accreditation systems), such as are likely to have an adverse effect on the operation of the internal market should be studied with a view to the preparation of a programme of Community measures including possibly budgetary measures as soon as possible;

— In its relations with third countries, the Community will endeavour to promote international trade in regulated products, in particular by concluding mutual recognition agreements on the basis of Art. 113 of the Treaty in accordance with Community law and with the Community's international obligations while ensuring in the latter case that:

. the competence of third country bodies is and remains on a par with that required of their Community counterparts;

. the mutual recognition arrangements are confined to reports, certificates and marks drawn up and issued directly by the bodies designated in the agreements;

. in cases where the Community wishes to have its own bodies recognised the agreements establish a balanced situation with regard to the advantages derived by the parties in all matters relating to conformity assessment for the products concerned.

The Commission is requested to submit recommendations to the Council as soon as possible for detailed negotiating directives under Art. 113 of the Treaty.

The Council calls on the Commission to prepare the measures necessary to put this Resolution into practice."

- 2.4. The Committee has not been asked for its Opinion on this Council Resolution, which it regards as a statement of political will by the Council. Nevertheless the Committee has taken this Resolution into consideration when preparing this Opinion.
- 2.5. In its consideration of the Commission Communication and indeed in all its previous considerations on technical harmonisation in the regulated sector, the Committee urges that a consistently high level of protection be set, with the active participation of producers, workers, consumers, for health, safety and the environment in accordance with Art. 100 (a) 3. No Member State should be asked to lower its regulatory levels or should find the need to invoke Art. 100 (a) 4.
- 2.6. This high level can be applied under both the Old Approach and the New Approach Directives in the form of essential requirements defining a base level of protection below which no product may be placed on the market whatever its origin.
- 2.7. The Old Approach Directives defined all the technical requirements. The New Approach Directives require (in all instances except the Construction Products Directive) the appropriate European standards bodies to agree the details of essential requirements and express them in European standards.
- 2.8. The Committee regards it as important that once these high levels have been set there should be a mechanism to ensure that they are respected.
- 2.9. For the market to function efficiently, an infrastructure will be necessary to ensure that products placed on the market conform to the regulatory requirements and may be marked accordingly. Procedures for the assessment of conformity must be given in Technical Harmonisation Directives and the bodies which operate these procedures in each Member State should be accredited by a European accreditation network which commands confidence.
- 2.10. However the major part of the goods traded in the internal market fall within the non-regulated sector where barriers to trade arise from voluntary rather than regulatory causes, for example variations in standards, testing and certification requirements imposed by individual purchasers reflecting different national commercial practices.
- 2.11. The harmonisation of standards can only be effective if it is matched by a harmonisation of the procedures used to assess conformity to those standards.
- 2.12. The Committee has considered this Communication in the light of the overall need for the smooth functioning of the internal market through the creation of fair trade, free competition and a high standard of protection for the benefit of producers, workers and consumers alike.

3. Scope

- 3.1. The Committee notes that the Commission has not defined the scope of "industrialised products".
- 3.2. It understands that the Commission intends to formulate a mechanism whereby products manufactured by industrialised methods or processes answer the requirements of consumers. This distinguishes clearly between products made by industrialised processes and products made either by craft processes or according to a specific design requirement by a consumer.
- 3.3. The Committee believes that this should be spelled out more clearly in the proposal to avoid border line difficulties which may arise.
- 3.4. This proposal as it stands does not apply to food and agricultural products, although many are subject to industrial processing. The Commission is studying the situation and food manufacturers have been interested in the New Approach since 1985. The Commission believes that the mechanisms are capable of application to food and agricultural products and indeed to pharmaceutical, veterinary and plant protection products if the manufacturers wish to make use of them as a means of ensuring safety through quality assessment.
- 3.5. The Commission does not intend to propose revision of the relevant directives unless all those concerned decide they want to move to the mechanisms described in this Global Approach.

- 3.6. "Global" refers to the need to build up an infrastructure throughout the Community and to the expectation by the Commission that a common approach to certification and testing will be adopted in future New Approach Directives and will be found to be attractive in the future to sectors of industrialised production which currently follow Old Approach Directives in the regulated sector and will recommend itself widely throughout the non-regulated sector.

It will bring in its train the overall infrastructure necessary to establish the technical environment for the free circulation of goods.

This proposal introduces measures in the context of which it will be necessary to create an infrastructure based not only on harmonised regulations and standards but also on mutual acceptance of certification and testing, on a degree of inspection and above all on confidence and trust between all parties.

The creation of the infrastructure together with the trust and confidence that it operates evenly over the Community will require positive action both by the Commission and by Member States.

- 3.7. An "approach" refers to the belief by the Commission that the climate in which certification and testing will be used to demonstrate conformity can never be created by regulation alone. It must grow by mutual agreement at trading level.
- 3.8. "Certification and Testing" refers to mechanisms whereby products made by industrialised processes and traded throughout the Community are shown to conform both to regulatory requirements and to standards followed by the manufacturers and required by the consumers.
- 3.9. The Committee understands that by "testing" the Commission means Conformity Assessment and Evaluation.

4. Principles

The Committee identified main foundations and basic principles which should underlie the proposals:

- 4.1.1. A European standardisation policy leading to the New Approach to technical harmonisation and standards (EC Council Resolution of July 1984 - Conclusions on Standardisation);
- 4.1.2. Agreement by the Member States on mutual recognition of the results of tests and the establishment where necessary of harmonized rules as regards the operation of certification bodies;
- 4.1.3. Extension of the Community practice in matters of technical harmonisation of entrusting the task of defining the technical characteristics of products to standards, preferably European but if necessary national, where the conditions necessary for this purpose, particularly as regards health protection and safety are fulfilled;
- 4.1.4. Cooperation at European level between official and voluntary interests within the framework of EEC Treaty Art. 100 (including Art. 100a added by the Single European Act) on the removal of non-tariff barriers to trade (ESC Opinion 1020/89, ⁽¹⁾ 27 September 1989).
- 4.2.1. In accordance with the Community doctrine of mutual recognition established in the Cassis de Dijon case and reconfirmed by subsequent decisions of the European Court of Justice, different national standards can coexist as available criteria to be freely invoked anywhere in Europe or indeed elsewhere. The standards reflect particular market preference which may legitimately differ but so long as the provisions of Art. 36 of the Treaty cannot be invoked by any authority, no barriers to trade need result (ESC Opinion 1020/89, ⁽¹⁾ 27 September 1989).
- 4.2.2. The mechanism put into place must achieve the aims of the Single European Act and the responsibilities of the Community in respect of all persons, industrialists, workers and consumers alike. No Member State should be compelled to change its legislation to permit a reduction in its minimum requirements for health and safety of its citizens and the protection of its workers. Levels of safety and protection must be respected. Furthermore Member States should be encouraged to improve them as envisaged in the Single European Act.

(1) OJ No. C 298, 27 November 1989, page 19.

- 4.2.3. The minimum level of regulatory requirement must be met by all products placed on the market in the regulated sector (suitably attested by the CE mark).
- 4.2.4. Consumer choice must remain paramount in any decision to purchase goods legally placed on the market both in the regulated and non-regulated sectors. The Commission must ensure that those purchasers who require goods to a higher level of protection than the essential requirements demand are not prevented from specifying them by questions of restraint of trade. Consumer information should set out the essential requirements to which the product must conform in order to carry the CE mark.
- 4.2.5. In the non-regulated sector the Commission should respect the principle of subsidiarity by encouraging bottom-up growth based on existing arrangements and promoting an organisation to support this.
- 4.2.6. Transparency is vital in that the overall organisation must be easy to understand, generate trust and confidence, apply the minimum but necessary checks with the least possible bureaucracy.
- 4.2.7. In the non-regulated sector Quality Assurance schemes must be available to meet consumer requirements and must not be subject to restriction on grounds of restraint of trade. Competition in quality, price and delivery subject only to minimum regulatory requirements is essential to the market.
- 4.3. The Committee believes that the proposals made in the Communication follow these principles in so far as they have been elaborated. However, it sees the risk that the conformity assessment infrastructure could easily become over-organised and excessively bureaucratic unless continuing care is taken to follow the bottom up approach with the minimum interference from the Commission.
- 4.4. The Committee also fears that procedures for the regulated public sector will diverge from the non-regulated private sector unless the European Organisation for Testing and Certification is actively encouraged to participate in the public sector.

5. The Social Implications

- 5.1. The Committee has always emphasised that the writing of standards at both national and European level and their harmonisation requires the cooperation and participation of all the interest groups involved, not only of manufacturers and authorities but also workers, users and consumers. This is essential particularly with regard to their health, safety and welfare.
- 5.2. In this respect the Committee draws attention to its Opinion CES 761/86 of 15 September 1986⁽²⁾ and to its Opinion CES 1020/89 of 27 September 1989⁽³⁾.
- 5.3. The Committee believes that this applies equally to the policies and procedures proposed in this Communication. It urges the Commission once again to extend the basis for cooperative discussion on standards, certification and test procedures affecting health, safety and welfare and to continue to promote the closer involvement of the social and other interest groups involved.
- 5.4. The Committee considers it to be essential that all interested parties should be involved in the preparation of an infrastructure for the Internal Market based on mutual confidence and trust.
- 5.5. It asks the Commission in this and in other Communications to consider ways of achieving the necessary consultation and involvement of all the interested parties.

6. Overlap with other Directives

- 6.1. The Committee is concerned that overlap and contradiction between the Global Approach and the Product Liability, General Product Safety and Safety at the Work Place Directives should be avoided.
- 6.2. The Commission intends the Global Approach to reinforce the Product Liability Directive in that the manufacturer is encouraged to take as much responsibility as possible and is given as much flexibility as possible over the requirements for safety of his products. The manufacturer must be responsible for the safety of the product he places on the market and the Global Approach does not reduce his legal responsibility although its applications may help him to defend himself in Court.

(2) OJ No. C 328, 22 December 1986, page 20.

(3) OJ No. C 298, 27 November 1989, page 19.

- 6.3.1. The Commission is proposing the General Product Safety Directive in order to strengthen the Council Resolution of 7.5.85 on a new approach to technical harmonisation and standards⁽⁴⁾ and the New Approach Directives which are based on it. Additional obligations are placed on the Member States, on those who manufacture and/or place a product on the market and on the Commission.
- 6.3.2. The Commission considers that the General Product Safety Directive approaches the problem in a different way without fundamental overlap by harmonising the mechanism for the withdrawal of unsafe products from the market and therefore it complements the Global Approach in acting as a safety net to catch what other Directives miss.
- 6.4. The Committee suggests that the Commission be asked to review the interrelation between the Directives on a strictly legal basis and then issue a simple guide which can be understood by producers, workers and consumers alike.

7. Creation of a Community-wide infrastructure

- 7.1. The Committee recognises the necessity in the Internal Market for a "global" infrastructure to be put in place which commands confidence and inspires mutual trust.
- 7.2. This will not be achieved without positive effort both by the Commission and by Member State governments.
- 7.3. The Committee welcomes the intention of the Commission to issue a Communication on the Internal Market Programme which will deal with requirements for a suitable infrastructure and another Communication on the implementation of New Approach Directives. This latter should include requirements for inspection arrangements and procedures for cooperation between notified bodies.
- 7.4. The Committee welcomes the Commission Decision to set up a computerised data base to cover all certification bodies.
- 7.5. It understands that the Commission will pay special attention to the needs of SMEs.
- 7.6. The Community appears to lack a sufficiency of basic laboratories for requirements such as calibration and metrology. The Commission needs to assess this need among the regions of the Community and to promote cooperation agreements whereby established laboratories will help each other with know-how and training.
- 7.7. There are numerous test laboratories in the Community but many may be inadequate and their distribution may be uneven. The Committee urges the Commission to assess this distribution together with that of certification bodies. The Commission should then come forward with proposals to redress inequalities by proposals to encourage a market-led operation to instal these bodies where they are needed.
- 7.8. The Committee urges the Commission to propose all necessary measures including budgetary measures to cause these bodies to be put in place where necessary and to be provided with the necessary know-how to begin operations without delay. The Commission should consider whether suitable resources can be found from within the Structural Funds. As the Global Approach takes effect, a market will be created in every Member State so these bodies once established should be self-financing. They must not however be supported in their operations in any way which could give cause for complaint on the grounds of unfair competition.

8. A European Organization on Testing and Certification

- 8.1. The Committee supports the concept of a European Organization for Testing and Certification (EOTC) proposed by the Commission as one of a series of measures to promote a Community infrastructure.
- 8.2. Its purpose will be to create and operate a mechanism to establish and demonstrate the competence of operators in the field of conformity assessment, especially, but not exclusively, in the private sector. It will need to promote cooperation between organizations and testing houses at Community level, perhaps along lines parallel to the voluntary European standards organizations.

(4) OJ No. C 136, 4 June 1985 - Council Resolution 85/C/136/01

- 8.3. The Committee realizes that the Commission will have the task, in cooperation with Member States, to act as a catalyst in the creation of the EOTC.
- 8.4. The Committee supports the Intention of the Commission, resulting from considerable discussion, to promote this structure within the aegis of the European standardization organizations, CEN and CENELEC. It also expects that all CEN and CENELEC experience will be available to EOTC.
- 8.5. The Committee has not been asked for its Opinion on the proposals made by the Commission to CEN/CENELEC. Nevertheless it has considered some basic principles concerning the structure proposed for EOTC.
- 8.5.1. It must be simple, transparent and basically free of bureaucracy.
- 8.5.2. It must clearly give equal weight to the interests of all Member States of both EC and EFTA, and to the interests of industrialists, workers and consumers.
- 8.5.3. It may operate under the umbrella of CEN/CENELEC but its identity must be clear, transparent and separate.
- 8.5.4. It may begin in the nursery of CEN/CENELEC using its administrative support but it must aim to remove itself to arms length as soon as possible.
- 8.5.5. It must have a Chief Executive at equal level to those of CEN and CENELEC responsible to a Governing Board independent of the Boards of CEN and CENELEC.
- 8.5.6. The organization must begin in the simplest form and only grow with its work load. It must avoid the taint of bureaucracy by having short lines of communication and a minimal committee structure.
- 8.5.7. The sectors should be formed by self-determination of the interested parties and do not need to conform to the fields covered by Directives. Initially they should be kept small and easy to define rather than compose an overall industry such as steel or construction products.
- 8.6. The Committee sees EOTC at first sight as the European body catalysing, advising and servicing groupings which have come together at industry level. It will develop criteria and guiding principles which will be available to all. It will support and sustain their work with a communal resource and where necessary advise and counsel them towards a common purpose.
- 8.7. It will also act as a centre of information making available to each potential new grouping on request experience gained in other sector groupings which have preceded them and encouraging best practice to come to the top. EOTC should resist any attempt to place sector agreements into any common mould relying rather on checking that agreements are sound, based on good practice and free of known difficulties.
- 8.8. The funding of EOTC will require careful consideration. There is much to be said for funding by means of a Commission mandate to CEN/CENELEC for the initial years in order to encourage fledgling sectors to make use of its services and avoid the temptation to look elsewhere. EOTC must make itself virtually indispensable.
- 8.9. The Commission has another important part to play. It must monitor performance in the light of its overall objectives for conformity assessment while keeping its hands off EOTC structure and rules.
- 8.9.1. It must ensure that EOTC is involved in the regulated sector whenever it can be of benefit.
- 8.9.2. It must bring the prenormative facilities of the JRC into the conformity of testing organization as an independent initiator of European test procedures.
- 8.9.3. It must ensure that the modules, essential tools for the use of sectors, are made workable, communicable and maintained in up-to-date condition by means of a flow-back of information and experience.
- 8.9.4. It must ensure that encouragement is given to certification and testing bodies working in the non-regulated sector under EOTC to come together or indeed be one and the same as notified bodies working the in the regulated sector.

- 8.10. The Committee welcomes the decision that the EOTC will involve the EFTA States in its organization as is the case with CEN/CENELEC.
- 8.11. The Committee urges the Commission to consider producing a Communication, allied perhaps to a draft Council Resolution on proposals for the EOTC, agreement with CEN/CENELEC to launch it and suggestions for the authority of the EOTC and for questions of liability and insurance.
- 8.12. Finally the Committee urges the Commission to encourage the EOTC to bring together the regulatory and non-regulatory procedures in order to avoid them becoming separate and distant compartments each operating separately. The responsibility for this will rest to a considerable extent with Member State governments which should endeavour to ensure that the nominated bodies which they notify under the Directives are also working under the aegis of EOTC, sector by sector, in the non-regulated sector.
- 8.13. The Committee realizes that this process cannot be hurried from the top down; rather it must be encouraged from the bottom up. It will not be complete by 1 January 1993.

9. Modules for conformity assessment

- 9.1. The Committee recommends the Council to adopt the Sole Article proposed for the Council Decision to agree the eight modules proposed for New Approach Directives and the criteria for their use.
- 9.2. At present there is inconsistency among the attestation procedures proposed for the various New Approach and Information Technology Directives.
- 9.3. These modules for inspecting, testing and certification (ITC) procedures leading to the CE mark, are proposed to harmonize the procedures of the New Approach Directives by offering a selection for choice for each specific Directive.
- 9.4. The modules to be chosen will depend inter alia on:
- the degree of risk and the safety precautions needed;
 - whether mass production is involved;
 - normal practice in that industrial sector.
- 9.5. The Committee approves the Commission principle that each Directive should provide the manufacturer with the maximum amount of choice of modules, although it realises that this may not be possible in every case.
- 9.6. Thus, each Directive should provide the manufacturer with the choice between a Quality Assurance and a Product Certification module. This will be of special assistance to SMEs.
- 9.7. The Committee approves the basic structure of the modules proposed and makes the following comments:
- 9.8. It foresees a number of tasks for the Commission:
- to explain in detail the operation of each module so that they become practicable and workable;
 - to devise a mechanism to ensure that the system operates fairly across the Community and to ensure that it is adequately policed;
 - to ensure uniformity of application by Member States through the issue of guidelines;
 - to simplify and reduce the information which "notified bodies" are required to publish and intercommunicate;
 - to clarify and improve the layout of the modular table and give more prominence to the footnotes;
 - to review the references to the EOTC in the modules before the status of that body has been defined;
 - to publish information adequate to ensure that every manufacturer understands his choice;
 - to ensure that the module details and procedures are available and accessible to those who have to use them.

10. The CE mark

- 10.1. The Committee urges that a Directive on the CE mark be produced as soon as possible.
- 10.2. It supports the Commission proposal that the CE mark applied to a product should indicate the conformity of that product with all relevant Directives which require a CE mark but not to others.
- 10.3. The Committee notes a number of points which will require attention:
 - 10.3.1. There is a need for compatibility between the terms "manufacturer" used in the Global Approach Directive, "placed on the market" used in the Construction Products Directive and "supplier" used in the General Product Safety Directive. This is among several problems of terminology which the Commission is urged to review.
 - 10.3.2. The grounds on which the CE mark may be withdrawn, the procedures for withdrawing it and the notification of its withdrawal should be harmonized.
 - 10.3.3. The question of how long a CE mark may be applied without some check must be tackled.
 - 10.3.4. The name of the organization which attached the CE mark and the date when it did so must be available publicly, perhaps in a register.
 - 10.3.5. National quality marks as they exist in Member States now or with future European quality marks as they are agreed by the EOTC may be appended but in no case displace the CE mark.
 - 10.3.6. The CE mark will be used first under the Toy Directive. The Commission should take steps to learn from the difficulties encountered there.
 - 10.3.7. The CE mark should be protected legally.

11. New Approach Directives adopted prior to the adoption of this Communication and Council Decision

- 11.1. The Committee understands that the "attestation requirements" set out in the Gas Appliance Directive and in similar New Approach Directives conform to the modules set out as appendices to the draft Council Decision.
- 11.2. The Committee notes, however, that this is not universally so. For the Construction Products Directive which is wide in coverage and which has a two stage process for selecting attestation procedures, a further decision has to be made by the Standing Committee, depending in part on the assessment of the risk of the product when correctly specified, installed and maintained within the building.
- 11.3. The Committee notes furthermore that the wording in the modules of the Construction Products Directive does not always have the same meaning as the wording in the Global Approach modules. For example, "type test" is a different concept from "EC type examination" in the Global Approach.
- 11.4. The Committee urges the Commission to tackle this problem as soon as the modules are adopted and to work to the principle that there must never be different attestation procedures for the same product under different Directives (example - for electrical lifts under Construction Products, Mechanical and Low Voltage Directives).

12. External aspects of the Global Approach

- 12.1. The Committee believes that the Commission needs to give further attention to its overall policy for third countries in its conformity assessment proposals.
- 12.2. In addition to its contribution to the smooth functioning of the internal market, the Global Approach must be structured in accordance with the developing relationship with EFTA States and take account of the position of the standards institutions of those States as members of CEN and CENELEC.

- 12.3. The Global Approach should not inhibit or retard progress towards the European Economic Space.
- 12.4. The Global Approach should contribute to a trading bloc which will function in accordance with GATT rules.
- 12.5. The Committee welcomes the intention to include mutual recognition agreements on the basis of Article 113 of the Treaty as set out in the Council Resolution on a Global Approach to conformity assessment (see above para. 2.3.).
- 12.6. It queries, however, the proposal that mutual recognition agreements should establish a balanced situation with regard to the advantages derived by the parties until it understands more clearly what is meant.
- 12.7. The Committee believes that the principles of confidence, mutual trust and a bottom up approach in the private sector should apply equally with third countries.
- 12.8. It does not believe that any alternative approach is practicable.
- 12.9. The Committee approves and supports the commitment of the Community to the work of the International Standardization Bodies ISO and IEC and to the principle of transparency in standards. It notes that the USA has announced a similar commitment and it supports the continuation of discussions between the two trading blocs with the shared goal of sustaining an effective liberalization of trade and investment.
- 12.10. In this respect the Committee urges the Commission to encourage the adoption of the "competence standards" EN 45000 series as international standards.
- 12.11. The Committee believes there must always be a legal requirement placed on the organization which places a product on the market within the Community.

13. Implementation

- 13.1. The Committee considers it important for the Council to agree the proposal as quickly as possible in order to demonstrate the political will required to achieve the objectives. Delay now will affect the achievement of the internal market in 1993 and beyond.
- 13.2. A Council Decision to adopt the modules will mean that these can be used in further New Approach Directives, as indeed is the case in the proposed Council Directive on the approximation of the laws of Member States concerning telecommunications terminal equipment including the mutual recognition of their conformity, COM(89) 289, 27 July 1989 (it proposes either an EC type examination (module B) or an EC declaration of conformity (module H)).
- 13.3. As soon as the modules have been approved by Council, the Committee urges Council and Commission to amend existing New Approach Directives.
- 13.4. The Committee considers that the accreditation mechanisms and certification testing procedures are on-going and encourages the Commission to proceed with them speedily.
- 13.5. The Committee also urges the detailed consideration of the steps necessary to set up the EOTC and the ongoing negotiations with the organizations of employers, workers and consumers which will be involved.
- 13.6. The Committee notes with satisfaction that the Commission has a detailed draft Memorandum of Understanding with CEN and CENELEC for the setting up of the European Organization for Testing and Certification.

14. Presentation of the Commission proposals

- 14.1. The Committee considers that the Global Approach document is too complex. It urges the Commission to prepare a simplified approach including visual explanations which can be used to inform and convince all groups of people including consumers, workers and industry (including SMEs).

Done at Brussels, 28 February 1990

The Chairman
of the Economic and
Social Committee

Alberto MASPRONE

The Secretary-General
of the Economic and
Social Committee

Jacques MOREAU

OPINION
of the Economic and Social Committee
on the
Report on the operation of Directive 83/189/EEC laying down
a procedure for the provision of information in the field
of technical standards and regulations 1984 - 1987
(COM(88) 722 final)

On 6 September 1989 the Commission decided, in accordance with Article 198 of the Treaty establishing the European Economic Community, to consult the Economic and Social Committee on the

Report on the operation of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations 1984 - 1987 (COM(88) 722 final).

The section for Industry, Commerce, Crafts and Services was instructed to prepare the work on this topic and adopted its Opinion on 6 September 1989. Rapporteur: Mr de NORMANN.

The Economic and Social Committee, at its 269th Plenary Session, meeting on 27 September 1989, adopted unanimously the following Opinion:

* * *

Summary

In this Opinion the Committee:

- comments on the Report on the implementation and operation of the Directive 83/189/EEC⁽¹⁾ over the years 1984 to 1987 (Article 11 of the Directive);
- makes suggestions for improvements in the operating procedures;
- recommends for the consideration of the Commission items for inclusion in a new draft directive which it understands is in preparation for submission to the Council.

1. General

1.1. The Council Directive 83/189/EEC of 28 March 1983 and its extension 88/182/EEC⁽²⁾ of 22 March 1988 have three objectives:

- to provide the Commission with an early warning of technical regulations proposed by Member States which may act as barriers to trade;
- to ensure total transparency of national plans for regulations and standards and to ensure effective cooperation between the Commission and the Member States in the creation of a single market;
- to ensure that the Commission and the Member States are jointly responsible for the proper working of these systems through a Standing Committee (Article 5 of Directive 83/189/EEC).

1.2. On 8 December 1988 the Commission issued a Report on the operation of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations 1984 - 1987. (COM(88) 722 final).

The Commission has undertaken this review four years after the entry into force of the Directive (1 January 1985) in accordance with Article 11 of the Directive which provides for a formal review of its operations and immediately before its extension to all products sectors in accordance with Council Directive 88/182/EEC of 22 March 1988.

1.3. The Committee considers that this Directive (the "Information Procedure Directive"), adopted on 28 March 1983, has operated effectively in preventing the creation of new technical barriers to trade within the Community in so far as it has instituted a mechanism for the collective scrutiny of draft technical legislation at national level and it has set up at the same time an institutional and procedural framework to facilitate and accelerate standardisation at European level.

(1) OJ No. L 109, 26.04.1983, page 8

(2) OJ No. L 81, 26.03.1988, page 75

- 1.4. This analysis by the Commission has led to proposals and plans for the more effective use of the procedures under the Directive. The Committee welcomes these proposals as a further contribution to improving transparency in standards work in the Community and to preventing the erection of new barriers to trade.
- 1.5. The Committee notes that Article 11 of the Directive is now amended to require an annual report from the Commission on the results of the application of the Directive and welcomes the intention of the Commission to submit these to the Economic and Social Committee, starting with the report for 1988.
- 1.6. The Committee notes that, although the Directive does not deal with general information about standards work, this is an essential precondition for the Directive to fulfil its objectives.

So the Committee underlines the need to increase substantially the diffusion within Member States of information about standards work amongst the Social Partners and to the public at large.

2. The social implications of the Directive

2.1. *The principle of voluntary cooperation.*

- 2.1.1. The Committee recognizes that an important aim of the Directive in the context of realizing a single European market is to stimulate initiatives to harmonize standards.

It emphasises yet again that the harmonisation of standards requires the cooperation and participation of all various interest groups involved, not only of manufacturers and authorities, but also workers, users and consumers. This is essential particularly with regard to their health, safety and welfare.

The Committee has always emphasised this and draws attention to its Opinion CES 761/86 of 17 September 1986⁽³⁾ in which it urged that particular attention be paid to the safety of users, workers and consumers in harmonising standards.

- 2.1.2. The Committee accordingly urges the Commission to extend the basis for cooperative discussion on standards affecting health, safety and welfare and to continue to promote the closer involvement of the social and other interest groups concerned.

2.2. *Cooperation in standards work*

- 2.2.1. The Committee notes that the Common Rules of CEN and CENELEC require that when forming and briefing their delegations to Technical Committee meetings, CEN and CENELEC members, which are the National Standards Institutions of the Member States, should ensure that they will convey a collective, national point of view which takes account not only of manufacturers but of all the interests affected by the work.

- 2.2.2. The Committee welcomes CEN/CENELEC Memorandum No. 5 "Trade Unions and the Preparation of a European Standard" which lays down a good basis for a substantial improvement in cooperation. In it the General Assemblies of CEN and CENELEC recommend:

- trade unions participation at national level in standards work and in policy matters relevant to the interest of the work force;
- the active participation of trade unions in national delegations to CEN or CENELEC committees developing an European standard;
- questions submitted by or proposals/drafts received from European trade union organisations should be given due consideration by the CEN/CENELEC body concerned.

- 2.2.3. Equally the Committee welcomes CEN/CENELEC Memorandum No. 2 "Consumer Interests and the Preparation of Standards" which makes equivalent recommendations to cover the interests of consumers.

- 2.2.4. The Committee believes however that further encouragement should be given to the involvement of the Social Partners in preparatory activity on standards projects at European level.

(3) OJ No. C 328, 22.12.1986, page 20

2.3. *Consultation on health and safety*

2.3.1. The Committee notes that a tripartite Consultative Committee composed of representatives of the Social Partners and the Commission meets several times a year in Luxembourg to exchange views and discuss proposals on health and safety.

Furthermore in March 1989 a tripartite working party, set up within the framework of the Consultative Committee, recommended that mandates for standardisation relating to Article 100 A (E.E.C. Treaty) be sent to that Committee for its opinion. The Committee supports this recommendation.

2.3.2. The Committee also welcomes the Commission proposal to give financial support to the ETUC (European Trades Union Confederation) to set up an operation to establish a technical expertise for the examination of proposals affecting hygiene and safety at work and to make their views known through the usual channels of the ETUC.

2.4. *Participation in the Standing Committee*

2.4.1. The Committee notes that the Standing Committee set up under Article 5 of Directive 83/189/EEC has the right of initiative and consists solely of two nominees from each Member State. There is no direct representation of Community social groups and the Commission does not intend to propose that there should be.

2.4.2. However, the Committee notes that the Commission holds at least two meetings a year of an extended Article 5 Standing Committee at which representatives of National Standards Institutions, CEN and CENELEC meet the nominees of the Member States.

The Committee asks the Commission to ensure that representatives of the consultative bodies of the Social Partners and the consumers are given the opportunity to submit their concerns to these meetings.

3. The information procedure for standards

3.1. *Principles of European standardization policy*

3.1.1. Chapter II of the report describes the operation of the information procedure for standards.

The Committee endorses the need for transparency in standards work and the role of CEN/CENELEC and their national members in ensuring it as a fundamental principle of European standardization policy.

3.1.2. The Committee supports the "General Guidelines" formally agreed by CEN/CENELEC with the Commission in November 1984 and with EFTA in April 1985.

These guidelines ensure cooperation at European level between official and voluntary interests within the framework of EEC Treaty Article 100 (including Article 100 A added by the Single European Act) on the removal of non-tariff barriers to trade.

3.1.3. The Committee notes that with this cooperation in view, the EC Council adopted a Resolution in July 1984 setting out the principles for a European standardization policy leading to the New Approach to technical harmonization and standards adopted by Council resolution 85/C 136/01. This established the principle of presumption of conformity to the essential requirements for products manufactured in accordance with CEN/CENELEC harmonised European standards. As a result the concept of general reference to standards has tended to replace the drafting of technical requirements for Technical Annexes to Directives.

3.1.4. The Committee recognises nevertheless that in order for CEN and CENELEC to play their necessary part in the Community and EFTA framework they must organise themselves and their relationship with their national standards institution members in such a way that they are able to anticipate demand, manage the necessary work, target and deliver it cost-effectively and competently. The Committee urges Member States and their national standards bodies to ensure that their input to these organisations in terms of resources of people and money is adequate, not only for the necessary work on standards making but also for the necessary promotion of the advantages of European standards.

- 3.1.5. The Committee also urges CEN/CENELEC and their national members to take the appropriate initiatives to promote and publicise the advantages of European standardisation, the means of achieving it and the opportunities for involvement in it, in forms which are simple and easily understood.

The Committee is concerned that the advantages of European standards and the procedures for making them are insufficiently understood and appreciated by industry and consumers.

The Committee would like to see active programmes of promotion by CEN/CENELEC at the European level and by the national standards bodies at Member State level to encourage industry to press for European standards as an integral part of their trading plans for 1993 and beyond.

The CEN/CENELEC members should encourage their constituents to establish the agenda and the timetable for European standardization, taking account of information on national requirements, and to consider opportunities of influencing any projects undertaken by national initiative.

The Committee urges the Commission to examine how this could be encouraged.

- 3.1.6. The Committee regrets that no reference to European certification and testing appears in the Report and notes that European standardisation policy will be complemented by proposals for a Community framework for certification and testing. It recognises that these elements are essential for the mutual recognition of national standards and the acceptance of harmonised European standards.

- 3.1.7. The Committee believes that the R&TD resources of the Community should be deployed to accelerate necessary prenormative work requirements as a contribution to the Single Market in 1993 and beyond.

- 3.1.8. The Committee urges the Commission in this initiative, as with standardisation, to include EFTA in its considerations.

- 3.1.9. The Committee believes that European standards institutions should not proliferate otherwise the task of coordination and collaboration with the Commission and with the EFTA Secretariat will become increasingly complex. It views the creation of a separate standards body for telecommunications (ETSI) with some anxiety and supports the efforts of the Commission to ensure that it can be coordinated with CEN and CENELEC.

3.2. Organization of the Information Procedure

3.2.1. *Integrated Standardisation Information System*

CEN and CENELEC jointly provide within their Integrated Information System (ISIS):

- information on the work programme of the national, European and international standards organisation, recording the stages reached in the drafting of standards (INFOPRO);
- information on the relationship of published national standards to European and international standards; whether identical, equivalent or related (ICONE).

The system covers the 18 European Community and EFTA countries and acts as a single point for collation and distribution for all the national information (the "CEN/CENELEC Central Unit").

3.2.2. *INFOPRO*

For the purposes of Articles 2 and 4 of Directive 83/189/EEC CEN and CENELEC set up a data base in 1985 funded under contracts signed with the Commission and the EFTA Secretariat.

It was compiled from the complete work programme of the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC), the complete programmes of CEN and CENELEC and notifications received from the CEN and CENELEC members.

These European national standards institutions (ISO members and the IEC national committees) have to inform the Central Unit about any new subject added to the national standards programme (Article 2 of Directive 83/189/EEC) and about any draft standard (Article 4). All the other CEN/CENELEC members, the Commission and the Secretariat of EFTA have to be informed at the same time.

The Committee notes that the Commission has undertaken legal action against a Member State for not communicating a draft national standard and hence for not having applied the provisions of the Directive.

3.2.3. ICONE

The Comparative Index of National Standards in Europe (ICONE) is managed by CEN under contracts with the Commission and EFTA as part of the Strategic Programme for Innovation and Technology Transfer (SPRINT) Programme set up in 1983.

CEN and CENELEC members notify the Central Unit of the references of their published standards which are related to ISO, IEC, CEN or CENELEC standards. From the data base it is possible to find the reference of the national implementation of the international or European standard.

ICONE was designed to help businesses and especially SMEs to overcome the obstacles posed by the existence of more than 50,000 national standards documents of which more than 60% had hardly any European or international equivalent. In practice however it goes no further than identifying the relevant standards. The Committee finds no evidence of its usefulness outside the CEN/CENELEC membership.

3.2.4. The efficiency of the procedure

In 1986 the Commission initiated a survey on the efficiency of the procedure. It identified a need for improvements in the practical and technical implementation of the arrangements. Proposals to effect this were approved by the Commission in February 1987 and are summarised in paragraph 35 of the Report. The Committee supports these proposals.

The Committee notes from the point of view of market research for the promotion of a complete bibliographic data base for standardisation in Europe, that a feasibility study into the future of the INFOPRO and ICONE systems has been initiated. The report has not been published yet (July 1989).

3.3. Use of the information

3.3.1. The Committee notes the limited use made by CEN and CENELEC of the information available from the procedure for the programming of European standardisation work, as summarised in paragraph 28 of the Commission's report.

It recognises that CEN and CENELEC programming activities represent the commitment of their members, the national standards institutions, to the progressive harmonisation of standards at European level.

3.3.2. The Committee notes that the funding available for the information procedure only enables the information to be collated centrally and disseminated nationally and that the CEN/CENELEC Central Unit is not intended to offer any evaluation. That would require a significant increase in financial resources both to employ the necessary experts, engineers, consultants, etc, and to provide for the translation of all relevant documents.

The Committee would therefore question the idea of enabling the CEN/CENELEC central unit to make a more detailed analysis of the data and to strengthen the power of initiative, as expressed in paragraphs 41 and 166 of the Report. The Committee believes that the available data can usefully be analysed only at industry level, and that this should be an integral part of the greater involvement of industry (para. 3.1.5. above).

3.3.3. The Committee understands that in accordance with the Community doctrine of mutual recognition established in the *Cassis de Dijon* case and reconfirmed by subsequent decisions of the European Court of Justice, different national standards can coexist as available criteria to be freely invoked voluntarily anywhere in Europe or indeed elsewhere. The standards reflect particular market preferences which may legitimately differ, but so long as the provisions of Article 36 of the Treaty of Rome cannot be adduced by any authority, no barriers to trade need result.

3.3.4. The Committee recognises that so far much European harmonisation activity has been generated by the EC legislative programme designed to replace regulations valid under Article 36 by common essential requirements established through directives, to be reflected in appropriate standards.

In cases where no regulatory trade barriers exist, however notifications made under Directive 83/189 should not necessarily be expected to attract widespread interest.

The Committee notes with concern that there has not yet been a significant reduction in national standards activity. It urges the Commission to sponsor concerted efforts to provide comprehensive and convenient information at all levels, publicizing European standardisation in order to stimulate collective activity amongst all interested parties within the framework of CEN and CENELEC.

3.4. **Amendments to List I, Annex, Directive 83/189**

The Committee notes that in Directive 88/182 no amendments were made to List I in the Annex to Directive 83/189 to include the national standards institutions of Spain and Portugal.

It assumes that these will be included in the further amending Directive proposed and that at the same time the European Telecommunications Standards Institution (ETSI) will be acknowledged.

4. **The Information Procedure for Technical Regulations**

4.1. The Directive requires the Commission to receive timely notification of technical regulations proposed by Member States; to circulate them to other Member States; to respond to any comments received and where appropriate to initiate a standstill procedure.

4.2. The Committee supports the conclusion of the Commission with regard to improvements in procedures set out in paragraph 168 of the Report. It emphasises in particular that transparency of information is desirable both to avoid accusations of "fortress Europe" mentality by the Commission and to facilitate examination and timely response by Member States.

The Committee believes that requirements for confidentiality of notifications made under this Directive should accordingly be reviewed and wherever possible removed, except where they can be justified in the context of GATT arrangements.

The Committee considers that discussions on a system for the exchange of information on technical regulations with EFTA countries should be pursued to a satisfactory conclusion.

4.3. The Committee urges that Member States publish the information nationally in accessible form and specifically inform their standards institutions, industry, worker and consumer organisations and other relevant bodies.

At European level, the Committee urges the Commission to consider means of communicating the information directly to those who may need it, in addition to publishing it in the Official Journal.

4.4. The Committee asks the Commission to review its procedures for ensuring receipt of the information required from Member States. The Committee welcomes the use of third parties under contract to the Commission to monitor and report the issue of regulations in each Member State.

4.5. The Committee welcomes measures to facilitate the translation of the drafts into Member States' own languages as this is an essential condition for efficient examination of the texts. In particular the Commission should take steps to accelerate its translation procedures in order to reduce the average time of five weeks for receipt of translation by Member States. Failing this the time given to Member States to respond to notification (Article 9.1.) should be increased equivalently.

4.6. The Committee notes the view of the Commission that technical regulations that have not been notified should be treated as unenforceable, as explained in paragraph 131 of the report, and the assertion in paragraph 80 that with regard to the option open to Member States to claim urgency as grounds for adopting regulations, it is up to the Commission and the Commission alone to assess whether such action is justified. The Committee observes that it is the role of the European Court of Justice to decide whether or not, in any circumstances, a claim that a Member State has infringed the Treaty should be upheld.

The Committee feels that the publication of a communication adopted in 1986 putting such a view is a precedent which should not be repeated unless there is a sound legal presumption that it will be upheld in the Courts.

4.7. The Committee observes that the original Directive 83/189 unlike its extension to more specialised sectors, 88/182, does not expressly cover Process and Production Methods (PPMs) which are obligations set by governments requiring a manufacturer to make or process a product in a certain way rather than testing it for safety or other requirements once it is made, irrespective of the process used.

It notes that the Report does not comment on PPMs as a technical barrier to trade. Nevertheless it believes that attention should be given to PPMs as a potential barrier to trade both within the European Community and under the GATT Technical Barriers to Trade Agreement when the Commission is proposing a revised Directive.

5. The operation of the Standing Committee (Article 5); overseeing the relationships between the Commission, CEN and CENELEC

- 5.1. The Committee has received no criticisms concerning the way in which the Commission has operated the Standing Committee under Article 5 of 83/189/EEC. It supports its use as a pivot of the Directive both as a clearing house for Member State problems and as a pragmatic and flexible forum through which to pursue all aspects of European standardisation policy (see 3.1.) in collaboration with the bodies involved at national as well as European level.
- 5.2. The Committee welcomes the recognition by the Commission of the importance of the Standing Committee in defining and vetting mandates for standardisation given to European standards bodies and reiterates its earlier opinion that this function is critically important as a means of maintaining relations with the Committees set up under New Approach Directives and as a means of ensuring a single channel of communication with the European standards bodies.
- 5.3. The Committee looks forward to a Communication from the Commission which will consider the progress of standardization in the Internal Market and the relationship between the Commission and the European standardisation bodies.

The Committee expects to be asked for an Opinion on this communication.

6. Financial implications

The Committee would like to see greater financial transparency in the area of Commission work on standards and regulations.

In particular this should cover:

- the funds available to promote European standardisation;
- an analysis of payments under contract to various standards bodies and the procedures used by the Commission to forecast and monitor this expenditure and to evaluate value for money;
- the costs incurred in managing the operation of the Directive over the period of the Report broken down to staff involved by categories and expenditure incurred under various headings of activity;

The Committee suggests that the Commission attach this information to their annual reports in the form of a financial fiche.

Done at Brussels 27 September 1989.

The Chairman
of the Economic and
Social Committee

Alberto MASPRONE

The Secretary-General
of the Economic and
Social Committee

Jacques MOREAU

IV. Composition of Study Groups

I.

In a letter dated 8 November 1990, the Commission asked the Economic and Social Committee for an Opinion on the

*Commission Green Paper on the Development of European Standardization:
Action for Faster Technological Integration in Europe
(COM(90) 456 final).*

By a decision dated 17 October 1990, the Committee Bureau instructed the Section for Industry, Commerce, Crafts and Services to prepare an Opinion and a Report on the subject.

To carry out this work, on 18 October 1990 the Section set up a Study Group composed as follows:

Chairman:	Mr	GREEN (DA)
Rapporteur:	Mr	de KNEGT (NL)
Members:	Mr	ASPINALL (UK)
	Mr	CAL (P)
	Mr	DONCK (B)
	Mr	FLUM (DE)
	Mrs	GREDAL (DA)
	Mr	LUSTENHOUWER (NL)
	Mr	MORGUES (F)
	Mr	MULLER (L)
	Mr	PEARSON (IRL)
	Mr	PELLARINI (I)
	Mr	PERRIN-PELLETIER (F)
	Mr	SCHLEYER (DE)
	Mr	SALA (I)
Experts:	Mr	SAPIR, Bureau Technique Syndical (for the Rapporteur)
	Mr	de NORMANN, Former ESC Member, Board Member of the British Standards Institution (for Group I)
	Mr	ADURNO, Confédération Européenne des Syndicats (for Group II)
	Mr	WEENINK, Consumenten Commissie voor Europa (for Group III)

The Study Group held 4 meetings.

Consultation of the Committee was made under Article 198 of the Treaty.

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II.

In a letter dated 18 August 1989, the Council asked the Economic and Social Committee for an Opinion on

A Global Approach to Certification and Testing - Proposal for a Council Decision concerning the modules for the various phases of the Conformity Assessment Procedures which are intended to be used in the technical harmonization Directives (COM(89) 209 final - SYN 208).

By a decision dated 11 July 1989, the Committee Bureau instructed the Section for Industry, Commerce, Crafts and Services to prepare an Opinion and a Report on the subject.

To carry out this work, on 5 September 1989 the Section set up a Study Group composed as follows:

Chairman:	Mr	FLUM (DE)
Rapporteur:	Mr	de NORMANN (UK)
Members:	Mr	ATAÍDE FERREIRA (P)
	Mr	BELTRAMI (I)
	Mr	CAL (P)
	Mr	CORTOIS (B)
	Mr	FORGAS I CABRERA (ESP)
	Mr	GIACOMELLI (L)
	Mr	HAGEN (DA)
	Mr	MARVIER (F)
	Mr	PEARSON (IRL)
	Mr	SANTOS (P)
Experts:	Mr	BROCKWAY, British Standards Institution (for the Rapporteur)
	Mr	MOTTEU, Centre Scientifique et Technique de la Construction (for Group I)
	Mr	SAPIR, Confédération Européenne des Syndicats (for Group II)
	Dr	HÖHFELD, Expert in Standards and Certification (for Group III)

The Study Group held 4 meetings.

Consultation of the Committee was made under Article 100 A of the Treaty.

* * *

III.

In a letter dated 6 September 1989, the Commission asked the Economic and Social Committee for an Opinion on the

Report on the operation 1984-1987 of Directive 83/189/EEC, laying down a procedure for the provision of Information in the field of Technical Standards and Regulations (COM(88) 722 final).

By a decision dated 21 February 1989, the Committee Bureau instructed the Section for Industry, Commerce, Crafts and Services to prepare an Opinion on the subject.

To carry out this work, on 1 March 1989 the Section set up a Study Group composed as follows:

Chairman:	Mr	FLUM (DE)
Rapporteur:	Mr	de NORMANN (UK)
Members:	Mr	ATAÍDE FERREIRA (P)
	Mr	BELTRAMI (I)
	Mr	CAL (P)
	Mr	CORTOIS (B)
	Mr	DONCK (B)
	Mr	FORGAS I CABRERA (ESP)
	Mr	HAGEN (DA)
	Mr	MARVIER (F)
	Mr	PEARSON (IRL)
	Mr	PERRIN-PELLETIER (F)
	Mr	PROENÇA (P)
Experts:	Mr	STRAWBRIDGE, British Standards Institution (for the Rapporteur)
	Mr	MOTTEU, Centre Scientifique et Technique de la Construction (for Group I)
	Mr	SAPIR, Confédération Européenne des Syndicats (for Group II)

The Study Group held 3 meetings.

Consultation of the Committee was made under Article 198 of the Treaty.

I

(Information)

COUNCIL

COUNCIL RESOLUTION

of 7 May 1985

on a new approach to technical harmonization and standards

(85/C 136/01)

THE COUNCIL,

in extension of its conclusions on standardization, approved on 16 July 1984 (Annex I);*emphasizes* the urgent need to resolve the present situation as regards technical barriers to trade and dispel the consequent uncertainty for economic operators;*emphasizes* the importance and desirability of the new approach which provides for reference to standards — primarily European standards, but national ones if need be, as a transitional measure — for the purposes of defining the technical characteristics of products, an approach outlined by the Commission in its communication of 31 January 1985, which follows certain guidelines adopted by the European Parliament in its resolution of 16 October 1980 and forms part of the extension of the Council's conclusions of 16 July 1984;*aware that* the new approach will have to be accompanied by a policy on the assessment of conformity, calls on the Commission to give this matter priority and to expedite all its work in this area;*approves* the guidelines encapsulated in the list of principles and main elements to be embodied in the main part of the Directives (Annex II to this resolution);*calls on* the Commission to submit suitable proposals as soon as possible.

ANNEX I

CONCLUSIONS ON STANDARDIZATION

Approved by the Council on 16 July 1984

The Council believes that standardization goes a long way towards ensuring that industrial products can be marketed freely and also towards creating a standard technical environment for undertakings in all countries, which improves competitiveness not only on the Community market but also on external markets, especially in new technology.

It recognizes that the objectives being pursued by the Member States to protect the safety and health of their people as well as the consumer are equally valid in principle, even if different techniques are used to achieve them.

Accordingly, the Council adopts the following principles for a European standardization policy:

- agreement by the Member States to keep a constant check on the technical regulations which are applied — whether *de jure* or *de facto* — on their territory so as to withdraw those which are obsolete or unnecessary;
- agreement by the Member States to ensure the mutual recognition of the results of tests and the establishment, where necessary, of harmonized rules as regards the operation of certification bodies;
- agreement to early Community consultation at an appropriate level, in accordance with the objectives of Directive 189/83/EEC where major national regulatory initiatives or procedures might have adverse repercussions on the operation of the internal market;
- extension of the Community practice in matters of technical harmonization of entrusting the task of defining the technical characteristics of products to standards, preferably European but if necessary national, where the conditions necessary for this purpose, particularly as regards health protection and safety, are fulfilled;
- a very rapid strengthening of the capacity to standardize, preferably at European level, with a view to facilitating on the one hand harmonization of legislation by the Community and on the other industrial development, particularly in the field of new technologies, since this could in specific circumstances involve the Community in introducing new procedures to improve the drawing up of standards (e.g. standardization bureaux, *ad hoc* committees). The adoption of European standards would be submitted to the European standardization bodies for approval.

In high technology sectors particularly, subjects should be identified where common specifications and standards will make for efficient exploitation of the Community dimension and the opening of public works and supply contracts so that the decisions required in this connection may be taken.

ANNEX II

GUIDELINES FOR A NEW APPROACH TO TECHNICAL HARMONIZATION AND STANDARDS

The following are the four fundamental principles on which the new approach is based:

- legislative harmonization is limited to the adoption, by means of Directives based on Article 100 of the EEC Treaty, of the essential safety requirements (or other requirements in the general interest) with which products put on the market must conform, and which should therefore enjoy free movement throughout the Community,
- the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives, while taking into account the current stage of technology, is entrusted to organizations competent in the standardization area,

- these technical specifications are not mandatory and maintain their status of voluntary standards,
- but at the same time national authorities are obliged to recognize that products manufactured in conformity with harmonized standards (or, provisionally, with national standards) are presumed to conform to the 'essential requirements' established by the Directive. (This signifies that the producer has the choice of not manufacturing in conformity with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive.)

In order that this system may operate it is necessary:

- on the one hand that the standards offer a guarantee of quality with regard to the 'essential requirements' established by the Directives,
- on the other hand that the public authorities keep intact their responsibility for the protection of safety (or other requirements envisaged) on their territory.

The quality of harmonized standards must be ensured by standardization mandates, conferred by the Commission, the execution of which must conform to the general guidelines which have been the subject of agreement between the Commission and the European standardization organizations. In so far as national standards are concerned their quality must be verified by a procedure at Community level managed by the Commission, assisted by a standing committee composed of officials from national administrations.

At the same time safeguard procedures must be provided for, under the management of the Commission assisted by the same committee, in order to allow the competent public authorities the possibility of contesting the conformity of a product, the validity of a certificate or the quality of a standard.

In following this system of legislative harmonization in each area in which it is feasible, the Commission intends to be able to halt the proliferation of excessively technical separate Directives for each product. The scope of Directives according to the 'general reference to standards' formula should encompass wide product categories and types of risk.

The Community could on the one hand, therefore, complete the extremely complex undertaking of harmonizing technical legislation and on the other hand promote the development and application of European standards. These are essential conditions for the improvement of the competitiveness of its industry.

OUTLINE OF THE PRINCIPLES AND MAIN ELEMENTS WHICH SHOULD MAKE UP THE BODY OF THE DIRECTIVES

A. JUSTIFICATIONS

Amongst the traditional principles justifying a Directive the following aspects should be emphasized:

- Member States have the responsibility of ensuring safety on their territory (in the home, at the workplace, etc.) of persons, domestic animals and goods, or the respect of other essential protection requirements in the general interest such as health, consumer or environmental protection etc., with regard to the hazards covered by the Directive itself ⁽¹⁾;
- the national provisions ensuring such protection must be harmonized in order to ensure the free movement of goods, without lowering existing and justified levels of protection in the Member States;
- CEN and CENELEC (one or the other, or both according to the products covered by the Directive) are the competent bodies to adopt European harmonized standards within the scope of the Directive, in accordance with the guidelines which the Commission, after consultation of the Member States, has signed with these bodies ⁽²⁾.

⁽¹⁾ For reasons of convenience and ease of drafting the rest of this document refers only to safety.

⁽²⁾ For specific sectors of industrial activity other competent European bodies for the drawing up of technical specifications could be involved.

1. In this outline a general approach is developed which should be applied according to the needs for legislation by Directives based on Article 100 of the Treaty relating to sectors or families of products as well as types of hazard.
2. The object of the Directive will be specified in each sphere of application according to the types of hazard (safety, health, environmental, consumer protection, etc.) and should the need arise to the circumstances (in the home, at the place of work, under road traffic conditions, during leisure activities, etc.).
3. Where appropriate, it should be stated that the Member States may make provision, in accordance with Community law, for national regulations concerning the conditions for use of products covered by the scope of the Directive.
4. Concerning the objective mentioned in the second principle, it is obvious that it is carried into effect by the very adoption of the Directive under Article 100 of the Treaty, as the essential safety requirements contained in it are of such a nature as to ensure the pursuit of such an objective.

B. MAIN ELEMENTS

I. Scope

Definition of the range of products covered, as well as the nature of the hazards it is intended to avert.

The scope should be defined in such a way that a consistent approach to the action is ensured, and that the proliferation of Directives on specific products is avoided. Moreover, it should be noted that the enacting terms of such a Directive do not preclude the possibility of several Directives being adopted on one and the same product according to the various types of hazard associated with that product (for example, mechanical safety of a machine on the one hand and pollution by that machine on the other hand).

II. General clause for placing on the market

The products covered by the Directive may be placed on the market only if they do not endanger the safety of persons, domestic animals or goods when properly installed and maintained and used for the purposes for which they are intended.

1. The Directives would provide for total harmonization as a general rule. Consequently, any product placed on the market falling within the scope of the Directive must be in conformity with the requirements of the Directive. In certain specific conditions, optional harmonization for certain products may prove to be opportune. The outline Directive, however, is drawn up with a view to total harmonization.

Appropriate solutions could be envisaged in order to take account of the need to support, in some Member States, a harmonious move towards the introduction of a system of binding regulations, in order in particular to ensure the establishment of appropriate certification infrastructures.

Point II therefore represents a general clause setting out the responsibilities of the Member States in relation to the placing of goods on the market.

2. In order to respect the general principle on which the outline Directive is based, which is to leave to the trade the choice of the means of attestation of conformity and thus to prohibit Member States from setting up any system of control prior to placing on the market (except, of course, in cases where prior control is required by specific Directives for special sectors, as is moreover clearly provided for in point VIII), it is obvious that the national authorities in order to acquit themselves of their responsibilities set out in this clause must be allowed to exercise control on the market by way of spot checks.
3. In certain cases, in particular with regard to the protection of workers and consumers, the conditions set out in this clause may be strengthened (foreseeable use).

III. Essential safety requirements

Description of the safety requirements which are essential for the application of the general clause in point II with which all products covered by the Directive must conform.

1. The essential safety requirements which must be met in the case of products which can be put on the market shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced. They should be so formulated as to enable the certification bodies straight away to certify products as being in conformity,

having regard to those requirements in the absence of standards. The degree of detail of the wording will depend on the subject matter. If the basic requirements for safety are observed, the general clause in point II can be applied.

2. Amendments to these requirements can be made only by means of a new Council Directive under Article 100 of the Treaty.

IV. Free movement clause

Obligation on the Member States to accept, under the conditions referred to in point V, the free movement of products which conform to points II and III.

1. Free movement will be ensured in the case of products declared to conform to the protection requirements laid down in the Directive, without recourse as a general rule to prior verification of compliance with the requirements set out in point III, it being understood that note 2 of point II also applies in this case.

The interpretation to be given to this provision should not have the consequence that third party certification is to be systematically required by the sectoral Directives.

2. The actual aim of the Directives in question is to cover all essential requirements, but in the exceptional case of cover proving incomplete, it would always be possible for a Member State to act under Article 36 of the Treaty.

V. Means of proof of conformity and effects

1. Member States shall presume to be in conformity with points II and III products which are accompanied by one of the means of attestation described in point VIII declaring that they are in conformity with:

(a) the harmonized standards adopted by the European standardization body which is particularly competent within the scope of this Directive, when these standards are adopted in accordance with the general guidelines agreed between that body and the Commission and the references of which are published in the *Official Journal of the European Communities*; such publication should, moreover, also be carried out by the Member States;

(b) or as a transitional measure, and in so far as harmonized standards do not exist in the field covered by such standards, national standards referred to in paragraph 2.

2. Member States shall communicate to the Commission the text of those national standards which they consider to meet points II and III. The Commission shall forthwith forward this text to the other Member States. In accordance with the procedure laid down in paragraph 2 of Point VI, the Commission shall notify the Member States of the national standards which enjoy the presumption of conformity with points II and III.

Member States are required to publish the references of these standards. The Commission shall also ensure that they are published in the *Official Journal of the European Communities*.

3. Member States shall accept that the products for which the manufacturer has not applied any standard (because of absence of a standard as laid down in paragraphs 1 (a) and (b) above or for other exceptional reasons, are considered to be in conformity with points II and III, when their conformity is demonstrated by one of the means of attestation set out in point VIII, paragraph 1 (a) and (b).

1. Only those means of attestation provided for in point VIII necessarily carry presumption of conformity.

2. The presumption of conformity is constituted by the fact that the conformity of a product to harmonized or national standards is declared by one of the means of attestation set out in point VIII. When the product is not in conformity with a standard, because the standards do not exist or because the manufacturer, for example in cases of innovation, prefers to apply other manufacturing criteria of his choice, conformity to points II and III is declared by the means of an attestation delivered by an independent body.

3. In cases under point V, paragraphs 1 and 3, Member States will therefore have the right, for the presumption to operate, to request at any time one of the means of attestation set out in point VIII.

4. The drafting and adoption of the harmonized standards mentioned in paragraph 1 (a) by the CEN and CENELEC, these bodies being generally considered to be the 'European standards bodies which are particularly competent', and the obligation relating to transposition into national standards are governed by these two bodies' internal rules and their regulations relating to standards work. The internal rules of CEN and CENELEC are in the process of being harmonized.

However, it is not ruled out that the harmonized standards referred to in paragraph 1 (a) will be prepared outside CEN and CENELEC by other bodies which may assume these functions in particular areas; in such cases adoption of the harmonized standards shall be submitted for approval by CEN/CENELEC. In any case, the drafting and introduction of the harmonized standards referred to in point V must be subject to the guidelines agreed between the Commission and these organizations. The guidelines deal in particular with the following principles and conditions:

- the availability of suitable staff and technical infrastructure at the standards body which the Commission mandates to proceed with standardization;
 - the association of public authorities and interested circles (in particular manufacturers, users, consumers, unions);
 - the adoption of harmonized standards and their transposition into national standards or, at least, the annulment of diverging national standards under conditions approved by the Commission when drawing up a frame of reference for standardization after consultation with the Member States.
5. In the selection of national standards, due consideration will be given to any practical difficulties arising from that selection.

National standards are selected only on a transitional basis. Accordingly, when a selection decision is made, the relevant European bodies will in principle be sent instructions to draft and adopt the corresponding European standards within a given period of time and under the conditions stated above.

VI. Management of the list of standards

1. Where a Member State or the Commission considers that harmonized standards or drafts thereof do not fully satisfy points II and III, the Commission or the Member State shall bring this to the attention of the committee (point X) setting out the reasons. The committee shall give an opinion as a matter of urgency.

The Commission shall, in the light of the committee's opinion, notify the Member States of the necessity of withdrawing or not withdrawing the standard from the publication referred to in point V, paragraph 1 (a). It shall inform the European standards body concerned and, if necessary, give it a new or revised mandate.

2. On receipt of the communication referred to in point V, paragraph 2, the Commission shall consult the committee. After the committee has given its opinion, the Commission shall, within a given period, notify the Member States whether the national standard in question should or should not enjoy presumption of conformity and, if so, be subject to national publication of its references.

If the Commission or a Member State considers that a national standard no longer fulfils the conditions for presumption of conformity to the safety requirements, the Commission shall consult the committee. In the light of the opinion of the committee, it shall notify the Member States whether or not the standard in question should continue to enjoy presumption of conformity and in the latter case be withdrawn from the publications referred to in point V, paragraph 2.

As indicated above (see notes to point V, paragraph 2) the Member States have the power to decide which of their national standards may be considered to be in conformity with points II and III and thus be subject to the Commission confirmation procedure.

VII. Safeguard clause

1. Where a Member State finds that a product might compromise the safety of individuals, domestic animals or property, it shall take all appropriate measures to withdraw or prohibit the placing on the market of the product in question or to restrict its free movement even if it is accompanied by one of the means of attestation referred to in point VIII.

Within a given period of time, and only when the product in question is accompanied by one of the means of attestation provided for in point VIII, the Member State shall inform the Commission of such a measure. It will indicate the reasons for its decision and in particular whether the non-conformity results from:

- (a) non-compliance with points II and III (when the product does not conform to any standard);
 - (b) incorrect application of the standards referred to in point V;
 - (c) a shortcoming in the standards themselves.
2. The Commission shall consult the Member States concerned as soon as possible. If the Member State which has taken measures intends to maintain them, the Commission shall refer the matter to the committee within a specified period. Where the Commission, after consultation of the committee, finds that the action is justified it shall, also within a given period of time, inform the Member State in question and point out to the other Member States that (all else being equal) they are also obliged to prevent the product in question from being placed on the market.
 3. Where failure of the product to comply with points II and III results from a shortcoming in the harmonized standards or in the national standards, the consequences shall be those set out in point VI.
 4. Where the non-conforming product is accompanied by a means of attestation issued by an independent body or by the manufacturer, the competent Member State shall take the appropriate measures against the author of the attestation and inform the Commission and the other Member States.
 5. The Commission shall ensure that all Member States are kept informed of the progress and of the outcome of this procedure.

This point describes the consequences when recourse by a Member State to the safeguard clause appears to be justified. It does not give any indication on the consequences when recourse does not appear to be justified after expiry of the Community examination procedure, because in such cases the general rules of the Treaty apply.

VIII. Means of attestation of conformity

1. The means of attestation referred to in point V which the trade may use are:
 - (a) certificates and marks of conformity issued by a third party;
 - (b) results of tests carried out by a third party;
 - (c) declaration of conformity issued by the manufacturer or his agent based in the Community. This may be coupled with the requirement for a surveillance system;
 - (d) other means of attestation which could possibly be determined in the Directive.
2. The choice by trade and industry between these different means may be limited, or even removed, according to the nature of the products and hazards covered by the Directive.
3. National bodies authorized to issue marks or certificates of conformity shall be notified by each Member State to the Commission and to the other Member States.
 1. The appropriate means of attestation will be established and expanded in the specific Directives taking into account the special requirements of their scope. It must be borne in mind that the certification bodies designated by the Member States for cases (a) and (b) will have to intervene in particular in the absence of standards and where the manufacturer does not observe standards (see point V, paragraph 3).
 2. The bodies referred to in paragraph 3 must carry out their duties according to recognized international practices and principles and especially in accordance with ISO Guides. The responsibility for the control of the operation of these bodies lies with the Member States. Questions concerning the carrying out of tests and certification may be put before the committee set up under point IX.

3. With regard to the manufacturer's declaration of conformity, the national authorities have the right to ask the manufacturer or the importer to communicate the data relating to the tests carried out concerning safety etc., when they have good grounds for believing that a product does not offer the degree of safety required in all respects. Refusal on the part of the manufacturer or the importer to communicate these data constitutes sufficient reason to doubt the presumption of conformity.
4. The determination of a limitative list of means of attestation only concerns the system of presumption of conformity but cannot have the effect of restricting the possibility for a member of the trade to prove, by any means he sees fit within the framework of a dispute or court proceedings, the conformity of the product with points II and III.

IX. Standing committee

A standing committee shall be set up chaired by a representative of the Commission and consisting of representatives appointed by the Member States who may avail themselves of the help of experts or advisers.

The committee shall be convened by its chairman either on his own initiative or at the request of a Member State.

The committee shall draw up its own rules of procedure.

X. Tasks and operation of the committee

1. The committee shall carry out the tasks entrusted to it by virtue of the foregoing points.
2. Furthermore, any question regarding the implementation of a Directive may be submitted to the committee.

The tasks of the committee shall be concerned with the implementation of the Directive. The object of the consultation of the Committee prior to the publication of the references of the national standards is more to provide for a forum for the discussion of the objections which the Commission or a Member State may formulate, than to carry out a systematic examination of the entire contents of the standards.

Criteria for choosing the priority areas in which this approach could initially be applied

1. The need to find a new approach to the harmonization of technical regulations, based on 'general reference to standards' and following the lines described earlier, is the outcome of a number of conditions (outlined in the first part of this communication) backed up by the experience already acquired by the Community. Consequently it is a general principle, the validity of which will have to be assessed in practical terms in the various areas in which it will be applied.

The Council took a similar view in its 'Conclusions' of 16 July 1984 when it confirmed the general need for an extension of the 'general reference to standards' practice, but only provided the necessary conditions were fulfilled, i. e. as regards the obligation on public authorities to protect the health and safety of their citizens.

2. Before the priority areas in which this approach should initially be applied can be chosen, it is therefore necessary to establish a number of selection criteria to be taken into consideration, criteria which cannot be taken separately.
 - (a) Since the approach calls for the 'essential requirements' to be harmonized and made mandatory by Directives based on Article 100 of the Treaty, the 'general reference to standards' approach will be appropriate only where it is genuinely possible to distinguish between 'essential requirements' and 'manufacturing specifications'. In other words, in all areas in which the essential requirements in the public interest are such that a large number of manufacturing specifications have to be included if the public authorities are to keep intact their responsibility for protection of their citizens, the conditions for the 'general reference to standards' approach are not fulfilled as this approach would have little sense. In the light of this statement areas involving safety protection certainly appear to have priority over those involving health protection (which applies to the scope of Directive 83/189).

(b) If 'general reference to standards' is to be possible, the area concerned must be covered by, or be capable of being covered by, standardization. Areas which are inherently ill suited to standardization work are certainly the areas referred to in (a) above where the need for regulations is felt unanimously throughout the Community. In other areas there is a standardization capacity or potential and in the latter case the Community should encourage it in close cooperation with both the industry concerned and the European standards bodies, whilst ensuring that the interests of consumers are taken into account.

(c) The progress of technical harmonization work in the Community under the general programme established by the Council resolutions of 1969 and 1973 varies greatly from one industrial sector to another. In manufacturing industry (which appears at first sight better to fulfil the abovementioned criteria) most of the Directives adopted concern three areas: motor vehicles, metrology and electrical equipment.

The new approach will therefore have to take this state of affairs into account and concentrate mainly on other areas in which there is a lack of Community activities (e.g. many engineering products and building materials) without calling into question regulations that are already well advanced (for example those referring to motor vehicles). The case of electrical equipment is different: this is the only area to have been tackled by a Directive of the 'general reference to standards' type and should certainly be included in the priority areas for all such products not yet covered, in view of the extremely important part played in this area by international and European standardization.

(d) One of the main purposes of the new approach is to make it possible to settle at a stroke, with the adoption of a single Directive, all the problems concerning regulations for a very large number of products, without the need for frequent amendments or adaptations to that Directive. Consequently in the selected areas there should be a wide range of products sufficiently homogeneous to allow common 'essential requirements' to be defined. This general criterion is, however, based mainly on practical and labour-saving considerations. There is nothing to prevent a single type of product, in certain cases, from being covered by the 'general reference to standards' formula if all the abovementioned criteria are met.

(e) Finally, mention should be made of one criterion that the Commission, in agreement with industry, has always regarded as essential. There must be grounds for considering that the existence of different regulations does in practice genuinely impede the free movement of goods. In some cases, however, even if these grounds are not obvious, a Directive may appear necessary to protect an essential public interest uniformly throughout the Community.



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