

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 491 final SYN 445

Brussels, 27 November 1992

Proposal for a

COUNCIL DIRECTIVE

amending for the second time
Directive 83/189/EEC
laying down a procedure
for the provision of information
in the field of technical standards
and regulations

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

1. Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations⁽¹⁾, as subsequently amended by Directive 88/182/EEC of 22 March 1988⁽²⁾ to include all products, introduced a mandatory requirement of transparency for new national technical specifications, whether standards or regulations. This transparency is essential in order to eliminate or minimize the difficulties which the measures in question may cause in respect of trade between Member States of the Community.
2. Designed as a means of preventing the emergence of new barriers to trade, this Directive has proved to be fundamental to the process of completing the internal market by promoting cooperation between Member States or identifying the areas where there is a need for joint action.

The notification procedures laid down in this Directive allow all the parties concerned in the Community to adopt a clear stance on the national drafts in question, namely

- either accepting the national system, ensuring that the principle of mutual recognition is applied in the case of technical regulations;
- or opposing that system by introducing harmonization measures whether regulatory (in the case of technical regulations) or voluntary (in the case of standards).

The notification mechanism itself does not pre-empt the choice between harmonization or mutual recognition, but rather provides the necessary transparency to enable an informed choice to be made.

This instrument sets out to reduce the constraints imposed by divergent national technical specifications on businesses wishing to operate Community-wide and to create a technical environment in which they can maintain or improve their ability to compete both on the Community market and outside.

3. From now on this strategy will have to take account of a new parameter, namely the establishment of the internal market on 1 January 1993. The instrument devised in 1983 to help with the completion of the internal market has to be adapted to its new role in the years ahead, namely to make sure that the internal market functions properly.

(1) OJ L 109, 26 April 1983, p. 8.

(2) OJ L 81, 26 March 1988, p. 75.

4. This will not require any changes to the basis on which the instrument rests - the concepts of product, standard and mandatory public regulations - nor any radical alteration of the procedures governing compulsory notification and dialogue. However, it is essential, in the light of experience and of developments which have already begun in the field of standardization and national regulations, to reinforce the basic principles of the information procedure, namely transparency of action at national level and discipline in the case of joint action.
5. This proposal has been discussed in depth by the Standing Committee set up under Article 5 of the Directive and with the European standardization bodies.

11. STANDARDIZATION

6. Standardization is a powerful medium for economic cohesion and standards play a key role in commercial transactions. The response to the Green Paper on the development of European standardization⁽¹⁾ shows the level of interest shown by society and economic operators in this subject. Standardization is therefore a perfectly proper subject for Community legislation.
7. The common factors linking Community policy and Community law on the one side and standardization on the other are, first, the framework or basis for cooperation in general and, secondly, the work under way in certain areas such as the harmonization of technical legislation, the opening up of access to public contracts and industrial competitiveness.
8. Directive 83/189/EEC is the cornerstone of the structure that links standards-making and the proper functioning of the internal market. It lays down a procedure for the provision of information on the work programmes of standardization bodies, acknowledges that these bodies have certain rights vis-à-vis one another and serves as a basis for cooperation between Community bodies and European standardization bodies. Although these three elements have worked satisfactorily overall, they now need to be adapted to bring them more closely into line with current circumstances.

A flexible notification procedure

9. The information procedure is an instrument which ensures that the measures taken by national standardization bodies are transparent.

(1) OJ C 20, 28 January 1991.

The information obtained provides a working basis for the Commission and the two committees comprising representatives of the Member States which were set up, respectively, by Directive 83/189/EEC and by Decision 87/95 in the field of information technologies. The procedure also covers the exchange of information between national standardization bodies, giving them an opportunity, as described below, to express their views on proposed national measures.

10. Although the need for and value of this information procedure are not in dispute, certain difficulties have arisen which have chiefly been due to the amount of information to be notified and a degree of unwieldiness in the procedure itself. The aim of this proposed amendment, therefore, is to specify which items of information must be notified and to simplify the procedure.
11. As regards the information to be notified, it is generally accepted that the systematic notification requirement applies only to new subject areas where there is an intention to prepare or amend a standard, in so far as the standard in question is likely to create barriers to trade between Member States. Consequently, standards which simply transpose the full text of an international or European standard will no longer need to be notified. Similarly, the amendment sanctions an existing practice whereby only amendments to national programmes, i.e. not the programmes themselves, are notified.
12. As far as procedures are concerned, the amendment makes it clear that only a single notification is required, but that notification must take place as soon as the nature of the work in question is clear; this is to ensure that comments and suggestions from the parties concerned can be taken into account. Once the parties concerned have had access to that information there is no requirement to submit any further information unless the parties have expressed a specific interest to that effect. Thus, the systematic communication of information or documents, which is currently required under Articles 3 and 4 of the Directive, has been replaced by the option of requesting such information and documents.

The respective remits of the standardization bodies and the authorities

13. The amendment also spells out certain rights which are now firmly accepted and enshrined in the field of European standardization. These include the right to participate passively or actively in the standards-making activities of another national standardization body, the right to request drafts of standards and the right to be told about the action taken on comments relating to the drafts.

Similarly, the Directive requires national standardization bodies to publish draft standards; this gives interested parties in other States an opportunity to submit comments and prevents the standardization bodies from objecting to the treatment of a topic in their programme at European level.

Cooperation between European standardization bodies and the Commission

14. The provisions of Directive 83/189/EEC relating to cooperation between the Commission and the European standardization bodies remain unchanged. Being able to call on these bodies to draw up European standards, in consultation with the committee set up under the Directive, has proved extremely useful and effective. It was felt, however, that the part of the Directive relating to the standstill arrangements for national standardization bodies needed to be brought into line with the stricter provisions which have long been accepted by these national organizations within the framework of the European standardization bodies.

Although the amendment to the Directive seeks to dispense with the obligation on national standardization bodies systematically to notify their work programmes, it still allows the Commission to impose that obligation or ask for certain parts of these programmes to be notified to it. The purpose of this provision is to ensure that, if the need arises, more detailed studies of the trends and developments in standardization activities in particular areas can be undertaken, particularly in cooperation with the European standardization bodies.

III. TECHNICAL REGULATIONS

A. INCREASED TRANSPARENCY

15. This proposal seeks to increase transparency by widening and defining in more detail the scope of the Directive, clarifying certain concepts and rules of procedure and introducing the possibility of informing economic operators.

Scope

16. The information procedure laid down in the Directive covers only regulations relating to products. In order to reaffirm this basic principle, which determines the Directive's scope, the definition of a product - which remains unchanged - is placed at the head of Article 1.
17. The definition of a technical specification is also expanded. In the light of experience of legal proceedings against certain Member States the wording has been amended to make it clear that the trade designation, which means the name under which a product is sold in a Member State, constitutes a technical specification.

This addition was also prompted by a desire to avoid any future ambiguity in the Member States after the adoption of Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of indications of geographical origin and designations of agricultural products and foodstuffs⁽¹⁾, which states explicitly that Directive 83/189/EEC shall not apply to the designations and indications covered by the Regulation. Secondly, since conformity assessment procedures may have an influence on the manufacture of products, they have been added to the illustrative list of technical specifications. Lastly, in the same spirit, the proposal takes account of production methods and procedures for all products by removing the words in the existing text which restricted its application to agricultural products, foodstuffs and medicinal products.

18. As originally conceived the Directive basically covers only those technical regulations applied to a product for the purposes of placing it on the market, and chiefly for safety reasons.

Given the underlying political objective of this proposal, which is to ensure the proper functioning of the internal market, there will inevitably be a need to consider broadening this original concept.

Increasingly in all the Member States national regulations are tending to reflect requirements other than product safety alone. This phenomenon is particularly apparent in the areas of consumer protection and the environment.

The requirements which such regulations impose on a product generally relate to the product after it has been placed on the market and include possible uses, maintenance, a change in its intended purpose (for example, considering a bottle as waste) or its removal from the market. In other words, they cover the product's life cycle. Clearly, rules of this kind are liable to have an effect on the product and may cause distortion of the market. Indeed, the Commission's recognition of the potential impact of environmental protection measures prompted it, in its 1985 White Paper on completing the internal market⁽²⁾, to recommend extending the type of procedure laid down in Directive 83/189/EEC to include such rules.

In the context of the operation of the internal market, it is therefore necessary to consider not just technical specifications in the strictest sense of the word but the whole body of regulatory requirements affecting the life of a product. This proposal therefore incorporate within the scope of the Directive these other requirements relating to the life cycle of the product after it has been placed on the market.

(1) OJ L 208, 24 July 1992.

(2) COM (85) 310 final of 14 June 1985.

19. The same concern, reinforced by the experience of a number of disputes which have given rise to serious problems between certain Member States under the existing arrangements, has prompted the Commission to clarify in this proposal the concept of a de facto technical regulation. It is also necessary to take account of trends that are already apparent in the attitude of the Member States towards products, that is to say increased reliance on voluntary and consensual measures negotiated between all the parties concerned rather than measures decreed unilaterally by a public authority.

This proposal therefore makes clear that certain types of normative acts which are not initially binding fall within the scope of the information procedure by virtue of the fact that the public authority, acting directly, imparts to the specifications or other requirements laid down in such acts a more binding force than they otherwise have as voluntary measures.

They may be made more binding, for example, by relaxing public inspection procedures or formalities or by the public authority using the texts in question as a reference to assess other specifications, or even by linking compliance with these texts to fiscal or financial incentives of sufficient size to alter the behaviour of economic operators.

It must be emphasized at this point that the basic principles of the Directive are not affected. Only technical specifications or other requirements relating to products are at issue. The Directive only covers provisions adopted by the public authority which refer to those specifications, or measures enacted in the public interest at the instigation or with the support or approval of the public authority. In other words, in order to fall within the scope of the Directive, there must be a close link between the regulation and the product and the public authority's involvement in implementing the regulation.

Clearer obligations

20. The information procedure has not raised any major operational problems. Nevertheless, difficulties have arisen from time to time owing to the wording of certain provisions, which have sometimes been interpreted differently by the Commission and the Member States concerned. Experience has shown that in order to improve transparency, which is one of the main objectives of this proposal, it will be necessary to clarify and set out in more detail a number of the Member States' obligations.
21. This proposal, taking account inter alia of the discussions within GATT, therefore indicates which types of public authority are required to notify draft technical regulations, defining in more detail the concept of a local authority, whose measures are not covered by the Directive.

22. The concept of transparency is embodied in Article 8 of the Directive, which spells out the obligations on the Member States to communicate information. There are two parts to this communication process: the notification of the draft regulation itself and a statement of the grounds for the technical regulation. Experience has shown that notification of the grounds for a technical regulation is often very important in terms of understanding its implications; this proposal therefore recommends that the grounds be explained as fully and clearly as possible.
23. The object of the procedure is to enable the impact of the national technical regulations on the internal market to be assessed at the draft stage.

There can be no doubt that any major change made to the draft by the Member State concerned after that draft has been notified, and for any purpose other than to take account of comments made under the information procedure, is detrimental to transparency and is liable to alter the original assessment of the text. This proposal clearly explains the circumstances in which a further communication will be necessary.

24. Experience has also shown that making a proper evaluation of a draft national technical regulation - in the limited time allowed under the procedure - is a complex and delicate exercise in those cases where the draft seeks, on public health, consumer protection or environmental grounds, to restrict or ban a chemical substance, preparation or product.

The desire to simplify the analysis is combined in this case with the need to satisfy the Member State which has drawn up the draft that the assessment has taken account of all the relevant grounds. This proposal therefore specifies the additional information which has to be submitted in those cases.

25. The obligation to disclose national intentions in the areas covered by the Directive is absolute. Member States are bound to comply with it. However, the Directive is but one of the Community instruments serving that purpose. Furthermore, in terms of the proposed widening of the scope of the Directive it is altogether possible that, some aspects of a draft technical regulation may also be covered by another Community act which requires it to be notified.

In order to reduce the administrative burden in cases where notification of a national text is required under more than one Community act, this proposal makes it clear that, in such cases, Member States need only notify the text once and that they can choose the instrument for that purpose.

This is merely a way of simplifying the administrative formalities, however, and does not alter the nature of the obligation or the specific character of the various Community instruments concerned in any way. Member States are still required to notify a draft technical regulation under Directive 83/189/EEC.

The specific nature of this obligation is shown by the requirement that, if a draft is notified under another Community act, Member States must formally state that such notification also satisfies the requirements of Directive 83/189/EEC. Once this initial communication is made the national draft remains covered by the procedure specific to each instrument applicable to it, is assessed on its intrinsic merits under that instrument and is the subject of an opinion on distinct legal bases.

26. The Directive requires Member States to observe a three-month standstill period following the communication of the draft in order that it may be examined. Article 9(1) of the existing Directive does not make the position sufficiently clear and so this proposal endeavours to rectify that state of affairs.
27. An important exception to the standstill requirement is provided for to deal with urgent cases. It is for the Commission, which is responsible for monitoring compliance with the Directive, to decide on the justification for invoking the urgent procedure under the terms of the Directive.

Ever since the Directive was put into force the Commission has consistently applied the same rigorous assessment criteria to ascertain whether the regulations for which urgency has been requested are indeed necessary to deal with serious and unforeseeable circumstances. These criteria were agreed with the representatives of the Member States in the committee set up under Article 5 of the Directive and are laid down in the vade mecum on the information procedure adopted in 1988, along with details of the time limit within which the Commission must express its view. The proposal formally embodies the provisions of the vade mecum.

More published information for economic operators

28. While the establishment of the internal market can be regarded as essentially a matter for the public authorities, by virtue of the political will involved and the instruments needed to put it in place, this precept no longer applies to quite the same extent once that market is in place and has to be kept operational. The free movement of goods in a single market is not an abstract principle but a reality which concerns all those involved in the day-to-day running of the economy, including economic operators.
29. It is customary for the national procedures for drafting technical regulations to include prior consultation with the economic operators concerned. In a Community-wide internal market all existing or potential operators on the market should be given the opportunity to express their views - if they so wish - on the various national provisions they will come up against in the single market. Not only will this arrangement provide valuable additional economic information on the likely effect of a measure, it will also help to complete the picture for the purposes of shaping industrial policy at Community level.

Just as widening the scope of the Directive is a way of embracing the whole national regulatory environment for products, providing economic operators with more systematic and comprehensive information is a way of improving the understanding of the economic environment in which these products are traded.

30. With this aim in mind, the proposal seeks to put an end to the absolute requirement of confidentiality which is a feature of the current Directive. In order to take account of the legitimate interest of the Member States - and it is they who ultimately determine what is legitimate - the confidentiality requirement is not abolished entirely but is replaced by confidentiality at the request of the individual Member State, supported by reasons in every case. In other words, confidentiality becomes the exception rather than the rule. In fact, a similar formula has already been accepted by the Member States in the Agreement between the Community and the EFTA countries laying down a procedure for the exchange of information in the field of technical regulations, which was signed on 19 December 1989 and entered into force on 1 November 1990⁽¹⁾.
31. By the same token, in order to give economic operators an opportunity to express their interest, the proposal states that the Commission shall regularly publish in the Official Journal the titles of the drafts notified to it.
32. In all legal systems the general principle underlying the formal or procedural conditions attached to a measure enacted by the public authority is that the public must be fully safeguarded against decisions liable to influence the exercise of their rights. Not all safeguards have equal effect; failure to implement certain safeguards properly may affect the ultimate decision, which therefore makes them particularly important.

Directive 83/189/EEC requires Member States to carry out certain procedural steps before the adoption of an act; their purpose is to ensure, during the preparatory stages, that the content of the decision adopted will not run counter to the Treaty or secondary Community law and will not adversely affect the direct rights of individuals under the Community's legal system.

These obligations are clear and unequivocal; Member States must comply with them in order for the national texts in question, which the Commission considers should be capable of being relied upon by individuals in court, to be in conformity with Community law⁽²⁾.

As a direct result of greater transparency for economic operators - who are the individuals concerned in this instance - and in order to reinforce the safeguards governing the exercise of their rights in an integrated economic area, this proposal requires the Member States to refer, in a way which they may determine, to the implementation of the procedure laid down in the Directive when adopting or publishing a technical regulation. Some Member States already do this, though not systematically.

(1) OJ L 291, 23 October 1990, p. 1.

(2) See Commission communication concerning the non-respect of certain provisions of Council Directive 83/189/EEC - OJ No C 254, 1st October 1986, p. 4.

The Commission believes that applying this formula across-the-board will increase legal certainty within the Member States, not only for individuals but also for public authorities when a matter is taken to court. It will also make it easier for the Commission to monitor Member States' compliance with the Directive.

B. IMPROVING THE BASIS FOR JOINT ACTION

33. By setting out to create transparency, the Directive is seeking to establish the conditions for maintaining and developing a unified market on a continuous basis. To this end it sets out two basic strategies - mutual recognition and harmonization - which involve a dialogue between the Member States and the Commission. In the case of mutual recognition the initiative is taken by the Member States themselves or by the Commission, in the form of a detailed opinion indicating that there are serious grounds for believing that a national draft is likely to jeopardize the proper functioning of the market. The initiative in the second case is taken by the Commission when major national differences in the rules governing economic sectors require it to act in order to safeguard the single market.

Mindful of the need to ensure the proper functioning of the internal market, the Commission has proposed a broadening of the conditions for unified action and a stepping-up of harmonization measures.

Detailed opinion

34. The 1983 Directive, which concentrated on the technical specifications applicable to a product prior to its placing on the market, took as the sole criterion for assessing a draft the potential technical barriers to the free movement of goods to which a draft might give rise. This criterion, embodied in Articles 30 to 36 of the Treaty, remains paramount and is not affected in any way by the present proposal.

However, when it comes to the actual operation of the internal market, the appraisal of a national measure has to be based on considerations which are not exclusively legal. It is a logical and necessary consequence of the proposed extension of the scope of the Directive, and particularly of the inclusion of requirements other than technical specifications and the desire to embrace the whole regulatory environment of the life of the product, that the basis for assessing regulations should be broadened to cover their potential repercussions on the market.

It is therefore proposed that the delivery of a detailed opinion should be based on an appraisal of how a national draft is likely to affect the proper functioning of the internal market.

This change is not only consistent with the new aims of the Directive, it is also an earnest of the Commission's determination to use the Directive as an instrument for shaping policy with regard to the internal market. As matters stand, the wording of a detailed opinion delivered by the Commission is designed to initiate the procedure laid down in Article 169 of the Treaty (letter of formal notice) (1). Naturally, this formula will continue to apply in cases where the draft under consideration contains aspects which are potentially in breach of the law. But the Commission believes, in keeping with the new approach underlying this proposal for an amendment to the Directive, that the dialogue and joint discussions with the Member States should be broadened out and no longer be restricted to a legal injunction.

Community action

35. The measures required to maintain and extend the internal market lead ultimately to harmonization. This is reflected in the Directive by the introduction of longer standstill periods either when the Commission has announced its intention to draw up Community rules or in cases where such rules have already been formally proposed and are before the Council.

The object of the standstill arrangements is to avoid a hardening of initial national positions, which might make consensus more difficult at a time when common solutions to major common problems are in preparation or actually under discussion.

36. Establishing conditions which will lead to agreement is vitally important when a proposal is before the Council. The current wording of the Directive stipulates a standstill period of one year for this purpose, in cases where the Commission takes the view that the subject of a draft technical regulation is one which is covered by a proposal for a Directive or Regulation already before the Council; the standstill period takes effect from the date on which the proposal in question is submitted. In practice this provision has proved unsuited to its intended purpose.

(1) Commission Decision COM (86) PV 813 of 5 February 1986.

The Commission has observed that Member States frequently take the initiative and enact regulations in such cases. In practice the time taken to consider a proposal in the Council is such that, in very many cases, the Commission is no longer able to implement the relevant standstill arrangements, either because more than one year has elapsed since the proposal was presented or because only a few weeks remain. To remedy this shortcoming it is proposed that the standstill period should no longer take effect from the date on which the proposal for harmonized measures was presented to the Council but from the date on which the Commission receives the national draft.

A proposal for the extension of the standstill period from 12 to 18 months in cases where the Commission ascertains that the proposed regulation is covered by a proposal to the Council is a reflection of the political will to ensure that, once harmonization measures have been initiated at Community level, Member States actually make every endeavour to bring them to fruition. Another argument in favour of extending the standstill period is the time which is normally needed to adopt a Community act. The aim is to make the standstill arrangement genuinely effective so that it can fulfil the purpose for which it was designed.

37. In keeping with that objective it is proposed that Member States should refrain from adopting regulations once the Council has adopted a common position on the Commission's harmonizing proposal.

This provision makes it clear that the political objective of the internal market is paramount and Member States must refrain from any measure liable to delay or endanger the achievement of that objective. It would be paradoxical in the extreme if a Member State which has agreed to a Community measure were allowed, before that measure was formally adopted, to take unilateral measures which often turn out in practice to be very different from the content of the common position.

38. The Commission would stress that the aim is not to prevent all national regulations, but simply to ensure that a Community solution is implemented as rapidly as possible once the need for such action has become apparent. After all, the need for harmonization stems in most cases from the absence of mutual recognition as between Member States in what is, by definition, an important area. It should also be remembered that the provisions described above only refer to new national measures which have been taken after the action planned at Community level has already been formally embodied in a Commission proposal.

39. The provisions of this proposal which state that the requirement to postpone or refrain from proposed measures in the event of Community harmonization shall no longer apply once such measures have been abandoned or have resulted in the adoption of a Community act are consistent with the importance attached to such measures.
40. The same thinking informs the proposal's definition of cases which are exempt from the requirements of the Directive. These exceptions are based in every case on the need to give precedence to the implementation of uniform provisions or to observance of the rules of the Treaty by the Member States.

Since the purpose of the Directive is to cover national technical regulations that are liable to interfere with the proper functioning of the internal market, it makes sense to exclude those obligations which transpose into national law common solutions set down in binding Community acts or arising from international commitments. However, it must be emphasized that this is not a blanket exemption.

For example, if a binding Community act simply lays down objectives and does not contain minimum requirements, thus leaving Member States a measure of discretion as regards the content of the corresponding national measures, such national measures shall be subject to the requirements of the Directive.

The exclusion of provisions whereby Member States implement safeguard clauses laid down in binding Community acts or implement Article 8(1) of the Directive on general product safety is warranted by the specific Community monitoring procedures laid down by these particular instruments.

Lastly, the paramount importance of fulfilling the obligations of the Treaty is reflected in the exclusion of national provisions implementing a judgment of the Court of Justice or removing, at the Commission's request, a barrier to trade. It should also be emphasized that this exemption is limited to those cases where the national provision is strictly the means by which the Member State implements the relevant Court decision or the request addressed to it by the Commission.

41. Under the current wording of the Directive the Commission is required to report annually to the Parliament on the results of its implementation. In the Commission's view this arrangement makes it difficult to obtain a sufficiently clear picture of the trends and developments in this particular area, the assessment of which is becoming very important in the context of the operation of the internal market. In view of this concern and the various administrative aspects involved, the Commission has proposed that a report be drawn up every two years and also that it be submitted to the Economic and Social Committee, a proposal which merely sanctions the existing practice.

Proposal for a
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amending for the second time
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laying down a procedure for
the provision of information in the field of
technical standards and regulations

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,
and in particular Articles 100a, 213 and 43 thereof,

Having regard to the proposal from the Commission⁽¹⁾,

In cooperation with the European Parliament⁽²⁾,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

whereas measures designed to ensure the proper functioning or to continue
the development of the internal market after 1 January 1993 should be
adopted;

whereas to this end as much transparency as possible should be ensured as
regards national initiatives for the establishment of technical standards
or regulations by amending the procedure for the provision of information
laid down in Directive 83/189/EEC;

whereas in order to remove barriers to the smooth functioning of the Single
Market the scope of the said Directive should be extended;

whereas in the light of past experience the procedure for notifying the
work programmes of the national standardization bodies should be amended in
order to define more clearly the information which has to be notified and
to make the procedure more flexible and less cumbersome;

whereas systematic notification is actually necessary only in the case of
new subjects for standardization and in so far as the treatment of these
subjects at national level may give rise to differences in national
standards which are liable to disturb the operation of the market as a
result; whereas any subsequent notification or communication relating to
the progress of national activities must depend on the interest in such
activities expressed by those to whom this new subject has already been
communicated;

(1) OJ No C
(2) OJ No C
(3) OJ No C

whereas the Commission must nevertheless be able to request the communication of part or all of the national standardization programmes so that it can review the development of standardization activity in particular economic sectors;

whereas the European standardization system must be organized by and for the parties concerned, on a basis of coherence, transparency, openness, consensus, independence of special interests, efficiency and decision-making based on national representation;

whereas the functioning of standardization in the Community must be based on fundamental rights for the national standardization bodies, such as the possibility of obtaining draft standards, being informed of the action taken in response to comments submitted, being associated with national standardization activities or requesting the preparation of European standards in place of national standards; whereas it is for the Member States to take the appropriate measures in their power to ensure that their standardization bodies observe these rights;

whereas the provisions contained in the Directive concerning the standstill arrangements applicable to national standardization bodies when a European standard is in preparation must be brought into line with the relevant provisions adopted by the standardization bodies within the framework of the European standardization bodies;

whereas, as far as technical regulations for products are concerned, the measures designed to ensure the proper functioning or the continued development of the market include greater transparency of national intentions and a broadening of the criteria and conditions for assessing the potential effect of the proposed regulations on the market;

whereas it is therefore necessary to assess all the requirements laid down in respect of a product and to take account of developments in national practices for the regulation of products;

whereas requirements, other than technical specifications, referring to the life cycle of a product after it has been placed on the market are liable to affect the free movement of that product or to create obstacles to the proper functioning of the internal market;

whereas the implementation of the Directive has revealed the need to clarify the concept of a de facto technical regulation; whereas, in particular, the provisions by which the public authority refers to technical specifications or other requirements, or encourages the observance thereof, and the provisions referring to products with which the public authority is associated, in the public interest, have the effect of conferring on such requirements or specifications a more binding value than they would otherwise have by virtue of their private origin;

whereas experience of the operation of the Directive has also revealed the need to clarify or explain in more detail certain definitions, rules of procedure or obligations of the Member States under the Directive, without prejudice to their obligations concerning the implementation of other Community Directives;

whereas the aim of the internal market is to create an environment that is conducive to the competitiveness of undertakings; whereas increased provision of information is one way of helping undertakings to make more of the advantages of this market; whereas it is therefore necessary to enable economic operators to give their assessment of the impact of the national technical regulations proposed by other Member States by providing for the regular publication of the titles of notified drafts and by amending the provisions relating to the confidentiality of such drafts;

whereas the Directive lays upon the Member States clear and unconditional obligations designed to ensure that new technical regulations, once adopted, are in conformity with Community law; whereas individuals may enforce these obligations before the courts; whereas it is therefore appropriate, in the interests of legal certainty, that Member States publicly announce that a national technical regulation has been adopted in accordance with the formalities laid down in the Directive;

whereas it is inherent in the internal market that, in particular where the principle of mutual recognition cannot be implemented by the Member States, the Commission proposes the adoption of binding Community acts; whereas a specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption, by the Council, of Commission proposals in the same field;

whereas experience has shown that, in order to be suited to its purpose, the standstill period must be prolonged in order to make additional allowance for the time taken by discussions in the Council; whereas, also with a view to facilitating the adoption of Community measures by the Council, Member States should refrain from adopting technical regulations once the Council has adopted a common position on the Commission proposal;

HAS ADOPTED THIS DIRECTIVE :

Article 1

Directive 83/189/EEC is hereby amended as follows :

1) Article 1 is amended as follows :

- paragraph 7) becomes paragraph 1);

- paragraph 1) is replaced by the following paragraphs :

"2. "technical specification", a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and production methods and processes, as well as conformity assessment procedures;

3. "other requirement", a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment and which affects its life cycle after it has been placed on the market, such as conditions of use, maintenance, recycling, re-use or disposal;'

- paragraphs 2), 3) and 4) become respectively paragraphs 4), 5) and 6).

- paragraph 7) is replaced by the following :

"7. European standardization body : a body referred to in Annex I to this Directive;"

- the following paragraphs are added :

"8. "national standardization body : a body referred to in Annex II to this Directive;"

"9. "technical regulation", technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions, except those provided for in Article 10 of this Directive, prohibiting the manufacture, importation, marketing or use of a product;

De facto technical regulations include :

- laws, regulations or administrative provisions of a Member State which refer to technical specifications or other requirements or to professional codes or codes of practice containing them, or which confer on compliance with such specifications, requirements or codes a presumption of conformity to the requirements they impose;

- voluntary agreements with which a public authority is associated and which provide, in the public interest, for compliance with technical specifications or other requirements, excluding public procurement contracts;
- laws, regulations or administrative provisions, except for those linked to national social security systems, referring to a technical specification or other requirement which, without formally making the latter mandatory, encourage compliance with it, in particular by fiscal or financial measures.

Technical regulations which are imposed by local authorities other than the authorities at the level immediately below central government shall be excluded.

10. "draft technical regulation", the text of a technical specification or other requirement, including administrative provisions, formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made;"

2) Article 2 is replaced by the following :

"Article 2

1. The Commission and the standardization bodies referred to in Annexes I and II shall be regularly informed of the new subjects for which the national bodies referred to in Annex II have decided, by including them in their standardization programme, to prepare or amend a standard, unless it is the transposition in full of an international or European standard;
2. This information shall indicate, in particular, whether the standard :
 - will transpose an international or European standard, incorporating certain national divergencies or amendments;
 - will be a new national standard;
 - will amend a national standard.

After consulting the Committee referred to in Article 5, the Commission may draw up rules for the consolidated presentation of this information and a plan and criteria governing the presentation of this information in order to facilitate its evaluation.

3. The Commission may ask for all or part of the standardization programmes to be communicated to it.

The Commission shall make this information available to the Member States in a form which allows the different programmes to be assessed and compared.

4. The Commission shall amend Annex II on the basis of communications from the Member States.
 5. The Council shall decide, on the basis of a proposal from the Commission, on any amendment to Annex I."
- 3) Article 3 is replaced by the following :

"Article 3

The standardization bodies referred to in Annexes I and II, and the Commission, shall be sent all draft standards on request; they shall be kept informed by the body concerned of the action taken on any comments they have made relating to drafts."

- 4) Article 4 is replaced by the following :

"Article 4

1. Member States shall take all necessary steps to ensure that their standardization bodies :
 - communicate information in accordance with the provisions of Article 2 and Article 3;
 - publish the draft standards in such a way that comments may also be obtained from parties established in other States;
 - grant the other bodies referred to in Annex II the right to be involved passively or actively (by sending an observer) in the planned activities;
 - do not object to a subject for standardization in their work programme being discussed at European level and undertake no action which may prejudice a decision in this regard.
 2. Member States shall refrain in particular from any act of recognition, approval or use by reference of a national standard adopted in breach of the provisions of Article 2, 3 and 4."
- 5) Article 7(1) is replaced by the following :

"1. Member States shall take all appropriate measures to ensure that, during the preparation of a European standard referred to in the first indent of Article 6(3) or after its approval, their standardization bodies shall not take any action which could prejudice the harmonization intended and, in particular, that they shall not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard."

6) Article 8 is amended as follows :

- paragraph 1 is replaced by the following :

"1. Subject to the provisions of Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where such technical regulation merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these are not already made clear in the draft.

Where appropriate - and unless it has already been sent with a prior communication - Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

Member States shall communicate the draft again under the above conditions if they make changes to the draft that have the effect inter alia of extending its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

Where, in particular, the draft seeks to limit the marketing or use of a chemical or pharmaceutical substance, preparation or product on grounds of public health, or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitute products, and communicate the anticipated effects of the measure on public health, the protection of the consumer and the environment.

The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it may also refer this draft to the Committee referred to in Article 5 and, where necessary, to the committee responsible for the field in question for an opinion."

- paragraphs 3 and 4 are replaced by the following :

- "3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.
4. The information supplied under this Article shall be confidential at the request of the notifying Member State, supported by reasons in every case."

- The following paragraph is added :

- "5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Community act, Member States may make a communication within the meaning of Article 8(1) of this Directive under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.

The absence of a reaction from the Commission under this Directive to a draft technical regulation of shall not prejudice any decision which might be taken under other Community acts."

7) Article 9 is replaced by the following :

"Article 9

1. Member States shall postpone the adoption of a draft technical regulation for three months from the date of the communication referred to in Article 8(1).
2. Without prejudice to paragraphs 3, 4 and 5, Member States shall postpone the adoption of a draft technical regulation for six months from the date of the communication referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the proper functioning of the internal market.

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

3. Member States shall postpone the adoption of a draft technical regulation for twelve months from the date of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its intention to propose or adopt a binding Community act on this matter.

4. Member States shall postpone the adoption of a draft technical regulation for eighteen months from the date of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal presented to the Council for a binding Community act.
5. Member States shall refrain from adopting a draft technical regulation as soon as the Council has adopted a common position on the proposal from the Commission.
6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse in any event
 - when the Commission informs the Member States that it no longer intends to propose or adopt a binding Community act;
 - when the Commission informs the Member States of the withdrawal of its draft or proposal;
 - when the Commission or the Council has adopted the act.
7. Paragraphs 1 to 5 shall not apply in those cases where, for urgent reasons, occasioned by serious and unforeseeable circumstances, relating to the protection of public health or safety, the protection of animals or the preservation of plants, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State shall give, in the communication referred to in Article 8, the reasons which warrant the urgency of the measures taken. The Commission shall decide whether to accept or refuse the urgent procedure within a time limit of not more than five working days. It shall take appropriate action in cases where improper use is made of this procedure.

8) Article 10 is replaced by the following :

"Article 10

Articles 8 and 9 shall not apply to the laws, regulations and administrative provisions of the Member States by means of which Member States :

- comply with binding Community acts which result in the adoption of technical specifications;
- fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications in the Community;

- make use of safeguard clauses provided for in binding Community acts;
- apply Article 8(1) of Directive 92/59/EEC on general product safety;
- restrict themselves to implementing a judgment of the Court of Justice of the European Communities;
- restrict themselves to amending a technical regulation within the meaning of Article 1(9) of this Directive, in conformity with a Commission request, with a view to removing an obstacle to trade."

9) Article 11 is replaced by the following :

"Article 11

The Commission shall report every two years to the European Parliament and the Economic and Social Committee on the results of the application of this Directive."

10) Article 12 is replaced by the following :

"Article 12

1. The Commission shall publish on a regular basis in the Official Journal of the European Communities a list of titles of the draft technical regulations which have been notified to it pursuant to Article 8(1).
2. Where Member States adopt a technical regulation, they shall contain a reference to this Directive or shall be accompanied by such a reference when they are published in the Official Journal.

The procedures for making such a reference shall be laid down by the Member States."

11) The Annex is replaced by the following :

"ANNEX I

European standardization bodies

CEN
Comité Européen de Normalisation

CENELEC
Comité Européen de Normalisation Electrotechnique

ETSI
Institut Européen des Normes de Télécommunication

ANNEX II

National standardization bodies in the Member States
of the European Community

1. BELGIUM :

IBN/BIN
Institut Belge de Normalisation
Belgisch Instituut voor Normalisatie

CEB/BEC
Comité Electrotechnique Belge
Belgish Elektrotechnisch Comité

2. DENMARK :

DS
Dansk Standardiseringsrad

DEK
Dansk Elektroteknisk Komite

3. GERMANY :

DIN
Deutsches Institut für Normung e.V.

DKE
Deutsche Elektrotechnische Kommission im DIN und VDE

4. GREECE :

ELOT
Hellenic Organization for Standardization

5. SPAIN :

AENOR
Asociación Española Normalización y Certificación

6. FRANCE :

AFNOR
Association Française de Normalisation

UTE
Union Technique de l'Electricité

7. IRELAND :

NSAI
National Standards Authority of Ireland

ETCI
Electro-Technical Council of Ireland

8. ITALY

UNI
Ente Nazionale Italiano di Unificazione

CEI
Comitato Elettrotecnico Italiano

9. LUXEMBOURG :

ITM
Inspection du Travail et des Mines

SEE
Service de l'Energie de l'Etat

10. NETHERLANDS :

NNI
Nederlands Normalisatie Instituut

NEC
Nederlands Elektrotechnisch Comité

11. PORTUGAL :

IPQ
Instituto Português da Qualidade

12. UNITED KINGDOM :

BSI
British Standards Institution

BEC
British Electrotechnical Committee

Article 2

1. Member States shall take the measures necessary to comply with this Directive not later than 1 January 1994. They shall forthwith inform the Commission thereof.
2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the Council,
The President

FINANCIAL STATEMENT

SECTION 1 - FINANCIAL IMPLICATIONS

1. Title of operation

Amendment for the second time of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations.

2. Budget headings involved

- Item A-1178 : administrative technical assistance in support of various activities.
- Article A-238 : operating expenditure on administrative technical assistance.
- Item A-2510 : expenditure on meetings of committees whose consultation is compulsory.
- Article A-340 : Official Journal.

3. Legal basis

Articles 100a, 213 and 43 of the EEC Treaty.

4. Description of operation

4.1 Specific objectives of operation

Amendment for the second time of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations : extension of the field of application, strengthening of European standardization.

Compulsory notification of draft national technical standards and regulations with a view to avoiding obstacles to the proper functioning of the internal market.

4.2 Duration

Indefinite.

5. Anti-fraud measures

Expenditure is subject to the anti-fraud measures laid down in the contracts. The following operations are carried out or monitored by the Commission :

- Translation work : breakdown of pages for translation, delivery deadline (2, 15 or 30 days), details of invoicing, quality control, confidentiality, written report of activities at the request of the Commission.
- Monitoring of publications : monthly report, quality of summary files.
- Outside staff : monitoring of time taken, quality.

SECTION 2 : ADMINISTRATIVE EXPENDITURE

The figure given represents the overall cost of administering Directive 83/189/EEC. It has been obtained by extrapolating the cost of previous years and taking account of the extension of the Directive's field of application.

a) Expenditure arising out of this Directive is essentially :

- the cost of translating notified drafts which are sent to the other EC Member States and translated at their request;
- Service contract providing technical assistance at the request of Member States for the translation of drafts. This expenditure is broken down as follows :
 - 1993 : ECU 6,000,000
 - 1994 : ECU 7,400,000 (+ 23.3 %)
- The Committee on Standards and Technical Regulations was set up in 1983, under Article 5 of the Directive. It is competent for both technical standards and regulations. It meets six times a year, at an estimated cost of ECU 69,120 in 1993, to be charged to Item A-2570 (ECU 480 per expert per meeting).
- Service contract for checking Member States' compliance with obligations under Directive 83/189/EEC : 420,000 ECU (reading and analysis of Member States' government gazettes to detect technical regulations, identification and analysis of any other official publications containing such regulations, drawing up summary files and monthly report to the Commission).
- Service contracts for in-house staff. Total cost ECU 674,000 broken down as follows :
 - 2 computer specialists (ECU 198,000)
 - 2 keyboard operators (ECU 88,000)
 - 6 typists (ECU 300,000)
 - 2 messengers (ECU 88,000)
- Publication of the list of titles of draft technical regulations in the Official Journal, to be charged to Article A-340 : P.M.

Table of administrative expenditure

YEAR	HEADING	AMOUNT	DESCRIPTION OF ACTIVITY	MAN/YEARS
1993	A-1178 A-238	4 800 000 1 200 000	Technical assistance for translation	75
	A-1178 A-238	336 000 84 000	Analysis of official gazettes and reporting	5.25
	A-1178 A-238	539 200 134 800	In-house services	12
	A-2510	69 120	Meetings of the Committee on Standards and Technical Regulations	
TOTAL 1993		7 163 120		116.25
	TOTAL A-1178	5 675 200		
	TOTAL A-238	1 418 800		
1994	A-1178 A-238	5 920 000 1 480 000	Technical assistance for translation	75
	A-1178 A-238	352 800 88 200	Analysis of official gazettes and reporting	5.25
	A-1178 A-238	566 160 141 540	In-house services	12
	A-2510	72 576	Meetings of the Committee on Standards and Technical Regulations	
TOTAL 1994		8 621 276		116.25
	TOTAL A-1178	6 838 960		
	TOTAL A-238	1 709 740		

- b) This proposal does not involve any new function or task in relation to the existing situation.

The contracts (translation, monitoring, staff) already exist.

Outside staff performing public service tasks will gradually be replaced by staff covered by the staff regulations as posts are granted by the budgetary authority as part of the process of converting appropriations into posts.

SECTION 3 : ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

I. Objectives and coherence with financial programming

1. The proposed operation aims to improve the transparency of Member States' intentions (standards or technical regulations) regarding technical specifications for products, and to step up action at Community level in areas where this proves necessary.

Essentially, the proposal extends the field of application of the Directive for technical regulations so as to cover requirements, other than technical specifications, affecting a product after it is placed on the market. It offers traders the opportunity to receive information, clarifies certain obligations of the Member States and introduces a tougher standstill procedure when a harmonization proposal is before the Council. Regarding standards, it increases cooperation between standardization bodies and also introduces a tougher standstill procedure when a harmonized standard is being drafted.

2. The operation is included in DG III's financial plan and in the appropriations allocated to technical standardization and harmonization work.
3. The overall objective is the completion of the internal market.

II. Grounds for the operation

Besides preventing the creation of new barriers to trade, the proposal aims to help ensure the proper functioning of the internal market after 1993. It also gives economic operators an opportunity to state their views, establishes the role of European standardization and endeavours to prevent Community harmonization, once decided, from being compromised by national initiatives in the same field.

III. Monitoring and application of the operation

Monitoring and application are carried out by the committee set up under Directive 83/189/EEC.

The Commission reports on the operation of the Directive to the other institutions every two years.

Impact assessment form

Impact of the proposal on business
with special reference to
small and medium-sized enterprises

TITLE OF PROPOSAL

Proposal for a Directive amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations.

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims ?

National technical standards and regulations can create barriers to trade. Directive 83/189/EEC introduced a mechanism to prevent new barriers which could arise out of national initiatives. The proposal adapts the instrument to the new requirement to ensure that the internal market functions properly from 1993.

IMPACT ON BUSINESS

2. Businesses are not affected by the proposal. It offers them a new opportunity to state their views on the planned national technical regulations. This concerns :

- all business sectors,
- businesses of all sizes, including multinationals and SMEs,
- no particular geographical areas.

3. What will businesses have to do to comply with the proposal ?

Nothing.

4. What economic effects is the proposal likely to have ?

- on employment = no significant effects are expected,
- on investment and the creation of new businesses : no effect is expected,

- on the competitive position of businesses :

this proposal extends the field of application of the procedure for the provision of information of Directive 83/189/EEC to include requirements, other than technical specifications, imposed on a product after it is placed on the market, and aims to prevent technical barriers to free movement of goods and to ensure the proper functioning of the internal market. It will also allow economic operators to state their views on planned national technical regulations. It is a means of creating a uniform economic environment for businesses and hence of improving their competitive position.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms ?

No.

CONSULTATION

The procedure for the provision of information introduced by Directive 83/189/EEC and this proposal to amend it for a second time imposes obligations on the Member States. The consultation of business circles is not relevant here.

Before making the proposal, the Commission consulted the committee of representatives of the Member States set up by Directive 83/189/EEC and held in-depth discussions with the European standardization bodies.

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