DIRECTIVE 94/10/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

of 23 March 1994

materially 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 EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure referred to in Article 189B of the Treaty,

Whereas in order to promote the smooth functioning of the internal market 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 [3];

Whereas in order to remove barriers to the smooth functioning of the internal 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 functioning 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;

Whereas the Commission must nevertheless be able to request the communication of all or part 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 Directive 83/189/EEC 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 Directive 83/189/EEC 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;

(1) OJ No C 340, 23. 12. 1992, p. 7.
(2) OJ No C 201, 26. 7. 1993, p. 11.
(3) OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Decision 92/400/EEC (OJ No L 221, 6. 8. 1992, p. 55).

Whereas it is therefore imperative that the urgency procedure be adapted in a way that reflects experience to date.

Whereas experience of the operation of Directive 83/189/EEC 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 inherent in 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 it is 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 Directive 83/189/EEC as last amended by this 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;

Where 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 a Commission proposal concerning that sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. Article 1 shall be amended as follows:

(a) paragraph 7 shall become paragraph 1;

(b) paragraph 1 shall be replaced by the following:

'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 conformity assessment procedures;

The term "technical specification" also covers production methods and processes used in respect of agricultural products as referred to in Article 38 (1) of the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65/65/EEC (*), as well as production methods and processes relating to other products, where these have an effect on their characteristics.

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, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

(*) OJ No 22, 9. 2. 1965, p. 369/65. Directive as last amended by Directive 93/39/EEC (OJ No L 214, 24. 8. 1993, p. 22).';

(c) paragraph 2 shall be replaced by the following:

'4. "standard", a technical specification approved by a recognized standardization body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

— international standard: a standard adopted by an international standardization organization and made available to the public,

— European standard: a standard adopted by a European standardization body and made available to the public,

— national standard: a standard adopted by a national standardization body and made available to the public;'

(d) paragraph 3 shall be replaced by the following:

'5. "standards programme", a work programme of a recognized standardization body listing the subjects on which standardization work is being carried out;'

(e) paragraph 4 shall become paragraph 6;

(f) paragraph 7 shall be replaced by the following:

'7. "European standardization body", a body referred to in Annex I';

(g) the following paragraphs shall be added:

'8. "national standardization body", a body referred to in Annex II;

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 of Member States, except those provided for in Article 10, 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 either to technical specifications or other requirements or to professional codes or codes of practice which in turn refer to technical specifications or other requirements and compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,

— voluntary agreements to which a public authority is a contracting party and which provide, in the public interest, for compliance with technical specifications or other requirements, excluding public procurement tender specifications,

— technical specifications or other requirements which are linked to fiscal or financial measures affecting the consumption of products by encouraging compliance with such technical specifications or other requirements; technical specifications or other requirements linked to national social-security systems are not included.

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list to be drawn up by the Commission before the entry into force of this Directive in the framework of the Committee referred to in Article 5.

The same procedure shall be used for amending this list;

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.

This Directive shall not apply to those measures Member States consider necessary under the Treaty for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.'

2. Article 2 shall be replaced by the following:

'Article 2

1. The Commission and the standardization bodies referred to in Annexes I and II shall be informed of the new subjects for which the national bodies referred to in Annex II have decided, by including them in their standards programme, to prepare or amend a standard, unless it is an identical or equivalent transposition of an international or European standard.

2. The information referred to in paragraph 1 shall indicate, in particular, whether the standard concerned:

— will transpose an international standard without being the equivalent,

— will be a new national standard, or

— 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 standards programmes to be communicated to it.