

## 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 <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

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 <sup>(3)</sup>;

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;

<sup>(1)</sup> OJ No C 340, 23. 12. 1992, p. 7.

<sup>(2)</sup> OJ No C 201, 26. 7. 1993, p. 11.

<sup>(3)</sup> 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.

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

4. Where appropriate, 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 shall be 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 shall be 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 Articles 2 and 3,
- publish the draft standards in such a way that comments may also be obtained from parties established in other Member 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 in accordance with the rules laid down by the European standardization bodies 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 Articles 2, 3 and 4.'

5. Article 7 (1) shall be 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 do not take any action which could prejudice the harmonization intended and, in particular, that they do 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 shall be amended as follows:

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

'1. Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it 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 have not already been 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 of significantly altering 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 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 substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10 (4) of Regulation (EEC) No 793/93 (\*) in the case of an existing substance or in Article 3 (2) of Directive 92/32/EEC (\*\*\*) in the case of a new substance.

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, for an opinion, to the Committee referred to in Article 5 and, where appropriate, to the committee responsible for the field in question.

With respect to the technical specifications or other requirements referred to in Article 1 (9), third indent, the detailed comments or opinions of the Commission or the Member States may concern only the aspect which may hinder trade and not the fiscal or financial aspect of the measure.

(\*) OJ No L 84, 5. 4. 1993, p. 1.

(\*\*) OJ No L 154, 5. 6. 1992, p. 1.;

- (b) paragraphs 3 and 4 shall be replaced by the following:

'3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.

4. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.

In cases of this kind, if necessary precautions are taken, the Commission and the national authorities may seek expert advice from physical or legal persons in the private sector.;

- (c) the following paragraph shall be 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 shall not prejudice any decision which might be taken under other Community acts.'

7. Article 9 shall be 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 receipt by the Commission of the communication referred to in Article 8 (1).

2. Member States shall postpone:

- for four months the adoption of a draft technical regulation in the form of a voluntary agreement

within the meaning of Article 1 (9), second indent,

- without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation,

from the date of receipt by the Commission 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 free movement of goods within 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 12 months from the date of receipt by the Commission 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 Directive, Regulation or Decision on the matter in accordance with Article 189 of the Treaty.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission 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 for a Directive, Regulation or Decision presented to the Council in accordance with Article 189 of the Treaty.

5. If the Council adopts a common position during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to Article 9 (6), be extended to 18 months.

6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:

- 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 a binding Community 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 give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.'

8. Article 10 shall be replaced by the following:

*'Article 10*

1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements 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 Council Directive 92/59/EEC of 29 June 1992 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 accordance with a Commission request, with a view to removing an obstacle to trade.

2. Article 9 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 (3) to (6) shall not apply to the voluntary agreements referred to in Article 1 (9), second indent.

4. Article 9 shall not apply to the technical specifications or other requirements referred to in Article 1 (9), third indent.'

(\* ) OJ No L 228, 11. 8. 1992, p. 24.'

9. Article 11 shall be replaced by the following:

*'Article 11*

The Commission shall report every two years to the European Parliament, the Council and the Economic and Social Committee on the results of the application of this Directive. Lists of standardization work entrusted to the European standardization organizations pursuant to this Directive, as well as statistics on the notifications received shall be published on an annual basis in the *Official Journal of the European Communities*.'

10. Article 12 shall be replaced by the following:

*'Article 12*

When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.'

11. The Annex shall be replaced by Annexes I and II appearing in the Annex to this Directive.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1995. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate the main provisions of national law which they adopt in the field covered by this Directive to the Commission.

*Article 3*

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

*For the  
European Parliament  
The President  
E. KLEPSCH*

*For the Council  
The President  
TH. PANGALOS*

## ANNEX

## ANNEX I

## European standardization bodies

CEN  
Comité Européen de Normalisation

Cenelec  
Comité Européen de Normalisation Electrotechnique

ETSI  
European Telecommunications Standards Institute

## ANNEX II

## National standardization bodies

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| <p>1. BELGIUM</p> <p>IBN/BIN<br/>Institut belge de normalisation<br/>Belgisch Instituut voor Normalisatie</p> <p>CEB/BEC<br/>Comité électrotechnique belge<br/>Belgisch Elektrotechnisch Comité</p> <p>2. DENMARK</p> <p>DS<br/>Dansk Standardiseringsråd</p> <p>DEK<br/>Dansk Elektroteknisk Komite</p> <p>3. GERMANY</p> <p>DIN<br/>Deutsches Institut für Normung e.V.</p> <p>DKE<br/>Deutsche Elektrotechnische Kommission im DIN und VDE</p> <p>4. GREECE</p> <p>ELOT<br/>Hellenic Organization for Standardization</p> <p>5. SPAIN</p> <p>AENOR<br/>Asociación Española de Normalización y Certificación</p> <p>6. FRANCE</p> <p>AFNOR<br/>Association française de normalisation</p> <p>UTE<br/>Union technique de l'électricité — Bureau de normalisation<br/>auprès de l'AFNOR</p> | <p>7. IRELAND</p> <p>NASI<br/>National Standards Authority of Ireland</p> <p>ETCI<br/>Electro-Technical Council of Ireland</p> <p>8. ITALY</p> <p>UNI<br/>Ente Nazionale Italiano di Unificazione</p> <p>CEI<br/>Comitato Elettrotecnico Italiano</p> <p>9. LUXEMBOURG</p> <p>ITM<br/>Inspection du travail et des mines</p> <p>SEE<br/>Service de l'énergie de l'Etat</p> <p>10. NETHERLANDS</p> <p>NNI<br/>Nederlands Normalisatie Instituut</p> <p>NEC<br/>Nederlands Elektrotechnisch Comité</p> <p>11. PORTUGAL</p> <p>IPQ<br/>Instituto Português da Qualidade</p> <p>12. UNITED KINGDOM</p> <p>BSI<br/>British Standards Institution</p> <p>BEC<br/>British Electrotechnical Committee.</p> |
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