

Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services; (repealed)

Article 1

For the purposes of this Directive, the following meanings shall apply:

1. ‘product’, any industrially manufactured product and any agricultural product, including fish products;
2. [^{F1}‘service’, any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

- ‘at a distance’ means that the service is provided without the parties being simultaneously present,
- ‘by electronic means’ means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,
- ‘at the individual request of a recipient of services’ means that the service is provided through the transmission of data on individual request.

An indicative list of services not covered by this definition is set out in Annex V.

This Directive shall not apply to:

- radio broadcasting services,
- television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC⁽¹⁾

3. ‘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 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⁽²⁾, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

4. ‘other requirements’, 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;
5. [^{F1}‘rule on services’, requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2, in particular provisions

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concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC⁽⁹⁾.

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex VI to this Directive.

With the exception of Article 8(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

For the purposes of this definition:

- a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,
 - a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner.]
6. ‘standard’, a technical specification approved by a recognised standardisation 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 standardisation organisation and made available to the public,
 - European standard: a standard adopted by a European standardisation body and made available to the public,
 - national standard: a standard adopted by a national standardisation body and made available to the public;
 7. ‘standards programme’, a work programme of a recognised standardisation body listing the subjects on which standardisation work is being carried out;
 8. ‘draft standard’, document containing the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the national standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny;
 9. ‘European standardisation body’, a body referred to in Annex I;
 10. ‘national standardisation body’, a body referred to in Annex II;
 11. ^{[F1}‘technical regulation’, technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator 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 or prohibiting the provision or use of a service, or establishment as a service provider.

De facto technical regulations include:

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- laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, 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 general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications,
- technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services 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 5 August 1999 (*), in the framework of the Committee referred to in Article 5.

The same procedure shall be used for amending this list;

12. ‘draft technical regulation’, the text of a technical specification or other requirement or of a rule on services, 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.

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).

Article 2

1 The Commission and the standardisation 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.

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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.

Article 3

The standardisation 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.

Article 4

1 Member States shall take all necessary steps to ensure that their standardisation 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 standardisation in their work programme being discussed at European level in accordance with the rules laid down by the European standardisation 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 to a national standard adopted in breach of Articles 2 and 3 and of paragraph 1 of this Article.

Article 5

A Standing Committee shall be set up consisting of representatives appointed by the Member States who may call on the assistance of experts or advisers; its chairman shall be a representative of the Commission.

The Committee shall draw up its own rules of procedure.

Article 6

1 The Committee shall meet at least twice a year with the representatives of the standards institutions referred to in Annexes I and II.

[^{F1}The Committee shall meet in a specific composition to examine questions concerning Information Society services.]

2 The Commission shall submit to the Committee a report on the implementation and application of the procedures set out in this Directive, and shall present proposals aimed at eliminating existing or foreseeable barriers to trade.

3 The Committee shall express its opinion on the communications and proposals referred to in paragraph 2 and may in this connection propose, in particular, that the Commission:

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- request the European standards institutions to draw up a European standard within a given time limit,
- ensure where necessary, in order to avoid the risk of barriers to trade, that initially the Member States concerned decide amongst themselves on appropriate measures,
- take all appropriate measures,
- identify the areas where harmonisation appears necessary, and, should the case arise, undertake appropriate harmonisation in a given sector.

4 The Committee must be consulted by the Commission:

- a before any amendment is made to the lists in Annexes I and II (Article 2(1));
- b when drawing up the rules for the consolidated presentation of information and the plan and criteria for the presentation of standards programmes (Article 2(2));
- c when deciding on the actual system whereby the exchange of information provided for in this Directive is to be effected and on any change to it;
- d when reviewing the operation of the system set up by this Directive;
- e on the requests to the standards institutions referred to in the first indent of paragraph 3.

5 The Committee may be consulted by the Commission on any preliminary draft technical regulation received by the latter.

6 Any question regarding the implementation of this Directive may be submitted to the Committee at the request of its chairman or of a Member State.

7 The proceedings of the Committee and the information to be submitted to it shall be confidential.

However, the Committee and the national authorities may, provided that the necessary precautions are taken, consult, for an expert opinion, natural or legal persons, including persons in the private sector.

[^{F18} With respect to rules on services, the Commission and the Committee may consult natural or legal persons from industry or academia, and where possible representative bodies, capable of delivering an expert opinion on the social and societal aims and consequences of any draft rule on services, and take notice of their advice whenever requested to do so.]

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).

Article 7

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 standardisation bodies do not take any action which could prejudice the harmonisation 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.

2 Paragraph 1 shall not apply to the work of standards institutions undertaken at the request of the public authorities to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products.

Member States shall communicate all requests of the kind referred to in the preceding subparagraph to the Commission as draft technical regulations, in accordance with Article 8(1), and shall state the grounds for their enactment.

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Article 8

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⁽⁴⁾ in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC⁽⁵⁾, 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.

[^{F1}With respect to the technical specifications or other requirements or rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1, the comments or detailed opinions of the Commission or Member States may concern only aspects which may hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators and not the fiscal or financial aspects of the measure.]

2 The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

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 Committee referred to in Article 5 and the national authorities may seek expert advice from physical or legal persons in the private sector.

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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 paragraph 1 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.

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).

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).

[^{F1}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 the second indent of the second subparagraph of point 11 of Article 1,
- without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation (except for draft rules on services),

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;

- without prejudice to paragraphs 4 and 5, for four months the adoption of any draft rule on services, 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 services or to the freedom of establishment of service operators within the internal market.

With regard to draft rules on services, detailed opinions from the Commission or Member States may not affect any cultural policy measures, in particular in the audiovisual sphere, which Member States might adopt in accordance with Community law, taking account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.

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.

With respect to rules on services, the Member State concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.

3 With the exclusion of draft rules relating to services, Member States shall postpone the adoption of a draft technical regulation for twelve months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within three months of that

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date, the Commission announces its intention of proposing or adopting 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 paragraph 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.

[^{F17} Paragraphs 1 to 5 shall not apply in 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, and for rules on services, also for public policy, notably the protection of minors, 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 or
- for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.

In the communication referred to in Article 8, the Member State shall give reasons for 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.]

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).

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:

- [^{F1}comply with binding Community acts which result in the adoption of technical specifications or rules on services,
- fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Community,]
- make use of safeguard clauses provided for in binding Community acts,
- apply Article 8(1) of Directive 92/59/EEC⁽⁶⁾,
- restrict themselves to implementing a judgment of the Court of Justice of the European Communities,

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— [^{F1}restrict themselves to amending a technical regulation within the meaning of point 11 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.]

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.

[^{F13} Paragraphs 3 to 6 of Article 9 shall not apply to the voluntary agreements referred to in the second indent of the second subparagraph of point 11 of Article 1.

4 Article 9 shall not apply to the technical specifications or other requirements or the rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1.]

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).

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 standardisation work entrusted to the European standardisation organisations 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*.

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.

Article 13

1 The Directives and Decisions listed in Annex III, Part A are hereby repealed without prejudice to the obligations of the Member States concerning the deadlines for transposition of the said Directives, set out in Annex III, Part B.

2 References to the repealed directives and decisions shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex IV.

Article 14

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 15

This Directive is addressed to the Member States.

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- (1) [^{F1}OJ L 298, 17.10.1989, p. 23. Directive as last amended by Directive 97/36/EC (OJ L 202, 30.7.1997, p. 1).]
- (2) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ 22, 9.2.1965, p. 369/65), Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
- (3) [^{F1}OJ L 192, 24.7.1990, p. 1. Directive as amended by Directive 97/51/EC OJ L 295, 29.10.1997, p. 23].]
- (4) Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).
- (5) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1). Directive, as amended by Directive 92/32/EEC (OJ L 154, 5.6.1992, p. 1).
- (6) Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ L 228, 11.8.1992, p. 24).

Textual Amendments

F1 Inserted by [Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998](#).