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EUROPEAN COMMISSION



Brussels, 23.4.2010 COM(2010)179 final

2010/0095 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services

(Codification)

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EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying the law of the Union so as to make it clearer and more accessible to the ordinary citizen, thus giving him new opportunities and the chance to make use of the specific rights it gives him.

This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

For this reason a codification of rules that have frequently been amended is also essential if the law is to be clear and transparent.

- 2. On 1 April 1987 the Commission decided¹ to instruct its staff that all legislative acts should be <u>codified</u> after <u>no more</u> than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the rules are clear and readily understandable.
- 3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this², stressing the importance of <u>codification</u> as it offers certainty as to the law applicable to a given matter at a given time.

Codification must be undertaken in full compliance with the normal procedure for the adoption of acts of the Union.

Given that no changes of substance may be made to the instruments affected by <u>codification</u>, the European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

4. The purpose of this proposal is to undertake a codification of 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 services³. The new Directive will supersede the various acts incorporated in it⁴; this proposal fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

See Annex V, Part A of this proposal.

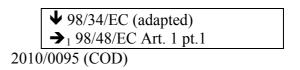
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COM(87) 868 PV.

See Annex 3 to Part A of the Conclusions.

³ Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

5. The <u>codification</u> proposal was drawn up on the basis of a <u>preliminary consolidation</u>, in all official languages, of Directive 98/34/EC and the instruments amending it, carried out by the Publications Office of the European Union, by means of <u>a data-processing system</u>. Where the Articles have been given new numbers, the correlation between the old and the new numbers is shown in a table contained in Annex VI to the codified Directive.



Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

 \Rightarrow_1 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services \leftarrow (codification)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles \boxtimes 114 \boxtimes , \boxtimes 337 \boxtimes and 43 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee⁵,

After transmission of the proposal to the national Parliaments,

Acting in accordance with the ordinary legislative procedure⁶,

Whereas:



(1) 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 services⁷; has been substantially amended several times⁸. In the interests of clarity and rationality the said Directive should be codified.



(2) The internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured. Therefore, the prohibition of quantitative restrictions on the movement of goods and of measures having an equivalent effect is one of the basic principles of the Union.

⁵ OJ C [...], [...], p. [...].

OJC [...], [...], p. [...].

OJ L 204, 21.7.1998, p. 37.

See Annex V, Part A.

- (3) 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.
- (4) Barriers to trade resulting from technical regulations relating to products may be allowed only where they are necessary in order to meet essential requirements and have an objective in the public interest of which they constitute the main guarantee.
- (5) It is essential for the Commission to have the necessary information at its disposal before the adoption of technical provisions. Consequently, the Member States which are required to facilitate the achievement of its task pursuant to Article 4(3) of the Treaty on European Union (TEU) must notify it of their projects in the field of technical regulations.
- (6) All the Member States must also be informed of the technical regulations contemplated by any one Member State.
- (7) The aim of the internal market is to create an environment that is conducive to the competitiveness of undertakings. Increased provision of information is one way of helping undertakings to make more of the advantages inherent in this market. 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 means of the provisions relating to the confidentiality of such drafts.
- (8) 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 this Directive.
- (9) 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.
- (10) 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.
- (11) 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.
- (12) It is necessary to clarify the concept of a *de facto* technical regulation. 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.
- (13) The Commission and the Member States must also be allowed sufficient time in which to propose amendments to a contemplated measure, in order to remove or reduce any barriers which it might create to the free movement of goods.

(14) The Member State concerned must take account of these amendments when formulating the definitive text of the measure envisaged.

♦ 98/34/EC (adapted)

- (15) 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 adopts or proposes the adoption of binding acts. A specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption of binding acts by ⋈ the European Parliament and ⋈ the Council or ⋈ by ⋈ the Commission in the same field.
- (16) The Member State in question must, pursuant to the general obligations laid down in Article 4(3) of the TEU, defer implementation of the contemplated measure for a period sufficient to allow either a joint examination of the proposed amendments or the preparation of a proposal for a ⋈ legislative ⋈ act or the adoption of a binding act of the Commission.

▶ 98/34/EC recital 18 (adapted)

With a view to facilitating the adoption of measures

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♦ 98/34/EC recital 19

(18) In practice, national technical standards may have the same effects on the free movement of goods as technical regulations.

▶ 98/34/EC recital 20 (adapted)

It would therefore appear necessary to inform the Commission of draft standards under similar conditions to those which apply to technical regulations. Pursuant to Article 337 of the TEU, the Commission may, within the limits and under the conditions laid down by the Council in accordance with the provisions of the ⊠ Treaties ⊠, collect any information and carry out any checks required for the performance of the tasks entrusted to it.

♦ 98/34/EC recital 21

(20) It is also necessary for the Member States and the standards institutions to be informed of standards contemplated by standards institutions in the other Member States.

♦ 98/34/EC recital 22

(21) Systematic notification is actually necessary only in the case of new subjects for standardisation 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. 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.

♦ 98/34/EC recital 23

(22) The Commission must nevertheless be able to request the communication of all or part of the national standardisation programmes so that it can review the development of standardisation activity in particular economic sectors.

♦ 98/34/EC recital 24

(23) The European standardisation system must be organised 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.

▶ 98/34/EC recital 25 (adapted)

(24) The functioning of standardisation in the Union must be based on fundamental rights for the national standardisation bodies, such as the possibility of obtaining draft standards, being informed of the action taken in response to comments submitted, being associated with national standardisation activities or requesting the preparation of European standards in place of national standards. It is for the Member States to take the appropriate measures in their power to ensure that their standardisation bodies observe these rights.

♦ 98/34/EC recital 26

(25) The provisions concerning the standstill arrangements applicable to national standardisation bodies when a European standard is in preparation must be brought into line with the relevant provisions adopted by the standardisation bodies within the framework of the European standardisation bodies.

▶ 98/34/EC recital 27 (adapted)

(26) It is necessary to ⊠ envisage ⊠ a Standing Committee, the members of which ⊠ are ⊠ appointed by the Member States with the task of helping the Commission to examine draft national standards and cooperating in its efforts to lessen any adverse effects thereof on the free movement of goods.

♦ 98/34/EC recital 28

(27) The Standing Committee should be consulted on the draft standardisation requests referred to in this Directive.

$\mathbf{\Psi}$	98/34/E0	7 recital	29
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(28) This Directive must not affect the obligations of the Member States concerning the deadlines for transposition in national law of the Directives set out in Annex V, Part B,

♦ 98/34/EC

HAVE ADOPTED THIS DIRECTIVE:

Article 1

- 1. For the purposes of this Directive, the following meanings shall apply:
- (a) 'product', any industrially manufactured product and any agricultural product, including fish products;

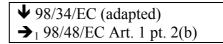
♦ 98/48/EC Art. 1 pt. 2(a)

(b) '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:

- (i) 'at a distance' means that the service is provided without the parties being simultaneously present,
- (ii) '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.
- (iii) '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 III;



→₁ (c) ← '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), second

subparagraph of the TFEU, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive \boxtimes 2001/83/EC of the European Parliament and of the Council \boxtimes ⁹, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

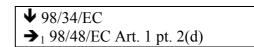
→ 1 (d) ← 'other requirements', a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

♦ 98/48/EC Art. 1 pt. 2(c)

(e) 'rule on services', requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point (b), in particular provisions 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.

For the purposes of this definition:

- (i) 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,
- (ii) 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;



- →₁ (f) ← '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:
 - (i) international standard: a standard adopted by an international standardisation organisation and made available to the public,
 - (ii) European standard: a standard adopted by a European standardisation body and made available to the public,
 - (iii) national standard: a standard adopted by a national standardisation body and made available to the public;
- →₁ (g) ← 'standards programme', a work programme of a recognised standardisation body listing the subjects on which standardisation work is being carried out;

- → (h) ← '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;
- \rightarrow_1 (i) \leftarrow 'European standardisation body', a body referred to in Annex I;
- \rightarrow ₁ (j) \leftarrow 'national standardisation body', a body referred to in Annex II;

▶ 98/48/EC Art. 1 pt. 2(e)

(k) '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:

- (i) 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,
- (ii) 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,
- (iii) 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

♦ 98/48/EC Art. 1 pt. 2(e) (adapted)

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list ⊠ drawn up and updated, where appropriate ⊠ by the Commission before, in the framework of the Committee referred to in Article 5.

♥ 98/48/EC Art. 1 pt. 2(e)

The same procedure shall be used for amending this list;

▶ 98/48/EC Art. 1 pt. 2(f)

(l) '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.

♦ 98/48/EC Art. 1 pt. 2(a) (adapted)

- 2. This Directive shall not apply to:
- (a) radio broadcasting services;
- (b) television broadcasting services covered by point ⋈ (e) ⋈ of Article 1 of ⋈ Council ⋈ Directive 89/552/EEC¹⁰.

♦ 98/48/EC Art.1 pt. 2(c) (adapted)

- 3. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of telecommunications services, as defined by Directive $\boxtimes 2002/21/EC$ of the European Parliament and of the Council \boxtimes 11.
- 4. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of financial services, as listed non-exhaustively in Annex IV to this Directive.
- 5. 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 ≥ 2004/39/EC of the European Parliament and of the Council 2 or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

♦ 98/34/EC (adapted)

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

OJ L 298, 17.10.1989, p. 23.

OJ L 145, 30.4.2004, p. 1.

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:
- (a) will transpose an international standard without being the equivalent;
- (b) will be a new national standard; or
- (c) 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.

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:
- (a) communicate information in accordance with Articles 2 and 3;
- (b) publish the draft standards in such a way that comments may also be obtained from parties established in other Member States;
- (c) 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;

- (d) 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.

♦ 98/48/EC Art. 1 pt. 3(a)

The Committee shall meet in a specific composition to examine questions concerning Information Society services.

♦ 98/34/EC

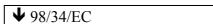
- 2. The Commission shall submit to the Committee a report on the implementation and application of the procedures set out in this Directive, and shall present proposals aimed at eliminating existing or foreseeable barriers to trade.
- 3. The Committee shall express its opinion on the communications and proposals referred to in paragraph 2 and may in this connection propose, in particular, that the Commission:
- (a) request the European standards institutions to draw up a European standard within a given time limit;
- (b) 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;
- (c) take all appropriate measures;
- (d) 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 point (a) 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.

♦ 98/48/EC Art. 1 pt. 3(b)

8. 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.



Article 7

- 1. Member States shall take all appropriate measures to ensure that, during the preparation of a European standard referred to in point (a) 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 first subparagraph of this paragraph to the Commission as draft technical regulations, in accordance with Article 8(1), and shall state the grounds for their enactment.

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.

▶ 98/34/EC (adapted)

Member States shall communicate the draft again under the conditions ⋈ set out in the first and second subparagraphs of this paragraph ⋈ 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.

⊠ Without prejudice to the provisions of Title VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council¹³, ⊠ 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 principles ⊠ provided for in the relevant part of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 ⊠.

▶ 98/34/EC

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.

▶ 98/48/EC Art. 1 pt. 4 (adapted)

With respect to the technical specifications or other requirements or rules on services referred to in point (iii) of the second subparagraph of point (k) of Article 1(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.

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OJ L 396, 30.12.2006, p. 1.

- 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.

5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Union 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 Union acts.

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 point (ii) of the second subparagraph of point (k) of Article 1(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 the law of the Union, 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 date, the Commission announces its intention of proposing or adopting a directive, regulation or decision on the matter in accordance with Article 288 of the TFEU.

♦ 98/34/EC (adapted)

- 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 ⋈ European Parliament and the ⋈ Council in accordance with Article 288 of the TFEU.
- 6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:
- (a) when the Commission informs the Member States that it no longer intends to propose or adopt a binding act;
- (b) when the Commission informs the Member States of the withdrawal of its draft or proposal;
- when ⋈ a binding act has been adopted by ⋈ the Commission or ⋈ by ⋈ the ⋈ European Parliament and the ⋈ Council.

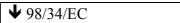
♦ 98/48/EC Art. 1 pt. 5(b)

- 7. Paragraphs 1 to 5 shall not apply in cases where:
- (a) 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

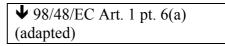
(b) for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.

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.



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:



- (a) comply with binding Union acts which result in the adoption of technical specifications or rules on services;
- (b) fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Union;

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▶ 98/34/EC (adapted)
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- (c) make use of safeguard clauses provided for in binding Union acts;
- (d) apply \boxtimes Article 12(1) of Directive 2001/95/EC of the European Parliament and of the Council \boxtimes^{14} ;
- (e) restrict themselves to implementing a judgment of the Court of Justice of the European Union;

(f) restrict themselves to amending a technical regulation within the meaning of point (k) of Article 1(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.

♦ 98/48/EC Art. 1 pt. 6(c) (adapted)

- 3. Paragraphs 3 to 6 of Article 9 shall not apply to the voluntary agreements referred to in point (ii) of the second subparagraph of point (k) of Article 1(1).
- 4. Article 9 shall not apply to the technical specifications or other requirements or the rules on services referred to in point (iii) of the second subparagraph of point (k) of Article 1(1).

♦ 98/34/EC (adapted)

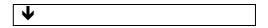
Article 11

The Commission shall report every two years to the European Parliament, the Council and the ⊠ European ⊠ 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 Union*.

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

Directive 98/34/EC, as amended by the Acts listed in Annex V, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex III, Part B of the repealed Directive, and in Annex V, part B of this Directive. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI

♦ 98/34/EC	

Article 14

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

Article 15

This Directive is addressed to the Member States.

Done at [...], [...]

For the European Parliament The President [...]

For the Council
The President
[...]

ANNEX I

EUROPEAN STANDARDISATION BODIES

CEN

European Committee for Standardisation

Cenelec

European Committee for Electrotechnical Standardisation

ETSI

European Telecommunications Standards Institute

ANNEX II

NATIONAL STANDARDISATION BODIES

1. BELGIUM

NBN

Bureau de normalisation

Bureau voor Normalisatie

CEB/BEC

Comité électrotechnique belge

Belgisch Elektrotechnisch Comité

2. BULGARIA

БИС

Български институт за стандартизация

3. CZECH REPUBLIC

ÚNMZ

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví

4. **DENMARK**

DS

Fonden Dansk Standard

NITA

IT- og Telestyrelsen, National IT and Telecom Agency

5. GERMANY

DIN

Deutsches Institut für Normung e.V.

DKE

Deutsche Elektrotechnische Kommission im DIN und VDE

6. ESTONIA

EVS

Eesti Standardikeskus

Sideamet

7. IRELAND

NSAI

National Standards Authority of Ireland

ETCI

Electrotechnical Council of Ireland

8. GREECE

ΕΛΟΤ

Ελληνικός Οργανισμός Τυποποίησης

9. SPAIN

AENOR

Asociación Española de Normalización y Certificación

10. FRANCE

AFNOR

Association française de normalisation

11. ITALY

 UNI^{15}

Ente nazionale italiano di unificazione

CEI¹⁶

Comitato elettrotecnico italiano

12. CYPRUS

КОПП

Κυπριακός Οργανισμός Προώθησης Ποιότητας (The Cyprus Organisation for Quality Promotion)

13. LATVIA

LVS

SIA "Standartizācijas, akreditācijas un metroloģijas centrs"

Standartizācijas birojs

14. LITHUANIA

LST

Lietuvos standartizacijos departamentas

15. LUXEMBOURG

ILNAS

Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services

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L'UNI and CEI, in cooperation with the *Istituto superiore delle Poste e Telecommunicazioni* and the ministero dell'Industria, have allocated the work within ETSI to CONCIT (*Comitato nazionale di coordinamento per le tecnologie dell'informazione*).

L'UNI and CEI, in cooperation with the *Istituto superiore delle Poste e Telecommunicazioni* and the ministero dell'Industria, have allocated the work within ETSI to CONCIT (*Comitato nazionale di coordinamento per le tecnologie dell'informazione*).

16. HUNGARY

MSZT

Magyar Szabványügyi Testület

17 MALTA

MSA

L-Awtorita' ta' Malta dwar l-Istandards (Malta Standards Authority)

18. NETHERLANDS

NEN

Nederlands Normalisatie instituut

NEC

Nederlands Elektrotechnisch Comité

19. AUSTRIA

ÖN

Österreichisches Normungsinstitut

ÖVE

Österreichischer Verband für Elektrotechnik

20. POLAND

PKN

Polski Komitet Normalizacyjny

21. PORTUGAL

IPQ

Instituto Português da Qualidade

22. ROMANIA

ASRO

Asociația de Standardizare din România

23. SLOVENIA

SIST

Slovenski inštitut za standardizacijo

24. SLOVAKIA

SÚTN

Slovenský ústav technickej normalizácie

25. FINLAND

SFS

Suomen Standardisoimisliitto SFS ry

Finlands Standardiseringsförbund SFS rf

FICORA

Viestintävirasto

Kommunikationsverket

SESKO

Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry

Finlands Elektrotekniska Standardiseringsförening SESKO rf

26. SWEDEN

SIS

Swedish Standards Institute

SEK

Svensk elstandard

ITS

Informationstekniska standardiseringen

27. UNITED KINGDOM

BSI

British Standards Institution

ANNEX III

Indicative list of services not covered by the second subparagraph of point (b) of Article 1(1)

1. SERVICES NOT PROVIDED 'AT A DISTANCE'

Services provided in the physical presence of the provider and the recipient, even if they involve the use of electronic devices:

- (a) medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present;
- (b) consultation of an electronic catalogue in a shop with the customer on site;
- (c) plane ticket reservation at a travel agency in the physical presence of the customer by means of a network of computers;
- (d) electronic games made available in a video-arcade where the customer is physically present.

2. SERVICES NOT PROVIDED 'BY ELECTRONIC MEANS'

- Services having material content even though provided via electronic devices:
 - (a) automatic cash or ticket dispensing machines (banknotes, rail tickets);
 - (b) access to road networks, car parks, etc., charging for use, even if there are electronic devices at the entrance/exit controlling access and/or ensuring correct payment is made,
- Off-line services: distribution of CD roms or software on diskettes.
- Services which are not provided via electronic processing/inventory systems:
 - (a) voice telephony services;
 - (b) telefax/telex services;
 - (c) services provided via voice telephony or fax;
 - (d) telephone/telefax consultation of a doctor;
 - (e) telephone/telefax consultation of a lawyer;
 - (f) telephone/telefax direct marketing.

3. SERVICES NOT SUPPLIED 'AT THE INDIVIDUAL REQUEST OF A RECIPIENT OF SERVICES'

Services provided by transmitting data without individual demand for simultaneous reception by an unlimited number of individual receivers (point to multipoint transmission):

▶ 98/48/EC Art. 1 pt. 7 (adapted)

(a) television broadcasting services (including near-video on-demand services), covered by point ⋈ (e) ⋈ of Article 1 of Directive 89/552/EEC;

♦ 98/48/EC Art. 1 pt. 7

- (b) radio broadcasting services;
- (c) (televised) teletext.

EN 29 EN

ANNEX IV

Indicative list of the financial services covered by Article 1(4)

- Investment services,
- Insurance and reinsurance operations,
- Banking services,
- Operations relating to pension funds,
- Services relating to dealings in futures or options.

Such services include in particular:

▶ 98/48/EC Art. 1 pt. 7 (adapted)

- (a) investment services referred to in the Annex to Directive ≥ 2004/39/EC ; services of collective investment undertakings;
- (b) services covered by the activities subject to mutual recognition referred to in

 → Annex I to Directive 2006/48/EC of the European Parliament and of the Council

 → 17:
- (c) operations covered by the insurance and reinsurance activities referred to in:
 - Article 1 of Council Directive 73/239/EEC¹⁸
 - Council Directive 64/225/EEC¹⁹,
 - Council Directive 92/49/EEC²⁰ and \boxtimes Directive 2002/83/EC of the Council and of the European Parliament \boxtimes ²¹.

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OJ L 228, 16.8.1973, p. 3.

OJ 56, 4.4.1964, p. 878. OJ L 228, 11.8.1992, p. 1.

 $[\]cong$ OJ L 345, 19.12.2002, p. 1 \cong .



ANNEX V

Part A

Repealed Directive with list of its successive amendments

(referred to in Article 13)

Directive 98/34/EC of the European Parliament and of the Council (OJ L 204, 21.7.1998, p. 37)

Directive 98/48/EC of the European Parliament and of the Council (OJ L 217, 5.8.1998, p. 18)

Part 1, Title H of Annex II to Act of Accession 2004 (OJ L 236, 23.9.2003, p. 68)

Council Directive 2006/96/EC (OJ L 363 of 20.12.2006, p. 81)

Only as regards the reference to point 2 of Directive 98/34/EC

Only as regards the reference to Article 1 of Directive 98/34/EC

Part B List of time-limits for transposition into national law (referred to in Article 13)

Directive	Time-limit for transposition
98/34/EC	-
98/48/EC	5 August 1999
2006/96/EC	1 January 2007

ANNEX VI

CORRELATION TABLE

Directive 98/34/EC	This Directive
Article 1, first subparagraph, introductory wording	Article 1(1), introductory wording
Article 1, first subparagraph, point (1)	Article 1(1), point (a)
Article 1, first subparagraph, point (2), first subparagraph	Article 1(1), point (b), first subparagraph
Article 1, first subparagraph, point (2), second subparagraph, first indent	Article 1(1), point (b), second subparagraph, point (i)
Article 1, first subparagraph, point (2), second subparagraph, second indent	Article 1(1), point (b), second subparagraph, point (ii)
Article 1, first subparagraph, point (2), second subparagraph, third indent	Article 1(1), point (b), second subparagraph, point (iii)
Article 1, first subparagraph, point (2), third subparagraph	Article 1(1), point (b), third subparagraph
Article 1, first subparagraph, point (2), fourth subparagraph, introductory wording	Article 1(2), introductory wording
Article 1, first subparagraph, point (2), fourth subparagraph, first indent	Article 1(2), point (a)
Article 1, first subparagraph, point (2), fourth subparagraph, second indent	Article 1(2), point (b)
Article 1, first subparagraph, point (3)	Article 1(1), point (c)
Article 1, first subparagraph, point (4)	Article 1(1), point (d)
Article 1, first subparagraph, point (5), first subparagraph	Article 1(1), point (e), first subparagraph
Article 1, first subparagraph, point (5), second subparagraph	Article 1(3)
Article 1, first subparagraph, point (5), third subparagraph	Article 1(4)
Article 1, first subparagraph, point (5), fourth subparagraph	Article 1(5)

Article 1, first subparagraph, point (5), fifth subparagraph, introductory sentence Article 1, first subparagraph, point (5), fifth subparagraph, first indent Article 1, first subparagraph, point (5), fifth subparagraph, second indent Article 1, first subparagraph, point (6), introductory sentence Article 1, first subparagraph, point (6), introductory sentence Article 1, first subparagraph, point (6), first indent Article 1, first subparagraph, point (6), second indent Article 1, first subparagraph, point (6), third indent Article 1, first subparagraph, point (6), third indent Article 1, first subparagraph, point (11), second subparagraph, point (11), second subparagraph, first indent Article 1, first subparagraph, point (11), second subparagraph, first indent Article 1, first subparagraph, point (11), second subparagraph, first indent Article 1, first subparagraph, point (11), second subparagraph, first indent Article 1, first subparagraph, point (11), second subparagraph, first indent Article 1, first subparagraph, point (11), second subparagraph, point (11), fourth subparagraph Article 1, first subparagraph, point (11), fourth subparagraph Article 1, point (k), second subparagraph Article 1, po		
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Article 2(1) Article 2(1)	Article 1, second subparagraph	Article 1(6)
	Article 2(1)	Article 2(1)

Article 2(2), first subparagraph, introductory wording	Article 2(2), first subparagraph, introductory wording
Article 2(2), first subparagraph, first indent	Article 2(2), first subparagraph, point (a)
Article 2(2), first subparagraph, second indent	Article 2(2), first subparagraph, point (b)
Article 2(2), first subparagraph, third indent	Article 2(2), first subparagraph, point (c)
Article 2(2), second subparagraph	Article 2(2), second subparagraph
Article 2(3), (4) and (5)	Article 2(3), (4) and (5)
Article 3	Article 3
Article 4(1), introductory wording	Article 4(1), introductory wording
Article 4(1), first indent	Article 4(1), point (a)
Article 4(1), second indent	Article 4(1), point (b)
Article 4(1), third indent	Article 4(1), point (c)
Article 4(1), fourth indent	Article 4(1), point (d)
Article 4(2)	Article 4(2)
Article 5	Article 5
Article 6(1) and (2)	Article 6(1) and (2)
Article 6(3), introductory wording	Article 6(3), introductory wording
Article 6(3), first indent	Article 6(3), point (a)
Article 6(3), second indent	Article 6(3), point (b)
Article 6(3), third indent	Article 6(3), point (c)
Article 6(3), fourth indent	Article 6(3), point (d)
Article 6(4) to (8)	Article 6(4) to (8)
Article 7	Article 7
Article 8	Article 8
Article 9(1) to (5)	Article 9(1) to (5)

Article 9(6), introductory wording	Article 9(6), introductory wording
Article 9(6), first indent	Article 9(6), point (a)
Article 9(6), second indent	Article 9(6), point (b)
Article 9(6), third indent	Article 9(6), point (c)
Article 9(7), first subparagraph, introductory wording	Article 9(7), first subparagraph, introductory wording
Article 9(7), first subparagraph, first indent	Article 9(7), first subparagraph, point (a)
Article 9(7), first subparagraph, second indent	Article 9(7), first subparagraph, point (b)
Article 9(7), second subparagraph	Article 9(7), second subparagraph
Article 10(1), introductory wording	Article 10(1), introductory wording
Article 10(1), first indent	Article 10(1), point (a)
Article 10(1), second indent	Article 10(1), point (b)
Article 10(1), third indent	Article 10(1), point (c)
Article 10(1), fourth indent	Article 10(1), point (d)
Article 10(1), fifth indent	Article 10(1), point (e)
Article 10(1), sixth indent	Article 10(1), point (f)
Article 10(2), (3) and (4)	Article 10(2), (3) and (4)
Article 11, first sentence	Article 11, first subparagraph
Article 11, second sentence	Article 11, second subparagraph
Article 12	Article 12
Article 13	-
-	Article 13
Article 14	Article 14
Article 15	Article 15
Annexe I	Annexe I
Annexe II	Annexe II

Annexe III

Annexe IV

Annexe III

Annexe VI Annexe IV

- Annexe V

- Annexe VI
