DIRECTIVE 98/34/EC 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

Unofficial consolidated version prepared by the services of the Commission*

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

Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations

* The provisions of Directive 98/34/EC which have been modified by Directive 98/48/EC on Information Society Services are indicated in bold.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Recitals of Directive 98/34/EC

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 Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 189b of the Treaty³,

- (1) Whereas Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations⁴ has been variously and substantially amended; whereas for reasons of clarity and rationality the said Directive should be consolidated;
- (2) Whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured; whereas, 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 Community;
- (3) 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;
- (4) Whereas 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) Whereas it is essential for the Commission to have the necessary information at its disposal before the adoption of technical provisions; whereas, consequently, the Member States which are required to facilitate the achievement of its task pursuant to

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OJ C 78, 12.3.1997, p.4.

OJ C 133, 28.4.1997, p. 5.

Opinion of the European Parliament of 17 September 1997 (OJ C 304, 6.10.1997, p. 79), Council Common Position of 23 February 1998 (OJ C 110, 8.4.1998, p. 1) and Decision of the European Parliament of 30 April 1998 (OJ C 152, 18.5.1998). Decision of the Council of 28 May 1998.

⁴ OJ L 109, 26.4.1983, p. 8. Directive as last amended by Commission Decision 96/139/EC (OJ L 32, 10.2.1996, p. 31).

Article 5 of the Treaty must notify it of their projects in the field of technical regulations;

- (6) Whereas all the Member States must also be informed of the technical regulations contemplated by any one Member State;
- (7) 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 means of the provisions relating to the confidentiality of such drafts;
- (8) 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 this Directive;
- (9) 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;
- (10) 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;
- (11) 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;
- (12) Whereas it is necessary 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;
- (13) Whereas 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) Whereas the Member State concerned must take account of these amendments when formulating the definitive text of the measure envisaged;
- (15) 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 adopts or 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 of binding Community acts by the Council or the Commission in the same field;
- (16) Whereas the Member State in question must, pursuant to the general obligations laid down in Article 5 of the Treaty, 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 binding act of the Council or the adoption of a binding act of the Commission; whereas the time limits laid down in the Agreement of the representatives of the Governments of the Member States meeting within the Council of 28 May 1969 providing for standstill and notification to the Commission⁵, as amended by the Agreement of 5 March 1973⁶, have proved inadequate in the cases concerned and should accordingly be extended;

- (17) Whereas the procedure concerning the standstill arrangement and notification of the Commission contained in the abovementioned agreement of 28 May 1969 remains applicable to products subject to that procedure which are not covered by this Directive:
- (18) Whereas, 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;
- (19) Whereas, in practice, national technical standards may have the same effects on the free movement of goods as technical regulations;
- (20) Whereas it would therefore appear necessary to inform the Commission of draft standards under similar conditions to those which apply to technical regulations; whereas, pursuant to Article 213 of the Treaty, the Commission may, within the limits and under the conditions laid down by the Council in accordance with the provisions of the Treaty, collect any information and carry out any checks required for the performance of the tasks entrusted to it;
- (21) Whereas 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;
- (22) Whereas 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; 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;
- (23) Whereas 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;
- (24) Whereas 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;

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⁵ OJ C 76, 17.6.1969, p. 9.

⁶ OJ C 9, 15.3.1973, p. 3.

- (25) Whereas the functioning of standardisation in the Community 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; whereas it is for the Member States to take the appropriate measures in their power to ensure that their standardisation bodies observe these rights;
- (26) Whereas 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;
- (27) Whereas it is necessary to set up a Standing Committee, the members of which will be 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;
- (28) Whereas the Standing Committee should be consulted on the draft standardisation requests referred to in this Directive;
- (29) Whereas this Directive must not affect the obligations of the Member States concerning the deadlines for transposition of the Directives set out in Annex III, Part B,

Recitals of Directive 98/48/EC

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee⁸,

Acting in accordance with the procedure laid down in Article 189b of the Treaty⁹,

(1) Whereas, in order to promote the smooth functioning of the internal market, as much transparency as possible should be ensured as regards the future national rules and regulations applying to Information Society services, by amending Directive $98/34/EC^{10}$;

OJ C 307, 16. 10. 1996, p. 11, and OJ C 65, 28. 2. 1998, p. 12.

⁸ OJ C 158, 26. 5. 1997, p. 1.

Opinion of the European Parliament of 16 May 1997 (OJ C 167, 2. 6. 1997, p. 238), Council Common Position of 26 January 1998 (OJ C 62, 26. 2. 1998, p. 48) and Decision of the European Parliament of 14 May 1998 (OJ C 167, 1. 6. 1998). Council Decision of 29 June 1998.

OJ L 204, 21. 7. 1998, p. 37.

- (2) Whereas a wide variety of services within the meaning of Articles 59 and 60 of the Treaty will benefit by the opportunities afforded by the Information Society of being provided at a distance, electronically and at the individual request of a recipient of services;
- (3) Whereas the area without internal frontiers comprising the internal market enables providers of such services to develop their cross-border activities with a view to increasing their competitiveness, and thus affords citizens new opportunities to transmit and receive information regardless of frontiers, and consumers new forms of access to goods and services;
- (4) Whereas the extension of the scope of Directive 98/34/EC should not prevent Member States from taking account of the different social, societal and cultural implications inherent in the advent of the Information Society; whereas, in particular, the use of the procedural rules laid down in that Directive for Information Society services should not affect cultural policy measures, particularly in the audio-visual field, 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; whereas the development of the Information Society should ensure, in any event, proper access of European citizens to the European cultural heritage supplied in a digital environment;
- (5) Whereas Directive 98/34/EC is not intended to apply to national rules relating to fundamental rights, such as constitutional provisions concerning freedom of expression and, more particularly, freedom of the press; whereas it is not intended to apply to the general criminal law either; whereas, furthermore, it does not apply to agreements governed by private law between credit institutions, in particular, to agreements on the execution of payments between credit institutions;
- (6) Whereas the European Council has stressed the need to create a clear and stable legal framework at Community level in order to foster the development of the Information Society; whereas Community law and the rules governing the internal market in particular, including both the principles enshrined in the Treaty and secondary legislation, already constitute a basic legal framework for the development of such services;
- (7) Whereas it should be possible to adapt the existing national rules and regulations applicable to services available at the present so as to take account of new Information Society services, either with a view to ensuring that the general interest is better protected or, on the other hand, with a view to simplifying such rules and regulations where their application is disproportionate to the objectives they pursue;
- (8) Whereas, without coordination at Community level, this foreseeable regulatory activity at national level might give rise to restrictions on the free movement of services and the freedom of establishment, leading in turn to a refragmentation of the internal market, over-regulation and regulatory inconsistencies;
- (9) Whereas, in order to ensure real and effective protection of the general-interest objectives involved in the development of the Information Society, there

is a need for a coordinated approach at Community level when questions relating to activities with such highly transnational connotations as those of the new services are dealt with;

- (10) Whereas, in the case of telecommunications services, there is already harmonisation at Community level or, in some cases, arrangements for mutual recognition, and whereas the existing Community legislation provides for adaptations to take account of technological developments and the supply of new services and, as a result, the majority of national regulations concerning telecommunications services will not be subject to notification under this Directive since they will come under the exemptions set out in Article 10(1) or Article 1 point 5 of Directive 98/34/EC; whereas, nevertheless, certain national provisions specifically aimed at matters which are not subject to Community legislation may affect the free movement of Information Society services and to that extent they must be notified;
- (11) Whereas, for the other still little known fields of the Information Society, it would, however, be premature to coordinate national rules and regulations by means of extensive or exhaustive harmonisation at Community level of the substantive law, given that enough is not yet known about the form the new services will take or their nature, that there is as yet at national level no specific regulatory activity in this field, and that the need for, and content of, such harmonisation in the light of the internal market cannot be defined at this stage;
- (12) Whereas it is therefore necessary to preserve the smooth functioning of the internal market and to avert the risks of refragmentation by providing for a procedure for the provision of information, the holding of consultations, and administrative cooperation in respect of new draft rules and regulations; whereas such a procedure will help, inter alia, to ensure that the Treaty, in particular Articles 52 and 59 thereof, is effectively applied and, where necessary, to detect any need to protect the general interest at Community level; whereas, moreover, the improved application of the Treaty made possible by such an information procedure will have the effect of reducing the need for Community rules to what is strictly necessary and proportional in the light of the internal market and the protection of general-interest objectives; whereas, lastly, such a procedure will enable businesses to exploit the advantages of the internal market more effectively;
- (13) Whereas Directive 98/34/EC pursues the same objectives and whereas this procedure is effective, being the most comprehensive one for attaining these objectives; whereas the experience that has been gained in implementing that Directive and the procedures provided for therein can be applied to draft rules on Information Society services; whereas the procedure it lays down is now well established among national authorities;
- (14) Whereas, moreover, in accordance with Article 7a of the Treaty, the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured and whereas Directive 98/34/EC provides only for an administrative cooperation procedure and not for any harmonisation of substantive rules;

- (15) Whereas, therefore, amendment of Directive 98/34/EC with a view to applying it to draft rules and regulations on Information Society services is the approach best suited, with regard to the legal framework of the said services, to meeting effectively the need for transparency in the internal market;
- (16) Whereas notification should be provided for notably in the case of rules which are likely to evolve in future; whereas services which are provided at a distance, electronically, and at the individual request of a recipient of services (Information Society services) are likely, in view of their diversity and their future growth, to necessitate and generate the largest number of new rules and regulations; whereas provision must accordingly be made for the notification of draft rules and regulations relating to such services;
- (17) Whereas specific rules on the taking-up and pursuit of service activities which are capable of being carried on in the manner described above should thus be communicated even where they are included in rules and regulations with a more general purpose; whereas, however, general regulations which do not contain any provision specifically aimed at such services need not be notified;
- (18) Whereas 'rules on the taking-up and pursuit of service activities` means rules laying down requirements concerning Information Society services, such as those relating to service providers, services and recipients of services and to economic activities capable of being provided electronically, at a distance and at the individual request of the recipient of the services; whereas, for example, rules on the establishment of service providers, in particular those on authorisation or licensing arrangements, are accordingly covered; whereas a provision specifically aimed at Information Society services must be considered as being such a rule even if part of a more general regulation; whereas, on the other hand, measures of direct and individual concern to certain specific recipients (such as, for example, telecommunications licences) would not be covered;
- (19) Whereas, under Article 60 of the Treaty as interpreted by the case-law of the Court of Justice, 'services' means those normally provided for remuneration; whereas that characteristic is absent in the case of activities which a State carries out without economic consideration in the context of its duties in particular in the social, cultural, educational and judicial fields; whereas national provisions concerning such activities are not covered by the definition given in Article 60 of the Treaty and therefore do not fall within the scope of this Directive;
- (20) Whereas this Directive is without prejudice to the scope of Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities¹¹, as amended by Directive 97/36/EC of the European Parliament and of the Council¹², or any future amendments;
- (21) Whereas, in any event, this Directive does not cover draft national provisions aimed at transposing the content of Community directives in force or awaiting adoption inasmuch as they are already subject to specific examination;

OJ L 298, 17. 10. 1989, p. 23.

OJ L 202, 30. 7. 1997, p. 1.

whereas it accordingly covers neither national rules and regulations transposing Directive 89/552/EEC, as amended by Directive 97/36/EC, or any future amendments, nor national rules and regulations transposing, or adopted subsequently within the context of, Directive 97/13/EC of the European Parliament and of the Council of 10 April 1997 on a common framework for general authorisations and individual licences for telecommunications services¹³;

- (22) Whereas, moreover, provision should be made for exceptional cases in which national rules and regulations concerning Information Society services might be adopted immediately and whereas it is also important to allow this possibility solely for urgent reasons linked to serious and unforeseeable circumstances, such as circumstances of which there was no previous knowledge and the origin of which is not attributable to any action on the part of the authorities of the Member State concerned, so as not to jeopardize the objective of prior consultation and administrative cooperation inherent in this Directive;
- (23) Whereas it is appropriate for a Member State to postpone for twelve months or possibly eighteen months in the case of a common position of the Council the adoption of a draft rule on services only where the draft rule relates to a matter which falls within the scope of a proposal for a directive, regulation or decision which the Commission has already submitted to the Council; whereas this standstill obligation may be imposed by the Commission on the relevant Member State only if the draft national rule contains provisions which are not substantively consistent with the proposal submitted by the Commission;
- (24) Whereas definition of the framework for the provision of information and the holding of consultations at Community level as established by this Directive is a precondition for consistent and effective participation by the Community in work involving matters relating to the regulatory aspects of Information Society services in the international context;
- (25) Whereas it is appropriate that, in the context of the functioning of Directive 98/34/EC, the Committee provided for in Article 5 thereof should meet specifically to examine questions relating to Information Society services;
- (26) Whereas, by the same token, it should be noted that whenever a national measure is required also to be notified at the draft stage under another Community act, the Member State concerned may make a single communication under that other act, by indicating that that communication constitutes a communication also for the purpose of this Directive;
- (27) Whereas the Commission will at regular intervals investigate developments in the market for new services in the field of the Information Society, especially in the framework of the convergence between telecommunications, information technology and media and, where necessary, take initiatives in order to adapt rules promptly in order to encourage the European development of new services,

HAVE ADOPTED THIS DIRECTIVE:

OJ L 117, 7. 5. 1997, p. 15.

Operative part of Directives 98/34/EC and 98/48/EC

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). "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/EEC¹⁴.
- **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

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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).

Article 1 of Directive 65/65/EEC¹⁵, 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). "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 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/EEC¹⁶.

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,

OJ L 192, 24.7.1990, p. 1. Directive as amended by Directive 97/51/EC (OJ L 295, 29.10.1997, p. 23).

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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).

- 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). "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:

- 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.

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.

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.

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:
- 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, paragraph 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.

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 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.

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 793/93¹⁷ in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC¹⁸, in the case of a new substance.

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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).

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

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 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.

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.

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 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 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.

7. 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.

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 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/EEC¹⁹,
- 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
 point 11 of Article 1, in accordance with a Commission request, with a view to

Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ L 228, 11.8.1992, p. 24).

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.
- 3. 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.

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.

Not later than two years from the 5th of August 1999, the Commission shall submit to the European Parliament and the Council an evaluation of the application of Directive 98/34/EC in particular in the light of technological and market developments for the services referred to in point 2 of Article 1. Not later than three years from the aboved mentioned date, the Commission shall, if necessary, make proposals to the European Parliament and to the Council for a revision of the said Directive.

To this end, the Commission shall take into account any observations that might be communicated to it by Member States.²⁰

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.

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The two last paragraphs of this article are taken from the article 3 of the Diretive 98/48/EC and adapted

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.
- 3. Member States shall bring into force the regulations and administrative provisions necessary in order to comply with the provisions relating to the Information Society services by 5 August 1999. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to Directive 98/48/EC or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

4. Member States shall communicate the main provisions of national law which they adopt in the field covered by Directive 98/48/EC to the Commission.²¹

Article 14

Directive 98/34/EC enters into force on the 20th day following that of its publication in the Official Journal of the European Communities (published the 21.7.1998).

Directive 98/48/EC enters into force on the day of its publication in the Official Journal of the European Communities (published on 5 August 1998). ²²

Article 15

The Directives 98/34/CE and 98/48/CE are addressed to the Member States.

Done at Luxembourg, 22 June 1998.

Paragrahs 3 and 4 of this article are taken from article 2 of the Directive 98/48/EC and adapted

This paragraph is adapted from article 4 of the Directive 98/48/EC

For the European Parliament

The President

J. M. GIL-ROBLES

J. CUNNINGHAM

Done at Brussels, 20 July 1998.

For the European Parliament

The President

J. M. GIL-ROBLES

W. MOLTERER

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

IBN/BIN

Institut belge de normalisation - Belgisch Instituut voor Normalisatie

CEB/BEC

Comité électrotechnique belge - Belgisch Elektrotechnisch Comité

2. DENMARK

DS

Dansk Standard

NTA

Telestyrelsen, National Telecom Agency

3. GERMANY

DIN

Deutsches Institut für Normung e.V.

DKE

Deutsche Elektrotechnische Kommission im DIN und VDE

4. GREECE

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5. SPAIN

AENOR

Asociación Española de Normalización y Certificación

6. FRANCE

AFNOR

Association française de normalisation

UTE

Union technique de l'électricité - Bureau de normalisation auprès de l'AFNOR

7. IRELAND

NSAI

National Standards Authority of Ireland

ETCI

Electrotechnical Council of Ireland

8. ITALY

 $IJNI^{23}$

Ente nazionale italiano di unificazione

 CEI^{24}

Comitato elettrotecnico italiano

9. LUXEMBOURG

ITM

Inspection du travail et des mines

SEE

Service de l'énergie de l'État

10. NETHERLANDS

NNI

Nederlands Normalisatie-instituut

NEC

Nederlands Elektrotechnisch Comité

11. AUSTRIA

ON

Österreichisches Normungsinstitut

ÖVE

Österreichischer Verband für Elektrotechnik

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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.

²⁴ Idem 23.

12. PORTUGAL

IPQ

Instituto Português da Qualidade

13. UNITED KINGDOM

BSI

British Standards Institution

BEC

British Electrotechnical Committee

14. FINLAND

SFS

Suomen Standardisoimisliitto SFS ry

Finlands Standardiseringsförbund SFS rf

THK/TFC

Telehallintokeskus

Teleförvaltningscentralen

SESKO

Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry

Finlands Elektrotekniska Standardiseringsförening SESKO rf

15. SWEDEN

SIS

Standardiseringen i Sverige

SEK

Svenska elektriska kommissionen

ITS

Informationstekniska standardiseringen

ANNEX III

PART A

Repealed Directives and Decisions (referred to by Article 13)

Directive 83/189/EEC and its following amendments Council Directive 88/182/EEC

Commission Decision 90/230/EEC

Commission Decision 92/400/EEC

Directive 94/10/EC of the European Parliament and Council

Commission Decision 96/139/EC

PART B

List of deadlines for transposition into national laws (referred to in Article 13)

98/48/EC (OJ No L 217, 5.8.1998, p.18)	5 August 1999
94/10/EC (OJ No L 100, 19.4.1994, p.30)	1 July 1995
88/182/EEC (OJ No L 81, 26.3.1988, p.75)	1 January 1989
83/189/EEC (OJ No L 109, 26.4.1983, p.8)	31 March 1984

ANNEX IV

Correlation table

Directive 98/34/EC This Directive (codification)

Article 1 Article 1 Article 2 Article 2 Article 3 Article 3 Article 4 Article 4 Article 5 Article 5 Article 6 Article 6 Article 7 Article 7 Article 8 Article 8 Article 9 Article 9 Article 10 Article 10 Article 11 Article 11 Article 12 Article 12 Article 13 Article 13 Article 14 Article 14 Article 15 Article 15 Annex I Annex I Annex II Annex II Annex III Annex III Annex IV Annex IV Annex V **Annex VI**

ANNEX V

Indicative list of services not covered by the second subparagraph of point 2 of Article 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):

- (a) television broadcasting services (including near-video on-demand services), covered by point (a) of Article 1 of Directive 89/552/EEC;
- (b) radio broadcasting services;
- (c) (televised) teletext.

ANNEX VI

Indicative list of the financial services covered by the third subparagraph of point 5 of Article 1

- 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:

- (a) investment services referred to in the Annex to Directive 93/22/EEC²⁵; services of collective investment undertakings,
- (b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC²⁶,
- (c) operations covered by the insurance and reinsurance activities referred to in:
- Article 1 of Directive 73/239/EEC²⁷,
- the Annex to Directive $79/267/EEC^{28}$,
- Directive 64/225/EEC²⁹,
- Directives 92/49/EEC³⁰ and 92/96/EEC³¹.

OJ L 141, 11. 6. 1993, p. 27.

OJ L 386, 30. 12. 1989, p. 1. Directive as amended by Directive 92/30/EEC (OJ L 110, 28. 4. 1992, p. 52).

OJ L 228, 16. 8. 1973, p. 3. Directive as last amended by Directive 92/49/EEC (OJ L 228, 11. 8. 1992, p. 1).

OJ L 63, 13. 3. 1979, p. 1. Directive as last amended by Directive 90/619/EEC (OJ L 330, 29. 11. 1990, p. 50).

OJ 56, 4. 4. 1964, p. 878/64. Directive as amended by the 1973 Act of Accession.

OJ L 228, 11. 8. 1992, p. 1.

OJ L 360, 9. 12. 1992, p. 1.