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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF
THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

(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 regulations (4) 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 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;

(1) OJ C 78, 12.3.1997, p. 4.
(2) OJ C 133, 28.4.1997, p. 5.
(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 \textit{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 Commission \textsuperscript{(1)}, as amended by the Agreement of 5 March 1973 \textsuperscript{(2)}, 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;

\textsuperscript{(1)} OJ C 76, 17.6.1969, p. 9.
\textsuperscript{(2)} OJ C 9, 15.3.1973, p. 3.
(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;

(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,

HAVE ADOPTED THIS DIRECTIVE:

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. ‘technical specification’, a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

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

3. ‘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;

4. ‘standard’, a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

   — international standard: a standard adopted by an international standardisation organisation and made available to the public,

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

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

5. ‘standards programme’, a work programme of a recognised standardisation body listing the subjects on which standardisation work is being carried out;

6. ‘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;

7. ‘European standardisation body’, a body referred to in Annex I;

8. ‘national standardisation body’, a body referred to in Annex II;

9. ‘technical regulation’, technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, \emph{de jure} or \emph{de facto}, in the case of marketing or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product. \emph{De facto} technical regulations include:

— laws, regulations or administrative provisions of a Member State which refer either to technical specifications or other requirements or to professional codes or codes of practice which in turn refer to technical specifications or other requirements and compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,

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

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

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list to be drawn up by the Commission before 1 July 1995, in the framework of the Committee referred to in Article 5.

The same procedure shall be used for amending this list;

10. ‘draft technical regulation’, the text of a technical specification or other requirement, including administrative provisions formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.

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

\textbf{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.

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(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.
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 793/93 (1) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC (2), in the case of a new substance.

The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it may also refer this draft, for an opinion, to the Committee referred to in Article 5 and, where appropriate, to the committee responsible for the field in question.

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

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 Article 1(9), second indent,

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

from the date of receipt by the Commission of the communication referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market.

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

3. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its intention to propose or adopt a directive, regulation or decision on the matter in accordance with Article 189 of the Treaty.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the Council in accordance with Article 189 of the Treaty.

5. If the Council adopts a common position during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to 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 those cases where, for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State shall give, in the communication referred to in Article 8, the reasons which warrant the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.

**Article 10**

1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

   — comply with binding Community acts which result in the adoption of technical specifications,

   — fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications in the Community,

   — make use of safeguard clauses provided for in binding Community acts,
— apply Article 8(1) of Directive 92/59/EEC (1),
— restrict themselves to implementing a judgment of the Court of Justice of the European Communities,
— restrict themselves to amending a technical regulation within the meaning of Article 1(9) of this Directive, in accordance with a Commission request, with a view to removing an obstacle to trade.

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

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

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

Article 11

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

Article 12

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

Article 13

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

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

Article 14

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

Article 15

This Directive is addressed to the Member States.

Done at Luxembourg, 22 June 1998.

For the European Parliament
The President
J. M. GIL-ROBLES

For the Council
The President
J. CUNNINGHAM

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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
   ΕΛΟΤ
   Ελληνικός Οργανισμός Τυποποίησης

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
   UNI (1)
   Ente nazionale italiano di unificazione
   CEI (1)
   Comitato elettrotecnico italiano

(1) 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.
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

12. PORTUGAL

IPQ
Instituto Portugês da Qualidade

13. UNITED KINGDOM

BSI
British Standards Institution

BEC
British Electrotechnical Committee

14. FINLAND

SFS
Suomen Standardisoimislitto 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
Commission Decision 90/230/EEC
Commission Decision 92/400/EEC
Commission Decision 96/139/EC

PART B
List of deadlines for transposition into national law
(referred to in Article 13)

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ANNEX IV
CORRELATION TABLE

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