Proposal for a COUNCIL DECISION

on the conclusion of bilateral Agreements laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Czech Republic, the European Community and the Republic of Estonia, the European Community and the Republic of Latvia, the European Community and the Republic of Lithuania, the European Community and the Republic of Malta, the European Community and the Republic of Poland, the European Community and the Slovak Republic, the European Community and the Republic of Slovenia

(presented by the Commission)
1. EXPLANATORY MEMORANDUM

On the basis of the negotiating directives adopted by the Council on 21.10.2002, the Commission has negotiated bilateral Agreements laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and eight candidate countries: the Czech Republic, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Republic of Poland, the Slovak Republic and the Republic of Slovenia.

The text of the Agreements and their Annexes are attached to this Communication. The following provides an assessment of the Agreements in the light of the negotiating directives approved by the Council, and proposes that the Council authorise the signature of these Agreements and decide to approve their conclusion on behalf of the Community.

1.1. Assessment of the Agreements

The Agreements provide for the participation of the above mentioned candidate countries in the notification procedure, which was introduced at Community level by Directive 83/189/CEE (amended several times, then codified by Directive 98/34/EC, and subsequently amended by Directive 98/48/EC)\(^1\).

Each bilateral Agreement contains exactly the same articles. Only the recitals differ. Where candidate countries have already concluded PECA Agreements, reference is made to them. With regard to the Republic of Malta, reference is made in the recitals to the Agreement establishing an Association between the European Community and the Republic of Malta, and not to the Europe Agreements, given that the Republic of Malta did not conclude a Europe Agreement with the European Communities.

In accordance with the negotiating mandate, the scope of the Agreements is exactly the same as that provided for in Directive 98/34/EC, as amended by Directive 98/48/EC. Furthermore, the definition of technical regulations and rules on information society services is identical with the definitions contained in Article 1 of Directive 98/34/EC, as amended by Directive 98/48/EC.

As regards the system of exchange of information, in accordance with the negotiating mandate, the Community is responsible for communicating to the countries concerned the draft technical regulations and draft rules on information society services notified to the Commission by the Member States in application of Directive 98/34/EC, as amended by Directive 98/48/EC.

Each of the candidate countries with which a bilateral Agreement has been drawn up is responsible for communicating to the Community its draft technical regulations and draft rules on information society services.

In accordance with the negotiating directives, the three-month standstill period provided for in Directive 98/34/EC, as amended by Directive 98/48/EC, has been included in each Agreement. During this three-month standstill period the Community has the right to make comments on the drafts notified by each candidate country with whom a bilateral Agreement has been drawn up; and each candidate country has the right to make comments on the drafts thus notified by the Member States.

Finally, as stated in the negotiating directives, the candidate countries have to submit information in one of the official Community languages.

1.2. Explanation article-by-article

1.2.1. The Agreement

An article-by-article assessment follows (given that the articles are the same in all agreements, the description given below applies to all bilateral Agreements):

Preamble. This sets out the basic objective of the Agreement, that is to extend the notification procedure to the candidate country concerned.

Article 1: Definitions. This is self-explanatory. The definitions are exactly the same as the ones used in Directive 98/34/EC, as amended by Directive 98/48/EC.

Article 2: Exception from scope. Like in Directive 98/34/EC, as amended by Directive 98/48/EC, it is foreseen that measures taken by the Member States or the candidate country concerned for the protection of persons (and in particular workers), when products are used, do not fall under the scope of the Agreement. However, it is specified that if such measures affect the products, then notification is required.

Article 3: System of exchange of information. This article stipulates that the Community is responsible for transmitting the notifications of the Member States to the candidate countries concerned. In the same way, the notifications of the candidate country concerned are to be transmitted to the Community. In accordance with Directive 98/34/EC, as amended by Directive 98/48/EC, where a technical regulation simply transposes the full text of an international or a European standard, it is not necessary to send the text of that standard, given that these texts are easily available to the Commission. In this case, it is sufficient to transmit the exact reference of the standard concerned.

Article 4: Language of transmission. It is specified that the draft technical regulations have to be submitted in a full translation into one of the official languages of the European Community.

Article 5: Basic texts and risk analysis. As foreseen in Directive 98/34/EC, as amended by Directive 98/48/EC, basic texts have also to be submitted where this is necessary in order to assess the implications of the draft technical regulations notified. Furthermore, in certain cases risk evaluations, where these are available, have to be transmitted.
Article 6: Notification in case of significant changes. This Article provides that a new notification has to be made if the Member States or the candidate country concerned modify their previously notified drafts. The definitions of what constitutes a significant change are identical with the ones of Directive 98/34/EC, as amended by Directive 98/48/EC.

Article 7: Further information. This stipulates that each contracting party has the right to ask for further information on the notified drafts where this is considered necessary for their evaluation.

Article 8: Comments. It is specified that each contracting party may make comments on the drafts notified by the other contracting party.

Article 9: Standstill period. A uniform standstill period of three months applies to the drafts notified by each contracting party. No extension of this standstill period is possible.

Article 10: Urgency procedure. This Article stipulates that where urgent reasons are invoked the three-month standstill period shall not apply. The definition of urgency of this Article is identical with the one of Directive 98/34/EC, as amended by Directive 98/48/EC.

Article 11: Final text and administrative arrangements for transmission. It is foreseen that the final text has also to be transmitted. This is because for some notifications, it is useful to be able to compare the notified text with the finally adopted one. The same article also refers to Annex III of the Agreement (see below) which lays down some general rules as to the administrative arrangements for communication of information under the Agreement.

Article 12: Exceptions to notification obligation. This Article stipulates the cases in which notification is not required. These exceptions are identical to those listed in Directive 98/34/EC, as amended by Directive 98/48/EC. With regard to international agreements concluded by the candidate country concerned, it is foreseen that it does not have to notify those laws, regulations and administrative provisions arising out of the obligations of an international agreement that applies in the candidate country and in the entire European Community. The reason for this is that the same provisions will apply in the candidate country and in the European Community, as the candidate country and all the Member States have transposed the international agreement.

On the other hand, if the candidate country adopts laws, regulations or administrative provisions arising out of an international agreement that applies in the candidate country and a third country, or that applies in the candidate country and only a part of the European Community, then notification is required, given that in these two cases, the provisions may create barriers to trade, as these two types of international agreement do not apply in the whole territory of the two contracting parties.

Article 13: Confidentiality. Information provided under the bilateral Agreement is in principle not confidential, however each contracting party has the possibility to ask for confidentiality.

Article 14: Management of the Agreement. For the management of the Agreement, it is foreseen that on the one hand, regular consultations shall take place between experts of the European Community and the candidate country concerned and on the other, candidate countries shall participate in the Standing Committee established under Directive 98/34/EC, as amended by Directive 98/48/EC.
Article 15: Territorial clause. This is a standard provision defining the geographical application of the Agreement.

Article 16: Entry into force. This is a standard provision that provides the arrangement for the entry into force.

Article 17: Expiry. It is self-explanatory that the Agreement will expire on the date of accession of the candidate country.

Article 18: Languages of the Agreement. This is a standard provision that the Agreement is drawn up in all Community languages and the language of the candidate country.

1.2.2. The Annexes to the Agreement

There follows an assessment of the content of the annexes.

Annex I: Information society services. This Annex provides a further clarification of the concept of information society services, as defined in point 2 of Article 1 of the Agreement. The Annex is identical with Annex V of Directive 98/34/EC, as amended by Directive 98/48/EC.

Annex II: Financial services. This Annex gives an indicative list of the financial services which are excluded from the scope of the Agreement (see Article 1, point 5, third subparagraph of the Agreement). The Annex is identical with Annex VI of Directive 98/34/EC, as amended by Directive 98/48/EC.

Annex III: Administrative procedure for transmission of information. This Annex lays down some general rules as to the administrative arrangements for communication of information under the Agreement. These arrangements are in principle identical with the ones currently in force with the EFTA countries signatory to the EEA Agreement.

2. DRAFT COUNCIL DECISION

A proposal for a Council Decision is attached. The proposal concerns the adoption and signature of the bilateral Agreements. Consequently, it foresees that the Council approves these bilateral Agreements.

Signature is required by each candidate country for the adoption of its bilateral Agreement. It is accordingly proposed that the President of the Council be authorised to designate the persons empowered to sign the Agreements on behalf of the Community.

The Commission therefore proposes that the Council adopt the attached Decision.
Proposal for a

COUNCIL DECISION

on the conclusion of bilateral Agreements laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Czech Republic, the European Community and the Republic of Estonia, the European Community and the Republic of Latvia, the European Community and the Republic of Lithuania, the European Community and the Republic of Malta, the European Community and the Republic of Poland, the European Community and the Slovak Republic, the European Community and the Republic of Slovenia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction with the first sentence of the first subparagraph of Article 300(2),

Having regard to the proposal from the Commission²,

Whereas the bilateral Agreements laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Czech Republic, the European Community and the Republic of Estonia, the European Community and the Republic of Latvia, the European Community and the Republic of Lithuania, the European Community and the Republic of Malta, the European Community and the Republic of Poland, the European Community and the Slovak Republic, the European Community and the Republic of Slovenia have been negotiated and should be approved;

HAS DECIDED AS FOLLOWS:

Article 1

The bilateral Agreements laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Czech Republic, the European Community and the Republic of Estonia, the European Community and the Republic of Latvia, the European Community and the Republic of Lithuania, the European Community and the Republic of Malta, the European Community and the Republic of Poland, the European Community and the Slovak Republic, the European Community and the Republic of Slovenia, are hereby approved on behalf of the European Community. The text of the Agreements and the Annexes are attached to this Decision.

² OJ C […], […], p. […]
Article 2

The President of the Council is hereby authorised to designate the persons empowered to sign the Agreements in order to bind the Community and to transmit, on behalf of the Community, the note provided for in Article 15 of the Agreements (3).

Done at Brussels,

For the Council
The President

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3 The date of entry into force of the Agreements will be published in the Official Journal of the European Union by the Secretariat of the Council.
AGREEMENT

laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Czech Republic

THE EUROPEAN COMMUNITY,
on the one hand, and

THE CZECH REPUBLIC,
on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part\textsuperscript{4}, and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community\textsuperscript{5},

HAVING REGARD to the Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part\textsuperscript{6}, on Conformity Assessment and Acceptance of Industrial Products and in particular to the aims set out in Article 12,

CONSIDERING the commitment of the Czech Republic and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Czech Republic in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Czech Republic,

HAVE AGREED AS FOLLOWS:

\textit{Article 1}

For the purpose of this Agreement, the following definitions 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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC.7

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC, 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC\(^9\).

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Czech Republic or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Czech Republic, except those provided for in Article 12, 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 of the European Community or the Czech Republic 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 drawn up by the Commission of the European Community\(^\text{10}\) (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Czech Republic shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

\(\text{Article 2}\)

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Czech Republic considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

\(\text{Article 3}\)

1. Subject to Article 12, the European Community shall notify the Czech Republic of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Czech Republic 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.

2. Subject to Article 12, the Czech Republic shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

\(^{10}\) OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Czech Republic 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\(^{11}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{12}\), in the case of a new substance.

Article 6

The Member States and the Czech Republic 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Czech Republic may make comments upon the drafts communicated. The comments of the Czech Republic shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Czech Republic.

2. The Member States and the Czech Republic shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Czech Republic thereof.

Article 9

The competent authorities of the Member States and the Czech Republic shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

Article 10

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

Article 11

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Czech Republic or voluntary agreements by means of which Member States or the Czech Republic:

- comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Czech Republic is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

- fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

- fulfil as far as the Czech Republic is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Czech Republic and the European Community,

- make use of safeguard clauses provided for in binding European Community acts,

- apply Article 8(1) of Directive 92/59/EEC\(^{13}\),

- restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

- restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Czech Republic prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Czech Republic may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Czech Republic in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Czech Republic shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Czech Republic. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Czech Republic being present. In that case the Czech Republic shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Czech Republic.

Article 16

This Agreement shall enter into force on the first day of the second month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Czech Republic to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Czech languages, each text being equally authentic.
ANNEX I

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 II

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/EEC\(^{14}\); services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{15}\),

(c) operations covered by the insurance and reinsurance activities referred to in:

– Article 1 of Directive 73/239/EEC\(^{16}\),
– the Annex to Directive 79/267/EEC\(^{17}\),
– Directive 64/225/EEC\(^{18}\),
– Directives 92/49/EEC\(^{19}\) and 92/96/EEC\(^{20}\).

\(^{14}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT

laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Estonia

THE EUROPEAN COMMUNITY,

on the one hand, and

THE REPUBLIC OF ESTONIA,

on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Estonia, of the other part21, and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community22,

CONSIDERING the commitment of the Republic of Estonia and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Estonia in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Estonia,

HAVE AGREED AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions 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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC23.

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC24, 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC\textsuperscript{25}.

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Estonia or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Estonia, except those provided for in Article 12, 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 of the European Community or the Republic of Estonia 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 drawn up by the Commission of the European Community26 (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Estonia shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

**Article 2**

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Estonia considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

**Article 3**

1. Subject to Article 12, the European Community shall notify the Republic of Estonia of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Estonia 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.

2. Subject to Article 12, the Republic of Estonia shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

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26 OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Estonia 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\(^{27}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{28}\), in the case of a new substance.

Article 6

The Member States and the Republic of Estonia 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Republic of Estonia may make comments upon the drafts communicated. The comments of the Republic of Estonia shall be forwarded to the


Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Estonia.

2. The Member States and the Republic of Estonia shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Estonia thereof.

*Article 9*

The competent authorities of the Member States and the Republic of Estonia shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

*Article 10*

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

*Article 11*

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Estonia or voluntary agreements by means of which Member States or the Republic of Estonia:

- comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Estonia is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

- fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

- fulfil as far as the Republic of Estonia is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Estonia and the European Community,

- make use of safeguard clauses provided for in binding European Community acts,

- apply Article 8(1) of Directive 92/59/EEC,

- restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

- restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Estonia prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Estonia may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Estonia in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Estonia shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Estonia. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Estonia being present. In that case the Republic of Estonia shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Estonia.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Estonia to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Estonian languages, each text being equally authentic.
ANNEX I

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 II**

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/EEC\(^{30}\) services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{31}\),

(c) operations covered by the insurance and reinsurance activities referred to in:

- Article 1 of Directive 73/239/EEC\(^{32}\),
- the Annex to Directive 79/267/EEC\(^{33}\),
- Directive 64/225/EEC\(^{34}\),
- Directives 92/49/EEC\(^{35}\) and 92/96/EEC\(^{36}\).

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30 OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;
2) the full text of the draft notified;
3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;
4) messages requesting supplementary information;
5) answers to request for supplementary information;
6) comments;
7) requests for ad hoc meetings;
8) answers to requests for ad hoc meetings;
9) requests for final texts;
10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;
12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT

laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Latvia

THE EUROPEAN COMMUNITY,

on the one hand, and

THE REPUBLIC OF LATVIA,

on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Latvia, of the other part, and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community,

HAVING REGARD to the Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Latvia, of the other part, on Conformity Assessment and Acceptance of Industrial Products and in particular to the aims set out in Article 12,

CONSIDERING the commitment of the Republic of Latvia and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Latvia in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Latvia,

HAVE AGreed AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions apply:

1. “product”: any industrially manufactured product and any agricultural product, including fish products;

37 OJ L 26, 2.2.1998, p. 3.
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 I.

This Agreement shall not apply to:

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

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC, 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC42.

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Latvia or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Latvia, except those provided for in Article 12, 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 of the European Community or the Republic of Latvia 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

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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 drawn up by the Commission of the European Community43 (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Latvia shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

Article 2

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Latvia considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 3

1. Subject to Article 12, the European Community shall notify the Republic of Latvia of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Latvia 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.

2. Subject to Article 12, the Republic of Latvia shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

43 OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Latvia 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\(^{44}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{45}\), in the case of a new substance.

Article 6

The Member States and the Republic of Latvia 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Republic of Latvia may make comments upon the drafts communicated. The comments of the Republic of Latvia shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Latvia.

2. The Member States and the Republic of Latvia shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Latvia thereof.

Article 9

The competent authorities of the Member States and the Republic of Latvia shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

Article 10

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

Article 11

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Latvia or voluntary agreements by means of which Member States or the Republic of Latvia:

- comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Latvia is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

- fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

- fulfil as far as the Republic of Latvia is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Latvia and the European Community,

- make use of safeguard clauses provided for in binding European Community acts,

- apply Article 8(1) of Directive 92/59/EEC46,

- restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

- restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Latvia prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Latvia may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Latvia in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Latvia shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Latvia. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Latvia being present. In that case the Republic of Latvia shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Latvia.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Latvia to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Latvian languages, each text being equally authentic.
ANNEX I

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 II

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/EEC\(^{47}\); services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{48}\),

(c) operations covered by the insurance and reinsurance activities referred to in:

– Article 1 of Directive 73/239/EEC\(^{49}\),
– the Annex to Directive 79/267/EEC\(^{50}\),
– Directive 64/225/EEC\(^{51}\),
– Directives 92/49/EEC\(^{52}\) and 92/96/EEC\(^{53}\).

\(^{47}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT

laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Lithuania

THE EUROPEAN COMMUNITY,

on the one hand, and

THE REPUBLIC OF LITHUANIA,

on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Lithuania, of the other part\(^54\), and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community\(^55\),

HAVING REGARD to the Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Lithuania, of the other part\(^56\), on Conformity Assessment and Acceptance of Industrial Products and in particular to the aims set out in Article 12,

CONSIDERING the commitment of the Republic of Lithuania and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Lithuania in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Lithuania,

HAVE AGREED AS FOLLOWS:

\(\text{Article 1}\)

For the purpose of this Agreement, the following definitions apply:

1. “product”: any industrially manufactured product and any agricultural product, including fish products;

\(^{54}\) OJ L 51, 20.2.1998, p. 3.


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 I.

This Agreement shall not apply to:

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

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC, 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC59.

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Lithuania or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Lithuania, except those provided for in Article 12, 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 of the European Community or the Republic of Lithuania 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 drawn up by the Commission of the European Community60 (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Lithuania shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

Article 2

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Lithuania considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 3

1. Subject to Article 12, the European Community shall notify the Republic of Lithuania of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Lithuania 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.

2. Subject to Article 12, the Republic of Lithuania shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

60 OJ C 23, 27.1.2000, p. 3.
**Article 4**

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

**Article 5**

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Lithuania 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\(^{61}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{62}\), in the case of a new substance.

**Article 6**

The Member States and the Republic of Lithuania 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

**Article 7**

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

**Article 8**

1. The European Community and the Republic of Lithuania may make comments upon the drafts communicated. The comments of the Republic of Lithuania shall be forwarded to

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the Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Lithuania.

2. The Member States and the Republic of Lithuania shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Lithuania thereof.

**Article 9**

The competent authorities of the Member States and the Republic of Lithuania shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

**Article 10**

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

**Article 11**

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Lithuania or voluntary agreements by means of which Member States or the Republic of Lithuania:

- comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Lithuania is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

- fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

- fulfil as far as the Republic of Lithuania is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Lithuania and the European Community,

- make use of safeguard clauses provided for in binding European Community acts,

- apply Article 8(1) of Directive 92/59/EEC63,

- restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

- restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Lithuania prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Lithuania may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Lithuania in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Lithuania shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Lithuania. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Lithuania being present. In that case the Republic of Lithuania shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Lithuania.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Lithuania to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Lithuanian languages, each text being equally authentic.
ANNEX I

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 II

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/EEC\(^64\); services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^65\),

(c) operations covered by the insurance and reinsurance activities referred to in:

– Article 1 of Directive 73/239/EEC\(^66\),
– the Annex to Directive 79/267/EEC\(^67\),
– Directive 64/225/EEC\(^68\),
– Directives 92/49/EEC\(^69\) and 92/96/EEC\(^70\).

\(^{64}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT

laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Malta

THE EUROPEAN COMMUNITY,

on the one hand, and

THE REPUBLIC OF MALTA,

on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Agreement establishing an Association between the European Economic Community, of the one part, and the Republic of Malta, of the other part, and in particular to the aims set out in Article 2(1),

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community,

CONSIDERING the commitment of the Republic of Malta and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Malta in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Malta,

HAVE AGREED AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions 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:

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– “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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC\(^{73}\).

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC\(^{74}\), 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.

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\(^{74}\) OJ L 311, 28.11.2001, p. 67.
This Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC.\(^{75}\)

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Malta or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Malta, except those provided for in Article 12, 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 of the European Community or the Republic of Malta 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 drawn up by the Commission of the European Community76 (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Malta shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

Article 2

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Malta considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 3

1. Subject to Article 12, the European Community shall notify the Republic of Malta of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Malta 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.

2. Subject to Article 12, the Republic of Malta shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

76 OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Malta shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No. 793/93 in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC, in the case of a new substance.

Article 6

The Member States and the Republic of Malta 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Republic of Malta may make comments upon the drafts communicated. The comments of the Republic of Malta shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Malta.

2. The Member States and the Republic of Malta shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Malta thereof.

**Article 9**

The competent authorities of the Member States and the Republic of Malta shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

**Article 10**

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

**Article 11**

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Malta or voluntary agreements by means of which Member States or the Republic of Malta:

- comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Malta is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

- fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

- fulfil as far as the Republic of Malta is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Malta and the European Community,

- make use of safeguard clauses provided for in binding European Community acts,

- apply Article 8(1) of Directive 92/59/EEC79,

- restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

- restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Malta prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Malta may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

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Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Malta in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Malta shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Malta. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Malta being present. In that case the Republic of Malta shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Malta.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Malta to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Maltese languages, each text being equally authentic.
ANNEX I

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.
\textbf{ANNEX II}

\textbf{Indicative list of the financial services covered by the third subparagraph of point 5 of Article 1}

\begin{itemize}
  \item Investment services
  \item Insurance and reinsurance operations
  \item Banking services
  \item Operations relating to pension funds
  \item Services relating to dealings in futures or options
\end{itemize}

Such services include in particular:

\begin{itemize}
  \item investment services referred to in the Annex to Directive 93/22/EEC\(^{80}\); services of collective investment undertakings,
  \item services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{81}\),
  \item operations covered by the insurance and reinsurance activities referred to in:
    \begin{itemize}
      \item Article 1 of Directive 73/239/EEC\(^{82}\),
      \item the Annex to Directive 79/267/EEC\(^{83}\),
      \item Directive 64/225/EEC\(^{84}\),
      \item Directives 92/49/EEC\(^{85}\) and 92/96/EEC\(^{86}\).
    \end{itemize}
\end{itemize}

\(^{80}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT
laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Poland

THE EUROPEAN COMMUNITY,
on the one hand, and

THE REPUBLIC OF POLAND,
on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Poland, of the other part \(^{87}\), and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community \(^{88}\),

CONSIDERING the commitment of the Republic of Poland and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Poland in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Poland,

HAVE AGREED AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions 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:

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“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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC90.

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC90, 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC\(^{91}\). This Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of financial services, as listed non-exhaustively in Annex II to this Agreement.

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Poland or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Poland, except those provided for in Article 12, 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 of the European Community or the Republic of Poland 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 drawn up by the Commission of the European Community\(^\text{92}\) (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Poland shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

**Article 2**

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Poland considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

**Article 3**

1. Subject to Article 12, the European Community shall notify the Republic of Poland of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Poland 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.

2. Subject to Article 12, the Republic of Poland shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

\(^{92}\) OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Poland 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. 793/9393 in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC94, in the case of a new substance.

Article 6

The Member States and the Republic of Poland 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Republic of Poland may make comments upon the drafts communicated. The comments of the Republic of Poland shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Poland.

2. The Member States and the Republic of Poland shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Poland thereof.

Article 9

The competent authorities of the Member States and the Republic of Poland shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

Article 10

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

Article 11

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Poland or voluntary agreements by means of which Member States or the Republic of Poland:

– comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Poland is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

– fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

– fulfil as far as the Republic of Poland is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Poland and the European Community,

– make use of safeguard clauses provided for in binding European Community acts,

– apply Article 8(1) of Directive 92/59/EEC95,

– restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

– restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Poland prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Poland may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

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Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Poland in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Poland shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Poland. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Poland being present. In that case the Republic of Poland shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Poland.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Poland to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Polish languages, each text being equally authentic.
ANNEX I

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 II

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/EEC96; services of collective investment undertakings,
(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC97,
(c) operations covered by the insurance and reinsurance activities referred to in:
   – Article 1 of Directive 73/239/EEC98,
   – the Annex to Directive 79/267/EEC99,
   – Directive 64/225/EEC100,

96 OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT
laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Slovak Republic

THE EUROPEAN COMMUNITY,
on the one hand, and

THE SLOVAK REPUBLIC,
on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Slovak Republic, of the other part103, and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community104,

CONSIDERING the commitment of the Slovak Republic and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Slovak Republic in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Slovak Republic,

HAVE AGREED AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions 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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC\(^{105}\).

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC\(^{106}\), 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC\textsuperscript{107}.

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

With the exception of Article 11, this Agreement 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:

\begin{itemize}
\item 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,
\item 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.
\end{itemize}

6. “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 one of the Member States of the European Community or a major part thereof, or in the Slovak Republic or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Slovak Republic, except those provided for in Article 12, 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:

\begin{itemize}
\item laws, regulations or administrative provisions of a Member State of the European Community or the Slovak Republic 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,
\item 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,
\end{itemize}

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 drawn up by the Commission of the European Community\textsuperscript{108} (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Slovak Republic shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

\textit{Article 2}

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Slovak Republic considers necessary:

- for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

\textit{Article 3}

1. Subject to Article 12, the European Community shall notify the Slovak Republic of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Slovak Republic 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.

2. Subject to Article 12, the Slovak Republic shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

\textsuperscript{108} OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Slovak Republic 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\(^{109}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{110}\), in the case of a new substance.

Article 6

The Member States and the Slovak Republic 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Slovak Republic may make comments upon the drafts communicated. The comments of the Slovak Republic shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Slovak Republic.

2. The Member States and the Slovak Republic shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Slovak Republic thereof.

Article 9

The competent authorities of the Member States and the Slovak Republic shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

Article 10

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

Article 11

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
Article 12

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Slovak Republic or voluntary agreements by means of which Member States or the Slovak Republic:

   – comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Slovak Republic is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

   – fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

   – fulfil as far as the Slovak Republic is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Slovak Republic and the European Community,

   – make use of safeguard clauses provided for in binding European Community acts,

   – apply Article 8(1) of Directive 92/59/EEC111,

   – restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

   – restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Slovak Republic prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

Article 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Slovak Republic may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Slovak Republic in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Slovak Republic shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Slovak Republic. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Slovak Republic being present. In that case the Slovak Republic shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Slovak Republic.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Slovak Republic to the European Union.

Article 18

This Agreement, is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Slovak languages, each text being equally authentic.
ANNEX I

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 II

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/EEC\(^{112}\); services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{113}\),

(c) operations covered by the insurance and reinsurance activities referred to in:
    – Article 1 of Directive 73/239/EEC\(^{114}\),
    – the Annex to Directive 79/267/EEC\(^{115}\),
    – Directive 64/225/EEC\(^{116}\),
    – Directives 92/49/EEC\(^{117}\) and 92/96/EEC\(^{118}\).

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\(^{112}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
AGREEMENT
laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services between the European Community and the Republic of Slovenia

THE EUROPEAN COMMUNITY,
on the one hand, and

THE REPUBLIC OF SLOVENIA,
on the other hand,

All the above being hereinafter referred to as the Contracting Parties,

HAVING REGARD to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Slovenia, of the other part\textsuperscript{119}, and in particular to the aims set out in Article 1,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community\textsuperscript{120},

CONSIDERING the commitment of the Republic of Slovenia and the European Community to promote harmonious economic relations between the Contracting Parties,

CONSIDERING the ongoing cooperation between the European Community and the Republic of Slovenia in the field of technical barriers to trade and the common understanding reached within the framework of that cooperation to extend this information procedure on technical regulations and rules on information society services applied in the European Community to the Republic of Slovenia,

HAVE AGREED AS FOLLOWS:

Article 1

For the purpose of this Agreement, the following definitions 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:

\textsuperscript{119} OJ L 51, 26.2.1999, p. 3.

– “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 I.

This Agreement shall not apply to:

– radio broadcasting services,

– television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC\(^{121}\).

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 establishing the European Community, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC\(^{122}\), 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 Agreement shall not apply to rules relating to matters which are covered by European Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC\(^\text{123}\).

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

With the exception of Article 11, this Agreement 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. “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 one of the Member States of the European Community or a major part thereof, or in the Republic of Slovenia or a major part thereof, as well as laws, regulations or administrative provisions of the Member States of the European Community or of the Republic of Slovenia, except those provided for in Article 12, 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 of the European Community or the Republic of Slovenia 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 drawn up by the Commission of the European Community\(^{124}\) (thereinafter called ‘the Commission’) in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. The Republic of Slovenia shall draw up such a list and forward it to the Commission the first day of the first month following entry into force of this Agreement.

The same procedure shall be used for amending this list.

7. “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.

Article 2

This Agreement shall not apply to those measures Member States consider necessary under the Treaty establishing the European Community or the Republic of Slovenia considers necessary:

– for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 3

1. Subject to Article 12, the European Community shall notify the Republic of Slovenia of the draft technical regulations notified to it by its Member States. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the Republic of Slovenia 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.

2. Subject to Article 12, the Republic of Slovenia shall likewise notify the European Community of its draft technical regulations. Where these technical regulations merely transpose the full text of an international or European standard, information regarding the relevant standard shall suffice. It shall also let the European Community 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.

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\(^{124}\) OJ C 23, 27.1.2000, p. 3.
Article 4

A full text of the draft technical regulation notified shall be made available in the original language as well as in a full translation into one of the official languages of the European Community.

Article 5

1. Where appropriate, and unless it has already been sent with a prior communication, a full text in the original language of the basic legislative or regulatory provisions principally and directly concerned shall also be simultaneously communicated, should knowledge of such text be necessary in order to assess the implications of the draft technical regulation notified.

2. 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 and the Republic of Slovenia 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\(^{125}\) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC\(^{126}\), in the case of a new substance.

Article 6

The Member States and the Republic of Slovenia 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. Transmission of these communications shall take place in accordance with the provisions set out in Article 3.

Article 7

Each Contracting Party may ask for further information on a draft technical regulation notified in accordance with this Agreement.

Article 8

1. The European Community and the Republic of Slovenia may make comments upon the drafts communicated. The comments of the Republic of Slovenia shall be forwarded to the

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Commission and the comments of the European Community shall be forwarded by the Commission to the Republic of Slovenia.

2. The Member States and the Republic of Slovenia shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. 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 6 of Article 1, the comments of the Contracting Parties 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.

4. The Commission shall, when a six-month standstill is invoked according to the rules set out in Directive 98/34/EC, inform the Republic of Slovenia thereof.

Article 9

The competent authorities of the Member States and the Republic of Slovenia shall postpone the adoption of draft technical regulations notified for three months from the date of receipt by the Commission of the text of the draft regulation.

Article 10

The standstill period referred to in Article 9 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 and, for rules on services, also for public policy, notably the protection of minors, the competent authorities are 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, the competent authorities are obliged to enact and implement rules on financial services immediately.

The reasons which warrant the urgency of the measures taken shall be given. The justification for urgent measures shall be detailed and clearly explained with particular emphasis on the unpredictability and the seriousness of the danger confronting the concerned authorities as well as the absolute necessity for immediate action to remedy it.

Article 11

1. The final text in the original language of the technical regulation shall also be communicated.

2. The administrative arrangements for the above mentioned notifications are detailed in Annex III, which forms an integral part of this Agreement.
**Article 12**

1. Articles 3 to 10 shall not apply to those laws, regulations and administrative provisions of the Member States and the Republic of Slovenia or voluntary agreements by means of which Member States or the Republic of Slovenia:

   – comply as far as the Member States are concerned with binding European Community acts which result in the adoption of technical specifications or rules on services, and as far as the Republic of Slovenia is concerned transpose into national law European Community acts which result in the adoption of technical specifications or rules on services,

   – fulfil as far as the Member States are concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the European Community,

   – fulfil as far as the Republic of Slovenia is concerned the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Republic of Slovenia and the European Community,

   – make use of safeguard clauses provided for in binding European Community acts,

   – apply Article 8(1) of Directive 92/59/EEC\(^{127}\),

   – restrict themselves to implementing a judgement of the Court of Justice of the European Communities,

   – restrict themselves to amending a technical regulation within the meaning of point 6 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Articles 9 and 10 shall not apply to the laws, regulations and administrative provisions of the Member States and of the Republic of Slovenia prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 and 10 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 6 of Article 1.

**Article 13**

Information supplied under this Agreement shall be considered as confidential upon request. However, both the European Community and the Republic of Slovenia may, provided that the necessary precautions are taken, consult for an expert opinion natural or legal persons, including persons in the private sector.

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Article 14

1. The Contracting Parties shall, within the framework of the established cooperation between experts of the European Community and the Republic of Slovenia in the field of technical barriers to trade, hold regular consultations both to ensure the satisfactory functioning of the procedure laid down in this Agreement and to exchange views on the comments which have been submitted by any Contracting Party concerning a draft technical regulation notified in accordance with this Agreement. Furthermore, by common consent, the Contracting Parties may hold additional ad hoc meetings to deal with specific cases of particular interest to any Contracting Party.

2. The Republic of Slovenia shall appoint an expert to represent it in meetings of the Committee established under article 5 of Directive 98/34/EC, part ‘information society services’ and ‘technical regulations’. The expert must be a member of the government services of the Republic of Slovenia. The expert shall not be entitled to vote.

3. The Commission shall, in good time, inform the expert of the dates of the meetings, and of the items on the agenda of the Committee. The Commission shall forward relevant information to the expert.

4. On the initiative of its chairman, the Committee may meet without the expert representing the Republic of Slovenia being present. In that case the Republic of Slovenia shall be informed.

Article 15

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Slovenia.

Article 16

This Agreement shall enter into force on the first day of the first month following the date on which the Contracting Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

Article 17

This Agreement shall expire on the date of accession of the Republic of Slovenia to the European Union.

Article 18

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Slovenian languages, each text being equally authentic.
**ANNEX I**

**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 II

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/EEC\(^{128}\); services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 89/646/EEC\(^{129}\),

(c) operations covered by the insurance and reinsurance activities referred to in:
   – Article 1 of Directive 73/239/EEC\(^{130}\),
   – the Annex to Directive 79/267/EEC\(^{131}\),
   – Directive 64/225/EEC\(^{132}\),
   – Directives 92/49/EEC\(^{133}\) and 92/96/EEC\(^{134}\).

\(^{128}\) OJ L 141, 11. 6. 1993, p. 27.
ANNEX III

Pursuant to Article 11 (2) of the Agreement, the following communications by electronic means are considered necessary:

1) notification slips. They may be communicated before or together with the transmission of the full text;

2) the full text of the draft notified;

3) acknowledgement of receipt of the draft text, containing inter alia, the relevant expiry date of the standstill period;

4) messages requesting supplementary information;

5) answers to request for supplementary information;

6) comments;

7) requests for ad hoc meetings;

8) answers to requests for ad hoc meetings;

9) requests for final texts;

10) information that a six-month standstill has been called.

The following communications may, for the time being, be transmitted by fax, however electronic means are preferable:

11) basic legal texts or regulatory provisions;

12) the final text;

Administrative arrangements concerning the communications shall be jointly agreed by the Contracting Parties.
LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Enterprise
Activit(y/ies): Getting still more from the Internal Market

TITLE OF ACTION: COUNCIL DECISION ON THE CONCLUSION OF BILATERAL AGREEMENTS LAYING DOWN A PROCEDURE FOR THE PROVISION OF INFORMATION IN THE FIELD OF TECHNICAL REGULATIONS AND RULES ON INFORMATION SOCIETY SERVICES WITH EIGHT CANDIDATE COUNTRIES

1. BUDGET LINE(S) + HEADING(S)
   
   A-110 "Officials and temporary staff holding a post provided for in the establishment plan"
   
   A-2422 Technical and logistical support and assistance to users
   
   B5-3002 Operation and development of the internal market, particularly in the field of notification, certification and sectoral approximation

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): € million in commitments: 0.128

2.2. Period of application:

The agreements will be of limited duration. Each agreement will end upon the accession to the European Union of the candidate country with which it was concluded. Accordingly, there is no provision for renewing the agreements.

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) (see point 6.1.1)

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>n + 5 and subs. years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commitments</td>
<td>0.128</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>0.128</td>
</tr>
<tr>
<td>Payments</td>
<td>0.064</td>
<td>0.064</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>0.128</td>
</tr>
</tbody>
</table>
(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

<table>
<thead>
<tr>
<th></th>
<th>Commitments</th>
<th>Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
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<tr>
<td>None</td>
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</tbody>
</table>

Subtotal a+b

<table>
<thead>
<tr>
<th></th>
<th>Commitments</th>
<th>Payments</th>
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</thead>
<tbody>
<tr>
<td>0.128 pm pm pm pm pm 0.128</td>
<td>0.064 0.064 pm pm pm pm 0.128</td>
<td></td>
</tr>
</tbody>
</table>

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

<table>
<thead>
<tr>
<th></th>
<th>Commitments/ payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.167 pm pm pm pm pm 0.167</td>
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</tr>
</tbody>
</table>

TOTAL a+b+c

<table>
<thead>
<tr>
<th></th>
<th>Commitments</th>
<th>Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.295 pm pm pm pm pm 0.295</td>
<td>0.231 0.064 pm pm pm pm 0.295</td>
<td></td>
</tr>
</tbody>
</table>

2.4. **Compatibility with financial programming and financial perspective**

Proposal is compatible with existing financial programming.

2.5. **Financial impact on revenue:**

Proposal has no financial implications (involves technical aspects regarding implementation of a measure).

3. **BUDGET CHARACTERISTICS**

<table>
<thead>
<tr>
<th>Type of expenditure (B5-3002)</th>
<th>New</th>
<th>EFTA contribution</th>
<th>Contributions from applicant countries</th>
<th>Heading in financial perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-comp</td>
<td>Diff</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

4. **LEGAL BASIS**

Article 133 EC
5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

5.1.1. Objectives pursued

The objective is for the 8 candidate countries with which the agreements have been negotiated (in the following the candidate countries) to participate, before their accession to the European Union, in the notification system for technical regulations established by Directive 98/34/EC, as amended by Directive 98/48/EC.

This Directive provides for the prior notification of draft regulations related to the products of all types and information society services of each of the 15 Member States of the European Community in order to avoid technical barriers to trade before they appear. According to the Directive, a standstill period (of at least three months) is provided during which the notified draft cannot be adopted at national level. A simplified notification system (with a maximum standstill period of three months and the possibility to make comments only) applies to the countries of the European Economic Area and, as of 1 January 2001, to Turkey also.

The mechanism envisaged by these agreements reproduces this simplified system so it can be applied to the candidate countries in order to:

- avoid new barriers to trade between the European Union and the candidate countries;
- prepare these countries as early as possible for accession to the European Union as regards the notification procedure;
- and thus strengthen the spirit of dialogue and mutual understanding.

5.1.2. Measures taken in connection with ex ante evaluation

The *ex ante* evaluation revealed the following:

- It is in the interests of the European Community and of its Member States to conclude such agreements in that the system envisaged will allow them to be kept regularly informed of the regulatory initiatives under preparation in the candidate countries and, then, where appropriate, to make comments on drafts which would have serious legal and economic implications, particularly from the point of view of the free movement of products and information society services (among other matters, for example, for Community subjects or enterprises operating in the candidate countries).

- Furthermore, the application, in simplified form, of a procedure which will apply fully from accession will enable all the parties to prepare for that accession and thus to implement Community obligations correctly

5.1.3. Measures taken following ex post evaluation

None.
5.2. Actions envisaged and budget intervention arrangements

The objective of the agreements with the candidate countries is that they should participate prior to their accession to the European Union in the notification system that was put in place at Community level in 1983. This system should prevent the emergence of new barriers to trade between the Community and the candidate countries.

The geographical coverage is limited to the 8 candidate countries with whom agreements have been negotiated.

The draft regulations will be exchanged between the Commission, the candidate countries and the Member States within the framework of the administrative mechanism provided for by Directive 98/34/EC, and which has already been operational at EC level since 1984.

A maximum of around 80 drafts per year can reasonably be expected from the candidate countries. This figure is based on the fact that:

- the candidate countries are concentrating their legislative activities more on incorporating the *acquis communautaire* (measures that are not covered by this planned notification procedure) than on strictly unilateral initiatives.

Participation in the notification procedure of 8 candidate countries at the same time should result in 10 notifications per candidate country per year. This figure is confirmed by experience with the EFTA countries.

5.3. Methods of implementation

**Action 1**

It will be necessary to set up a computer application for the automatic transmission of texts from the Community Member States to the candidate countries and vice versa.

Setting up such an application by adapting the existing application administering the current Community system, and running it, will require about 10 days' work per year, or an annual amount of € 5 000 (10 days at € 500/day) (cf. point 7.3.). This amount will be funded from the existing computer budget of DG Enterprise (Unit F/1).

**Action 2**

In line with the notification procedure established with the European Economic Area countries, the candidate countries will have to make their notifications in one of the official Community languages. It can be reasonably expected that most notifications will be in English or German.

Similarly, as with the European Economic Area countries, notifications will be translated only into English, French and German.

Based on 80 notifications per year (cf. point 6.2.) with an average of 20 pages per notification, 1 600 pages of translation per year, can be expected. This figure has to be doubled because a text notified in English, for example, will be translated into French and German. The annual cost is therefore estimated at € 128 000 (3 200 pages at € 40 / page). This amount will be funded from DG Enterprise's existing budget (B5-3002),
which already provides for a slight increase in translation costs for 2003 in view of the preparation for enlargement.

Action 3

DG Enterprise will be responsible for:

- coordinating the analysis of the drafts by the other departments concerned within the Commission;
- coordinating with the Member States comments on the candidate countries' texts and the replies to the comments from the candidate countries on the Member States' texts;
- managing the database and translations, and forwarding of messages.

The staff required for this will be paid for out of DG Enterprise's financial resources.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

6.1.1. Financial intervention

<table>
<thead>
<tr>
<th>Breakdown</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>n+5 and subs. years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 2</td>
<td>0.128</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>0.128</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0.128</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>pm</td>
<td>0.128</td>
</tr>
</tbody>
</table>

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

None.
6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)

Commitments (in € million to three decimal places)

<table>
<thead>
<tr>
<th>Breakdown</th>
<th>Type of outputs (projects, files)</th>
<th>Number of outputs (total for years 1…n)</th>
<th>Average unit cost</th>
<th>Total cost (total for years 1…n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 2</td>
<td>- translation</td>
<td>Files</td>
<td>80</td>
<td>0.0016</td>
</tr>
<tr>
<td>TOTAL COST</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Action 2: 80 notifications of 20 pages each = 1 600 pages to be translated into two languages = 3 200 pages of translation at a cost of € 40 / page).

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

<table>
<thead>
<tr>
<th>Types of post</th>
<th>Staff to be assigned to management of the action using existing and/or additional resources</th>
<th>Total Description of tasks deriving from the action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of permanent posts</td>
<td>Number of temporary posts</td>
</tr>
<tr>
<td>Officials or temporary staff</td>
<td>A</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>0.5</td>
</tr>
<tr>
<td>Other human resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of human resources</th>
<th>Amount (€)</th>
<th>Method of calculation *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Officials</td>
<td>162 000</td>
<td></td>
</tr>
<tr>
<td>Temporary staff</td>
<td></td>
<td>108 000 x 1.5</td>
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<tr>
<td>Other human resources</td>
<td></td>
<td>(specify budget line)</td>
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<tr>
<td>Total</td>
<td>162 000</td>
<td></td>
</tr>
</tbody>
</table>

The amounts are total expenditure for 12 months.
7.3. Other administrative expenditure deriving from the action

<table>
<thead>
<tr>
<th>Budget line (number and heading)</th>
<th>Amount €</th>
<th>Method of calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall allocation (Title A7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A0701 – Missions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A07030 – Meetings</td>
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<td></td>
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<tr>
<td>A07031 – Compulsory committees¹</td>
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</tr>
<tr>
<td>A07032 – Non-compulsory committees¹</td>
<td></td>
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<tr>
<td>A07040 – Conferences</td>
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<tr>
<td>A0705 – Studies and consultations</td>
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<td></td>
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<tr>
<td>Other expenditure (specify)</td>
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<tr>
<td>Information systems</td>
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<tr>
<td>Other expenditure – (A-2422)</td>
<td>5 000</td>
<td>10 days at € 500 / day</td>
</tr>
<tr>
<td>Total</td>
<td>5 000</td>
<td></td>
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</tbody>
</table>

The amounts are total expenditure for 12 months.

<table>
<thead>
<tr>
<th>I. Annual total (7.2 + 7.3)</th>
<th>€ 167 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>II. Duration of action</td>
<td>Until the accession of the 8 candidate countries concerned to the Community</td>
</tr>
<tr>
<td>III. Cost of the operation (I xII)</td>
<td></td>
</tr>
</tbody>
</table>

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the annual allocation procedure.

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The candidate countries' notifications will be integrated in the existing database system (TRIS) for the notification procedure. This system will allow a "day by day" follow-up of the candidate countries' notifications, the Community's reactions to these notifications, and also the reactions of the candidate countries to the Member States' notifications.

8.2. Arrangements and schedule for evaluation

The data supplied by TRIS will be used to evaluate annually the impact of the Community intervention.

9. ANTI-FRAUD MEASURES

None (in the absence of actions and follow-up studies).