COUNCIL DECISION
of 21 December 2006

on the conclusion of bilateral Agreements between the European Community and the Republic of Bulgaria and Romania, respectively, laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services

(2006/1004/CE)

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 Commission,

Whereas the bilateral Agreements between the European Community and the Republic of Bulgaria and Romania, respectively, laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services e have been negotiated and should be approved,

HAS DECIDED AS FOLLOWS:

Article 1

The bilateral Agreements between the European Community and the Republic of Bulgaria and Romania, respectively, laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services are hereby approved on behalf of the Community.

The text of the Agreements and the Annexes is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) 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 16 of the Agreements [1].

Done at Brussels, 21 December 2006

For the Council
The President
J. KORKEAOJA

---

[1] 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
BETWEEN THE EUROPEAN COMMUNITY
AND THE REPUBLIC OF BULGARIA
LAYING DOWN A PROCEDURE FOR THE PROVISION OF INFORMATION
IN THE FIELD OF TECHNICAL REGULATIONS AND
OF RULES ON INFORMATION SOCIETY SERVICES

THE EUROPEAN COMMUNITY,

hereinafter referred to as "the Community",

on the one hand, and

THE REPUBLIC OF BULGARIA,

hereinafter referred to as "Bulgaria",

on the other hand,

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 Bulgaria, of the other part [1], and in particular to the objectives set out in Article 1 thereof,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community [2],

---

1 OJ L 358, 31.12.1994, p. 3.

2 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

CONSIDERING the commitment of the Contracting Parties to promote harmonious economic relations between themselves,

CONSIDERING the ongoing cooperation between the Contracting Parties 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 Community to Bulgaria,

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, by which is meant 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 [1];

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

[1] Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities (OJ L 298, 17.10.1989, p. 23). Directive as last amended by Directive 97/36/EC of the European Parliament and of the Council (OJ L 202, 30.7.1997, p. 1).

This definition 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 [1], 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 therein.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Directive as last amended by Directive 2004/27/EC (OJ 136, 30.4.2004, p. 34).

This Agreement shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, defined as "services whose provision consists wholly or partly in the transmission and routing of signals on a telecommunications network by means of telecommunications processes, with the exception of radio broadcasting and television" [1].

This Agreement shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex 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 2004/39/EC [2] or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

[1] This definition arises by virtue of Directive 98/48/EC which makes reference to Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision (OJ L 192, 24.7.1990, p. 1). The latter Directive has been repealed by Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services (OJ L 108, 24.4.2002, p. 3) However, the definition of "telecommunications services" found in Directive 90/387/EEC should be retained for the purposes of Directive 98/48/EC.

[2] Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments (OJ L 145, 30.4.2004, p. 1). Directive as amended by Directive 2006/31/EC (OJ L 114, 27.4.2006, p. 60).

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, hereinafter referred to as "Member States", or a major part thereof, or in Bulgaria or a major part thereof, as well as laws, regulations or administrative provisions of the Member States or of Bulgaria, 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 or Bulgaria 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 [1] drawn up by the Commission of the European Community, hereinafter referred to as "the Commission", in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. Bulgaria 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 Bulgaria considers necessary for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

[1] OJ C 23, 27.1.2000, p. 3.

ARTICLE 3

1. Subject to Article 12, the Community shall notify Bulgaria 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 Bulgaria 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, Bulgaria shall likewise notify the 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 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.

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 institutions of the European Union.

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 Bulgaria shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93 [1] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC [2], in the case of a new substance.

[1] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p.1). Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[2] Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1). Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

ARTICLE 6

The Member States and Bulgaria shall communicate the draft technical regulation 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

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

ARTICLE 8

1. The Community and Bulgaria may make comments upon the draft technical regulations communicated. The comments of Bulgaria shall be forwarded to the Commission and the comments of the Community shall be forwarded by the Commission to Bulgaria.

2. The Member States and Bulgaria 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 Bulgaria thereof.

ARTICLE 9

The competent authorities of the Member States and Bulgaria 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 set out in Annex III.

ARTICLE 12

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

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

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

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

– apply Article 12(1) of Directive 2001/95/EC [1],

– 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 Bulgaria prohibiting manufacture insofar as they do not impede the free movement of products.

3. Articles 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.

[1] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.01.2002, p. 4).

ARTICLE 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the Community and Bulgaria 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 Community and Bulgaria 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 either Contracting Party.

2. Bulgaria 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 Bulgaria. 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 Bulgaria being present. In that case Bulgaria 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 Bulgaria.

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 Bulgaria to the European Union.

ARTICLE 18

This Agreement is drawn up in two originals in the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovene, Slovak, Spanish, Swedish and Bulgarian languages, each text being equally authentic.

FOR THE EUROPEAN COMMUNITY: FOR THE REPUBLIC OF BULGARIA

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 2004/39/EC; services of collective investment undertakings;

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 2006/48/EC [1];

[1] Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions (recast) (OJ L 177, 30.6.2006, p. 1).

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

– Article 1 of Directive 73/239/EEC [1],

– Directive 64/225/EEC [2],

– Directive 92/49/EEC [3] and Directive 2002/83/EC [4].

---

[1] First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life insurance (OJ L 228, 16.8.1973, p. 3). Directive as last amended by Directive 2005/68/EC of the European Parliament and of the Council (OJ L 323, 9.12.2005, p. 1).

[2] Council Directive 64/225/EEC of 25 February 1964 on the abolition of restrictions on freedom of establishment and freedom to provide services in respect of reinsurance and retrocession (OJ 56, 4.4.1964, p. 878/64). Directive as amended by the 1973 Act of Accession.

[3] Council Directive 92/49/EEC of 18 June 1992 on the coordinating of laws, regulations and administrative provisions relating to direct insurance other than life assurance (OJ L 228, 11.8.1992, p. 1). Directive as last amended by Directive 2005/68/EC.

[4] Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance (OJ L 345, 19.12.2002, p. 1). Directive as last amended by Directive 2005/68/EC.

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 on by the Contracting Parties.

AGREEMENT
BETWEEN THE EUROPEAN COMMUNITY
AND ROMANIA
LAYING DOWN A PROCEDURE FOR THE PROVISION OF INFORMATION IN THE FIELD OF TECHNICAL REGULATIONS AND OF RULES ON INFORMATION SOCIETY SERVICES

THE EUROPEAN COMMUNITY,

hereinafter referred to as "the Community"

on the one hand, and

ROMANIA,

on the other hand,

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 Romania, of the other part [1], and in particular to the aims set out in Article 1 thereof,

HAVING REGARD to the information procedure on technical regulations and rules on information society services applied within the European Community [2],

---

1 OJ L 357, 31.12.1994, p. 2.

2 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

CONSIDERING the commitment of the Contracting Parties to promote harmonious economic relations between themselves,

CONSIDERING the ongoing cooperation between the Contracting Parties 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 Community to Romania,

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, by which is meant 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 [1];

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

[1] Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities (OJ L 298, 17.10.1989, p. 23). Directive as last amended by Directive 97/36/EC of the European Parliament and of the Council (OJ L 202, 30.7.1997, p. 1).

This definition 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 [1], 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 therein.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

This Agreement shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, defined as "services whose provision consists wholly or partly in the transmission and routing of signals on a telecommunications network by means of telecommunications processes, with the exception of radio broadcasting and television." [1]

This Agreement shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex 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 2004/39/EC[2] or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

[1] This definition arises by virtue of Directive 98/48/EC which makes reference to Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision (OJ L 192, 24.7.1990, p. 1). The latter directive has been repealed by Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services (OJ L 108, 24.04.2002, p.3). However, the definition of "telecommunications services" found in Directive 90/387/EEC has been retained for the purposes of Directive 98/48/EC.

[2] Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments (OJ L 145, 30.4.2004, p. 1). Directive as amended by Directive 2006/31/EC (OJ L 114, 27.4.2006, p. 60).

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, hereinafter referred to as "Member States", or a major part thereof, or in Romania or a major part thereof, as well as laws, regulations or administrative provisions of the Member States or of Romania, 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 or Romania 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 [1] drawn up by the Commission of the European Community, hereinafter referred to as "the Commission" in the framework of the Committee referred to in Article 5 of Directive 98/34/EC. Romania 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 Romania considers necessary for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

[1] OJ C 23, 27.1.2000, p. 3.

ARTICLE 3

1. Subject to Article 12, the Community shall notify Romania 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 Romania 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, Romania 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 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.

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 institutions of the European Union.

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 Romania shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93 [1] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC [2], in the case of a new substance.

[1] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[2] Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1). Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

ARTICLE 6

The Member States and Romania shall communicate the draft technical regulation 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

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

ARTICLE 8

1. The Community and Romania may make comments upon the draft technical regulations communicated. The comments of Romania shall be forwarded to the Commission and the comments of the Community shall be forwarded by the Commission to Romania.

2. The Member States and Romania 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 Romania thereof.

ARTICLE 9

The competent authorities of the Member States and Romania 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 set out in Annex III.

ARTICLE 12

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

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

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

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

– apply Article 12(1) of Directive 2001/95/EC [1],

– 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 Romania 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.

[1] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

ARTICLE 13

Information supplied under this Agreement shall be considered as confidential upon request. However, both the Community and Romania 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 Community and Romania 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 either Contracting Party.

2. Romania 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 Romania. 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 Romania being present. In that case Romania 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 Romania.

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 Romania to the European Union.

ARTICLE 18

This Agreement is drawn up in two originals in the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovene, Slovak, Spanish, Swedish and Romanian languages, each text being equally authentic.

FOR THE EUROPEAN COMMUNITY: FOR ROMANIA:

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 2004/39/EC; services of collective investment undertakings;

(b) services covered by the activities subject to mutual recognition referred to in the Annex to Directive 2006/48/EC [1];

[1] Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions (recast) (OJ L 177, 30.6.2006, p. 1).

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

– Article 1 of Directive 73/239/EEC [1],

– Directive 64/225/EEC [2],

– Directive 92/49/EEC [3] and Directive 2002/83/EC [4].

---

[1] First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life insurance (OJ L 228, 16.8.1973, p. 3). Directive as last amended by Directive 2005/68/EC of the European Parliament and of the Council (OJ L 323, 9.12.2005, p. 1).

[2] Council Directive 64/225/EEC of 25 February 1964 on the abolition of restrictions on freedom of establishment and freedom to provide services in respect of reinsurance and retrocession (OJ 56, 4. 4. 1964, p. 878/64). Directive as amended by the 1973 Act of Accession.

[3] Council Directive 92/49/EEC of 18 June 1992 on the coordinating of laws, regulations and administrative provisions relating to direct insurance other than life assurance (OJ L 228, 11.8.1992, p. 1). Directive as last amended by Directive 2005/68/EC.

[4] Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance (OJ L 345, 19.12.2002, p.1). Directive as last amended by Directive 2005/68/EC.

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 on by the Contracting Parties.