II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 4 April 2001

on the conclusion of a 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, on Conformity Assessment and Acceptance of Industrial Products (PECA)

(2001/365/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof, in conjunction with the first sentence of the first subparagraph of Article 300(2), the first sentence of the first subparagraph of Article 300(3) and Article 300(4) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) 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 [1], hereinafter referred to as the 'Europe Agreement', entered into force on 1 February 1995.

(2) Article 75(2) of the Europe Agreement provides that cooperation in the fields of standardisation and conformity assessment shall seek to achieve, amongst other things, the conclusion of agreements on mutual recognition.

(3) Article 108(2) of the Europe Agreement provides that the Association Council may delegate to the Association Committee any of its powers.

(4) Article 2 of Decision 94/910/ECSC, EC, Euratom of the Council and the Commission of 19 December 1994 on the conclusion of the Europe Agreement [2], provides for the Community decision-making procedures and for the presentation of the Community position in the Association Council and in the Association Committee.

(5) Article 14 of Decision No 1/95 of the Association Council between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part of 4 April 1995 on its rules of procedure provides that the Association Committee may set up further subcommittees or groups to assist in carrying out its duties.

(6) The Protocol to the Europe Agreement, on Conformity Assessment and Acceptance of Industrial Products, was signed on behalf of the Community in Brussels on 26 February 2001 and should be approved.

(7) Certain tasks for implementation have been conferred upon the Association Council and, in particular, the power to amend the Annexes to the Protocol.

(8) The appropriate internal procedures should be established to ensure the proper functioning of the Protocol.

(9) It is necessary to empower the Commission to make certain technical amendments to the Protocol and to take certain decisions for its implementation,

HAS DECIDED AS FOLLOWS:

Article 1

The Protocol to the Europe Agreement, on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as 'the Protocol'), as well as the declarations annexed to the Final Act thereto, are hereby approved on behalf of the Community.

[1] OJ L 360, 31.12.1994, p. 2.
[2] OJ L 360, 31.12.1994, p. 1.

The text of the Protocol, and of the declarations annexed to the Final Act thereto, is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the diplomatic note provided for in Article 17 of the Protocol ([1]).

Article 3

1. After consultation with the special committee appointed by the Council, the Commission shall:

(a) carry into effect the notifications, acknowledgements, suspensions and withdrawals of bodies, and appointments of joint team or teams of experts, in accordance with Articles 10, 11 and 14(c), of the Protocol, and Section III of the Good Manufacturing Practice (GMP) Annex to the Protocol;

(b) bring about the consultations, exchange of information, the requests for verifications and for participation in verifications, in accordance with Articles 3, 12 and 14(d), (e), and Sections III and IV of the Annexes to the Protocol concerning machinery, lifts, personal protective equipment, electrical safety, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmospheres, hot water boilers, gas appliances, pressure equipment and GMP;

(c) if necessary, reply to requests in accordance with Article 11, Sections III and IV of the Annexes to the Protocol concerning machinery, lifts, personal protective equipment, electrical safety, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmospheres, hot-water boilers, gas appliances, pressure equipment and GMP.

2. Following consultation of the special committee referred to in paragraph 1, the Commission shall determine the position to be taken by the Community in the Association Council and, where applicable, in the Association Committee, with regard to:

(a) amendments to the Annexes in accordance with Article 14(a) of the Protocol;

(b) any decisions regarding disagreements on the results of the verifications and the suspensions, in part or totally, of any notified body in accordance with the second and third subparagraphs of Article 11 of the Protocol;

(c) any measures taken in the application of the safeguard clauses in Section IV of the Annexes of the Protocol concerning machinery, lifts, personal protective equipment, electrical safety, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmospheres, hot-water boilers, gas appliances, and pressure equipment;

(d) the pre-operational phase and the measures to be taken in accordance with points 3.3, 3.4, 4.12, 4.17 and 5.1 of Section III of the GMP Annex to the Protocol;

(e) any measures concerning the verification, suspension, or withdrawal of industrial products as having mutual acceptance under Article 4 of the Protocol.

3. In all other cases, the position to be taken by the Community in the Association Council and, where applicable, in the Association Committee, with regard to this Protocol shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

Done at Luxembourg, 4 April 2001.

For the Council

The President

B. ROSENGREN

([1]) The date of entry into force of the Protocol will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

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, on Conformity Assessment and Acceptance of Industrial Products (PECA)

THE EUROPEAN COMMUNITY AND THE CZECH REPUBLIC, hereinafter referred to as 'the Parties',

WHEREAS the Czech Republic has applied for membership of the European Union and such membership implies the effective implementation of the *acquis* of the European Community,

RECOGNISING that the progressive adoption and implementation of Community law by the Czech Republic provides the opportunity to extend certain benefits of the internal market and to ensure its effective operation in certain sectors before accession,

CONSIDERING THAT, in the sectors covered by this Protocol, Czech national law substantially takes over Community law,

CONSIDERING their shared commitment to the principles of free movement of goods and to promoting product quality, so as to ensure the health and safety of their citizens and the protection of the environment, including through technical assistance and other forms of cooperation between them,

DESIRING to conclude a Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as 'this Protocol') providing for the application of the mutual acceptance of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties and of the mutual recognition of the results of conformity assessment of industrial products which are subject to Community or national law, noting that Article 75 of the Europe Agreement provides, where appropriate, for the conclusion of an agreement on mutual recognition,

NOTING the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel European Conformity Assessment Agreement between the Czech Republic and these countries equivalent to this Protocol,

BEARING IN MIND their status as Contracting Parties to the Agreement establishing the World Trade Organisation, and conscious in particular of their obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

HAVE AGREED AS FOLLOWS:

Article 1

Purpose

The purpose of this Protocol is to facilitate the elimination by the Parties of technical barriers to trade in respect of industrial products. The means to this end is the progressive adoption and implementation by the Czech Republic of national law, which is equivalent to Community law.

This Protocol provides for :

(1) the mutual acceptance of industrial products, listed in the Annexes on mutual acceptance of industrial products, which fulfil the requirements to be lawfully placed on the market in one of the Parties;

(2) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent Czech national law, both listed in the Annexes on mutual recognition of results of conformity assessment.

Article 2

Definitions

For the purpose of this Protocol,

— 'Industrial products' means products, as specified in Article 9 of the Europe Agreement and in Protocol 3 thereto,

— 'Community law' means any legal act and implementing practice of the European Community applicable to a particular situation, risk or category of industrial products, as interpreted by the Court of Justice of the European Communities,

— 'national law' means any legal act and implementing practice by which the Czech Republic takes over Community law applicable to a particular situation, risk or category of industrial products.

The terms used in this Protocol shall have the meaning given in Community law and Czech national law.

Article 3

Alignment of legislation

For the purpose of this Protocol, the Czech Republic agrees to take appropriate measures, in consultation with the Commission of the European Communities, to maintain or complete the take-over of Community law, in particular in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producer's liability.

Article 4

Mutual acceptance of industrial products

The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the Annexes on mutual acceptance of industrial products, which fulfil the requirements to be lawfully placed on the market of a Party, may be placed on the market of the other Party, without further restriction. This shall be without prejudice to Article 36 of the Europe Agreement.

Article 5

Mutual recognition of the results of conformity assessment procedures

The Parties agree to recognise the results of conformity assessment procedures carried out in accordance with the Community or national law listed in the Annexes on mutual recognition of the results of conformity assessment. The Parties shall not require procedures to be repeated, nor shall they impose additional requirements, for the purposes of accepting that conformity.

Article 6

Safeguard clause

Where a Party finds that an industrial product placed on its territory by virtue of this Protocol, and used in accordance with its intended use, may compromise the safety or health of users or other persons, or any other legitimate concern protected by legislation identified in the Annexes, it may take appropriate measures to withdraw such a product from the market, to prohibit its placing on the market, putting into service or use, or to restrict its free movement. The Annexes shall provide for the procedure to be applied in such cases.

Article 7

Extension of coverage

As the Czech Republic adopts and implements further national law taking over Community law, the Parties may amend the Annexes or add new Annexes, in accordance with the procedure laid down in Article 14.

Article 8

Origin

The provisions of this Protocol shall apply to industrial products which originate in the Parties according to non-preferential rules of origin. In the case of divergent rules, the rules of the Party in whose territory the product is marketed shall be determining. Proof of origin may be demonstrated by a certificate of origin. Such certificate is not required in the case of importation of products covered by a proof of origin according to Protocol 4 to the Europe Agreement.

Article 9

Obligations of Parties as regards their authorities and bodies

The Parties shall ensure that authorities under their jurisdiction which are responsible for the effective implementation of Community and national law shall continuously apply it. Further, they shall ensure that these authorities are able, where appropriate, to notify, suspend, remove suspension and withdraw notification of bodies, to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market.

The Parties shall ensure that bodies, notified under their respective jurisdiction to assess conformity in relation to requirements of Community or national law specified in the Annexes, continuously comply with the requirements of Community or national law. Further, they shall take all necessary steps to ensure that these bodies maintain the necessary competence to carry out the tasks for which they are notified.

Article 10

Notified bodies

Initially, the bodies notified for the purpose of this Protocol shall be those included in the lists which the Czech Republic and the Community have exchanged before the completion of the procedures for entry into force.

Afterwards, the following procedure shall apply for the notification of bodies to assess conformity in relation to the requirements of Community or national law specified in the Annexes:

(a) a Party shall forward its notification to the other Party in writing;

(b) on the acknowledgement of the other Party, given in writing, the body shall be considered as notified and as competent to assess conformity in relation to the requirements specified in the Annexes from that date.

If a Party decides to withdraw a notified body under its jurisdiction, it shall inform the other Party in writing. The body shall cease to assess conformity in relation to the requirements specified in the Annexes from the date of its withdrawal at the latest. Nevertheless, conformity assessment carried out before that date shall remain valid, unless otherwise decided by the Association Council.

Article 11

Verification of notified bodies

Each Party may request the other Party to verify the technical competence and compliance of a notified body under its jurisdiction. Such request shall be justified in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties may also jointly examine the body, with the participation of the relevant authorities. To this end, the Parties shall ensure the full cooperation of bodies under their jurisdiction. The Parties shall take all appropriate steps, and use whatever available means may be necessary, with a view to resolving any problems which are detected.

If the problems cannot be resolved to the satisfaction of both Parties, they may notify the Chairman of the Association Council of their dissent, giving their reasons. The Association Council may decide on appropriate action.

Unless and until decided otherwise by the Association Council, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of Community or national law specified in the Annexes shall be suspended in part or totally from the date on which the disagreement of the Parties has been notified to the Chairman of the Association Council.

Article 12

Exchange of information and cooperation

In order to ensure a correct and uniform application and interpretation of this Protocol, the Parties, their authorities and their notified bodies shall:

(a) exchange all relevant information concerning implementation of law and practice including, in particular, on procedure to ensure compliance of notified bodies;

(b) take part, as appropriate, in the relevant mechanisms of information, coordination and other related activities of the Parties;

(c) encourage their bodies to cooperate with a view to establishing mutual recognition arrangements in the voluntary sphere.

Article 13

Confidentiality

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Protocol which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Protocol.

Article 14

Management of the Protocol

Responsibility for the effective functioning of this Protocol shall be held by the Association Council in conformity with Article 106 of the Europe Agreement. In particular, it shall have the power to take decisions regarding:

(a) amending the Annexes;

(b) adding new Annexes;

(c) appointing a joint team or teams of experts to verify the technical competence of a notified body and its compliance with the requirements;

(d) exchanging information on proposed and actual modifications of the Community and national law referred to in the Annexes;

(e) considering new or additional conformity assessment procedures affecting a sector covered by an Annex;

(f) resolving any questions relating to the application of this Protocol.

The Association Council may delegate the responsibilities set out under this Protocol, in conformity with Article 108(2) of the Europe Agreement.

Article 15

Technical cooperation and assistance

The Community may provide technical cooperation and assistance to the Czech Republic where necessary in order to support the effective implementation and application of this Protocol.

Article 16

Agreements with other countries

Agreements on conformity assessment concluded by either Party with a country which is not a Party to this Protocol shall not entail an obligation upon the other Party to accept the results of conformity assessment procedures carried out in that third country, unless there is an explicit agreement between the Parties in the Association Council.

Article 17

Entry into force

This Protocol shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force of the Protocol.

Article 18

Status of the Protocol

This Protocol shall constitute an integral part of the Europe Agreement.

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

Hecho en Bruselas, el veintiseis de febrero del dos mil uno.

Udfærdiget i Bruxelles den seksogtyvende februar to tusind og en.

Geschehen zu Brüssel am sechsundzwanzigsten Februar zweitausendundeins.

Έγινε στις Βρυξέλλες, στις είκοσι έξι Φεβρουαρίου δύο χιλιάδες ένα.

Done at Brussels on the twenty-sixth day of February in the year two thousand and one.

Fait à Bruxelles, le vingt-six février deux mille un.

Fatto a Bruxelles, addì ventisei febbraio duemilauno.

Gedaan te Brussel, de zesentwintigste februari tweeduizendeneen.

Feito em Bruxelas, em vinte e seis de Fevereiro de dois mil e um.

Tehty Brysselissä kahdentenakymmenentenäkuudentena päivänä helmikuuta vuonna kaksituhattayksi.

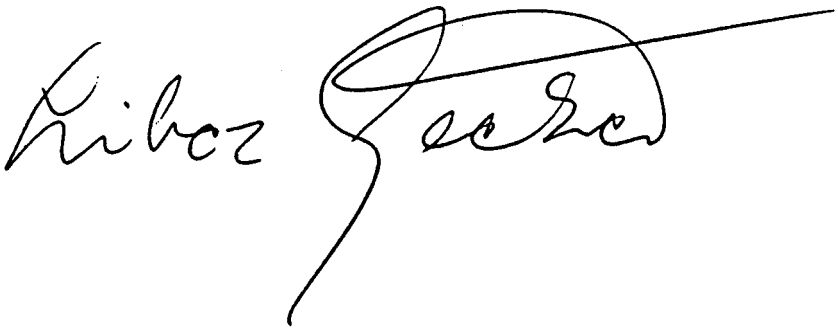
Som skedde i Bryssel den tjugosjätte februari tjugohundraett.

Dáno v Bruselu dne dvacátého šestého února roku dvoutisícího prvního.

Por la Comunidad Europea
For Det Europæiske Fællesskab
Für die Europäische Gemeinschaft
Για την Ευρωπαϊκή Κοινότητα
For the European Community
Pour la Communauté européenne
Per la Comunità europea
Voor de Europese Gemeenschap
Pela Comunidade Europeia
Euroopan yhteisön puolesta
På Europeiska gemenskapens vägnar
Za Evropské společenství



Por la República Checa
For Den Tjekkiske Republik
Für die Tschechischen Republik
Για την Τσεχική Δημοκρατία
For the Czech Republic
Pour la République tchèque
Per la Repubblica ceca
Voor de Tsjechische Republiek
Pela República Checa
Tšekin tasavallan puolesta
På Tjeckiska Republikens vägnar
Za Českou republiku



ANNEXES

ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

(for the record)

ANNEXES ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

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1. Machinery

2. Lifts

3. Personal protective equipment

4. Electrical safety

5. Electromagnetic compatibility

6. Equipment and protective systems intended for use in potentially explosive atmospheres

7. Hot-water boilers

8. Gas appliances

9. Pressure equipment

10. Good Manufacturing Practice (GMP) for medicinal products: inspection and batch certification

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

MACHINERY

Section I

Community and national law

Community law:	Parliament and Council Directive 98/37/EC of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1), as amended by European Parliament and Council Directive 98/79/EC of 27 October 1998 (OJ L 331, 7.12.1998, p. 1).
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/03.11.1986) of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 170/1997 Coll. (part 60/31.7.1997), that lays down the technical requirements for machinery, as amended by Government order No 15/1999 Coll. (part 6/25.1.1999) and Government order No 283/2000 Coll. (part 82/29.8.2000).

SECTION II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Direktoratet for Arbejdstilsynet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'emploi et de la solidarité, Direction des relations du travail, Bureau CT 5.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère du Travail (Inspection du travail et des Mines).
— Netherlands:	Ministerie van Sociale Zaken en Werkgelegenheid.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Sosiaali-ja terveysministeriö / Social-och hälsovårdsministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic:

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

LIFTS

Section I

Community and national law

Community law:	European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 14/1999 Coll. (part 6/25.1.1999), that lays down the technical requirements for lifts, as amended by Government order No 227/1999 Coll. (part 77/14.10.1999), and Government Order No 288/2000 Coll. (part 82/29.8.2000)

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Direktoratet for Arbejdstilsynet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'équipement, des transports et du logement, Direction générale de l'urbanisme, de l'habitat et de la construction.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère du Travail (Inspection du travail et des Mines).
— Netherlands:	Ministerie van Sociale Zaken en Werkgelegenheid.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa- ja teollisuusministeriö / Handels- och industriministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

PERSONAL PROTECTIVE EQUIPMENT

Section I

Community and national law

Community law:	Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18), as last amended by Parliament and Council Directive 96/58/EC of 3 September 1996 (OJ L 236, 18.9.1996, p. 44).
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000). Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000). Government order No 172/1997 Coll. (part 61/4.8.1997), that lays down the technical requirements for personal protective equipment, as amended by Government order No 284/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Direktoratet for Arbejdstilsynet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'emploi et de la solidarité, Direction des relations du travail, Bureau CT 5. Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DiGITIP) — SQUALPI.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère du Travail (Inspection du travail et des Mines).
— Netherlands:	Ministerie van Volksgezondheid, Welzijn en Sport.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Sosiaali-ja terveyministeriö / Social-och hälsovårdsministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) ustified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

ELECTRICAL SAFETY

Section I

Community and national law

Community law:	Council Directive 73/23/EEC of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 77, 26.3.1973, p. 29), as last amended by Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 168/1997 Coll. (part 60/31.7.1997), that lays down the technical requirements for low voltage electrical equipment, as amended by Government order No 281/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Boligministeriet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DiGITIP) — SQUALPI.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère de l'Economie — Service de l'Energie de l'Etat.
	Ministère du Travail (Inspection du Travail et des Mines).
— Netherlands:	Ministerie van Volksgezondheid, Welzijn en Sport (Verbrauchsgüter).
	Ministerie van Sociale Zaken en Werkgelegenheid (Sonstige).
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa ja teollisuusministeriö/Handels och industriministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified and competent bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

ELECTROMAGNETIC COMPATIBILITY

Section I

Community and national law

Community law:	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 139, 23.5.1989, p. 19), as last amended by Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 169/1997 Coll. (part 60/31.7.1997), that lays down the technical requirements for products relating to their electromagnetic compatibility, as amended by Government order No 282/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Telestyrelsen.
— Germany:	Bundesministerium für Wirtschaft und Technologie.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DiGITIP) — SQUALPI.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère de l'Economie — Service de l'Energie de l'Etat.
— Netherlands:	Ministerie van Verkeer en Waterstaat.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa-ja teollisuusministeriö/Handels-och industriministeriet.
	For EMC aspects of telecommunications and radio equipment: Liikenne-ja viestintäministeriö/Kommunikationsministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic:

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví (Czech Office for Standards, Metrology and Testing).

Section III

Notified and competent bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Section I

Community and national law

Community law:	European Parliament and of the Council Directive 94/9/EC of 23 March 1994, on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.4.1994, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll; (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997. Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 176/1997 Coll. (part 63/8.8.1997), that lays down the technical requirements for equipment and protective systems intended for use in potentially explosive atmospheres, as amended by Government order No 286/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Elektricitetsrådet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας. (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI), Sous-direction de la sécurité industrielle.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère de l'Economie — Service de l'Energie de l'Etat.
— Netherlands:	Ministerie van Sociale Zaken en Werkgelegenheid.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa-ja teollisuusministeriö/Handels-och industriministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

1. *Transitional arrangements*

   The certificates issued in the EC Member States in conformity with Directives 76/117/EEC, 79/196/EEC and 82/130/EEC will be recognised as a proof of the conformity assessment under the Article 17 of Act No 22/1997 Coll., on technical requirements for products and on amendments to some acts, as amended by Act No 71/2000 Coll. Based on these certificates, the importer of these products in the Czech Republic will issue a declaration of conformity of the relevant product to the applicable requirements referred to in this paragraph.

2. *Safeguard clauses*

   A. Safeguard clause relating to industrial products:

      1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
      2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
      3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
      4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.
      5. Where the Association Council finds that the measure is:
         (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
         (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

   B. Safeguard clause relating to harmonised standards:

      1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.
      2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
      3. The Community shall keep the Association Council and the other Party informed of the proceedings.
      4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

HOT-WATER BOILERS

Section I

Community and national law

Community law:	Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17), as amended by Council Directive 93/68/EEC of 22 July 1993(OJ L 220, 30.8.1993, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 180/1999 Coll. (part 61/17.8.1999), that lays down the technical requirements for new hot-water boilers fired with liquid or gaseous fuels, as amended by Government order No 289/2000 Coll. (part 89/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Boligministeriet.
— Germany:	Bundesministerium für Wirtschaft und Technologie.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI), Sous-direction de la sécurité industrielle.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère de l'Environnement.
— Netherlands:	Ministerie van Economische Zaken.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Ympäristöministeriö/Miljöministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of the Environment, Transport and the Regions.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

GAS APPLIANCES

Section I

Community and national law

Community law:	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (OJ L 196, 26.7.1990, p. 15) as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 177/1997 Coll. (part 64/12.8.1997), that lays down the technical requirements for appliances burning gaseous fuels, as amended by Government Order No 287/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Danmarks Gasmateriel Prøvning.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI). Sous-direction de la sécurité industrielle.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère du Travail (Inspection du Travail et des Mines).
— Netherlands:	Ministerie van Economische Zaken.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa-ja teollisuusministeriö / Handels-och industriministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

PRESSURE EQUIPMENT

Section I

Community and national law

Community law:	Council Directive 87/404/EEC of 25 June 1987 on the approximation of the laws of the Member States relating to simple pressure vessels (OJ L 220, 8.8.1987, p. 48), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220), 30.8.1993, p. 1)
	European Parliament and Council Directive 97/23/EC of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1)
National law:	Act No 22/1997 Coll. (part 6/27.2.1997) on technical requirements for products and on amendments to some Acts, as amended by Act No 71/2000 Coll. (part 24/3.4.2000).
	Act No 64/1986 Coll. (part 22/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No 240/1992 Coll. (part 49/29.5.1992), Act No 22/1997 Coll. (part 6/27.2.1997), Act No 110/1997 Coll. (part 38/19.5.1997), and Act No 71/2000 Coll. (part 24/3.4.2000).
	Government order No 175/1997 Coll. (part 63/8.8.1997), that lays down the technical requirements for simple pressure vessels, as amended by Government order No 80/1999 Coll. (part 30/4.5.1999) and Government order No 285/2000 Coll. (part 82/29.8.2000).
	Government order No 182/1999 Coll. (part 62/24.8.1999) that lays down the technical requirements for pressure equipment, as amended by Government order No 290/2000 Coll. (part 82/29.8.2000).

Section II

Notifying authorities

European Community

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken.
— Denmark:	Direktoratet for Arbejdstilsynet.
— Germany:	Bundesministerium für Arbeit und Sozialordnung.
— Greece:	Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry).
— Spain:	Ministerio de Ciencia y Tecnología.
— France:	Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale de la Petite et Moyenne Industrie (DARPMI), Sous-direction de la sécurité industrielle.
— Ireland:	Department of Enterprise and Employment.
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato.
— Luxembourg:	Ministère du Travail et de l'Emploi.
— Netherlands:	Ministerie van Sociale Zaken en Werkgelegenheid.
— Austria:	Bundesministerium für Wirtschaft und Arbeit.
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
— Finland:	Kauppa-ja teollisuusministeriö / Handels-och industriministeriet.
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
— United Kingdom:	Department of Trade and Industry.

Czech Republic

Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
(Czech Office for Standards, Metrology and Testing).

Section III

Notified bodies

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Czech Republic in accordance with Article 10 of this Protocol.

Czech Republic

Bodies which have been authorised by the Czech Republic in accordance with the Czech national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

Specific arrangements

Safeguard clauses

A. Safeguard clause relating to industrial products:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

1. Where the Czech Republic considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present Annex.

3. The Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS INSPECTION AND BATCH CERTIFICATION

Section I

Community and national law

Community law:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ L 22, 1.1.1965, p. 369), as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22)

Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ L 147, 9.6.1975, p. 1), as last amended by Commission Directives 1999/82/EC and 1999/83/EC of 8 September 1999 (OJ L 243, 15.9.1999, p. 7 and 9)

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ L 147, 9.6.1975, p. 13), as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22).

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ L 317, 6.11.1981, p. 1), as last amended by Council Directive 90/676/EEC of 13 December 1990 (OJ L 373, 31.12.1990, p. 15).

Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ L 317, 6.11.1981, p. 16), as last amended by Commission Directive 1999/104/EC of 22 December 1999 (OJ L 3, 6.1.2000, p. 18).

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 193, 17.7.1991, p. 30).

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1) as last amended by Commission Regulation (EC) No 649/98 of 23 March 1998 (OJ L 88, 24.3.1998, p. 7).

Council Directive 92/25/EEC of 31 March 1992 on the whole sale distribution of medicinal products for human use (OJ L 113, 30.4.1992, p. 1) and Guide to Good Distribution Practice.

Guide to Good Manufacturing Practice, Volume IV of the Rules Governing Medicinal Products in the European Community.

Compilation of Community Procedures on Administrative Collaboration and Harmonisation of Inspections (III/5698/94-EN).

National law:

Act No 79/1997 Coll. (part 26/15.4.1997) on pharmaceuticals and on amendments to some Acts as amended by Act No 149/2000 Coll. (part 47/13.6.2000).

Decree of the Ministry of Health and Ministry of Agriculture No 296/2000 Coll. (part 83/28.8.2000) on Good Manufacturing Practice, Good Distribution Practice and Specific Conditions for Permitting Drug Manufacturing and Distribution, including Medicated Feedingstuffs.

Recommended Procedures for Implementation of Good Manufacturing Practice and Good Distribution Practice, Official Journal of SUKL, Special Issue, February 1998.

General Requirements of the State Institute for Drug Control, Praha (SUKL) on Validation of Manufacturing Process, Official Journal of SUKL No 12/1995 (VYR-3).

General Requirements of SUKL on Cleaning Procedures and Their Validation, Official Journal of SUKL No 7/1996 (VYR-5).

Clean Rooms, Official Journal of SUKL No 6/1997 (VYR-7).

Principles of Control Activities of SUKL in the Field of Good Manufacturing Practice (GMP) for Manufacturers and Distributors of Pharmaceuticals, Official Journal of SUKL No 3/1998 (VYR-8).

Issuing of GMP Certificates, Official Journal of SUKL No 10/1998 (VYR-9).

General Requirements of SUKL on Validation of Aseptic Procedures, Official Journal of SUKL No 12/1998 (VYR-10).

Requirements of SUKL on Distributors of Medicinal Gases, Official Journal of SUKL No 12/1998 (DIS-5).

Guidelines of the Institute for State Control of Veterinary Immunologicals and Medicaments, Brno (USKVBL).

Recommended Procedures for Implementation of Good Distribution Practice, Official Journal of USKVBL No 1/1998.

Section II

Official GMP inspection services of each Party

European Community

— Belgium: Ministère de la Santé Publique, de l'Environnement et de l'Intégration Sociale. Inspection Pharmaceutique/Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie.

— Denmark: Lægemiddelstyrelsen (Danish Medicines Agency).

— Germany: Bundesministerium für Gesundheit.

— Greece: Υπουργείο Υγείας και Πρόνοιας, Εθνικός Οργανισμός Φαρμάκου
(Ministry of Health and Welfare, National Drug Organisation).

— Spain: Agencia Española del Medicamento.

— France: Ministère de l'emploi et de la solidarité, Direction générale de la santé.

Pour les médicaments à usage humain (human medicinal products): Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS).

Pour les médicaments à usage vétérinare (veterinary medicinal products): Agence Française de Sécurité Sanitaire des Aliments (AFSSA, Agence nationale du médicament vétérinaire).

— Ireland: Irish Medicines Board.

— Italy: Ministero della Sanità. Dipartimento Farmaci e Farmacovigilanza (human medicinal products).

Ministero della Sanità. Dipartimento alimenti e nutrizione e sanità pubblica veterinaria — (veterinary medicinal products).

— Luxembourg: Direction de la Santé, Division de la Pharmacie et des Médicaments.

— Netherlands: Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid.

— Austria: Bundesministerium für soziale Sicherheit und Generationen.

— Portugal: Under the authority of the Government of Portugal:

— Finland: Sosiaali-ja terveysministeriö / Social-och hälsovårdsministeriet.

— Sweden: Läkemedelsverket (Medical Products Agency).

— United Kingdom: Medicines Control Agency.

Veterinary Medicines Directorate.

Czech Republic

Státní ústav pro kontrolu léčiv – SUKL (State Institute for Drug Control) Praha.

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv –USKVBL. (Institute for State Control of Veterinary Immunologicals and Medicaments) Brno.

Section III

Specific arrangements

1. DEFINITION

'Medicinal products': means all products regulated by the pharmaceutical legislation in the Community and the Czech Republic as listed in Section I.

'Good Manufacturing Practice (GMP)': as defined in Commission Directive 91/356/EEC and Commission Directive 91/412/EEC and the relevant legislation of the Czech Republic as listed in Section I.

'Inspection': means an on-site evaluation of a manufacturing facility carried out by an inspection service listed in Section II to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practice or commitments made as part of the marketing authorisation.

'Inspection Report': means the written observations and Good Manufacturing Practice compliance assessment completed by an authority listed in Section II.

2. SCOPE AND COVERAGE

2.1. The provisions of this Annex cover all medicinal products for human and veterinary use which are industrially manufactured in the Czech Republic and the Community, and to which the GMP requirements apply.

2.2. For the medicinal products covered by this Annex, each Party shall recognise the conclusions of inspections carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the Competent Authorities of the other Party.

2.3. In addition, the manufacturer's certification of the conformity of each batch to its specifications shall be recognised by the other Party without re-control at import.

3. PRE-OPERATIONAL PHASE

3.1. In the pre-operational phase the following activities will be carried out:

— The effective implementation of legislative, regulatory and administrative requirements of the Community on GMP by the Czech Republic will be determined according to a procedure established by the Community.

— The practical implementation of the requirements of the Community on GMP will be determined through joint inspections, examination of inspection reports and other documents linked to an inspection.

3.2. The length of the pre-operational phase will be six months.

3.3. The results of the activities in the pre-operational phase will be discussed in the competent expert group (European Community inspector's Working Party) with the participation of the Competent Authorities of the Czech Republic. The Parties will decide on the prolongation or termination of the pre-operational phase in the Association Council. The operational phase will start immediately after the successful termination of the pre-operational phase.

3.4. The Parties may decide, in the Association Council, to renounce the pre-operational phase at any time in the light of the demonstration of implementation and maintenance of GMP in the Czech Republic.

4. OPERATIONAL PHASE

Certification of manufacturers

4.1. At the request of an exporter, importer or the Competent Authority of the other party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture and control of medicinal products shall certify that the manufacturer of the medicinal product:

(a) is appropriately authorised to manufacture and/or control the relevant medicinal product or to carry out the relevant specified operations;

(b) complies with the Community and Czech Republic GMP requirements; and

(c) is regularly inspected by the competent inspection service.

4.2. The certificates shall also identify the site(s) of manufacture. Guidance on a common format for such certificate will be given.

4.3. Certificates shall be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, for example when a new inspection has to be carried out, this period may be extended to 60 days.

Batch certification

4.4. Each batch exported shall be accompanied by a batch certificate issued by the manufacturer (self certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specification and has been manufactured in accordance with the relevant marketing authorisation. This certificate shall be retained by the importer of the batch and will be made available upon request of the Competent Authority.

4.5. When issuing a certificate, the manufacturer shall take account of the provisions of the current Community certification system. The batch certificate shall be signed by the person responsible for releasing the batch for export, i.e. the 'qualified person' referred to in Article 17 of Directive 75/319/EEC and Article 29 of Directive 81/851/EEC, and in Sections 4 and 19 of Act 79/1997 Coll.

Official batch release

4.6. The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (for example vaccines) and blood derivatives, carried out by the competent authorities before the distribution of each batch of product. This Protocol does not encompass mutual recognition of these official batch releases.

Inspections

4.7. GMP inspections shall be carried out by the locally competent inspection service against the GMP requirements as listed in Section I.

4.8. The following types of inspections may be carried out:

(a) General or system inspections: carried out to verify whether a manufacturer complies generally with GMP requirements (for example routine inspection covering especially the fundamental requirements of GMP).

(b) Process inspections: carried out to verify whether a manufacturer conducts a certain process(es) according to GMP requirements (for example production of sterile water).

(c) Product inspection: carried out to verify whether a manufacturer produces certain medicinal product or a series of product(s) according to GMP requirements. It focuses on the validation of compliance with specific process or control aspects as described in the marketing authorisation (for example 'pre-marketing' inspections) and therefore the inspector shall have available and be conversant with the relevant information (the quality dossier and an application/authorisation dossier).

4.9. The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees will not be charged to manufacturers located on the territory of the other Party for products covered by this Protocol.

Transmission of inspection reports

4.10. Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing or control site, in case control operations are contracted out. Each Party shall deal with these inspection reports with the degree of confidentiality requested by the Party of origin.

4.11. If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years, or a particular need to inspect has been identified, a specific and detailed inspection may be requested. The Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 days should a new inspection be carried out.

Alert system

4.12. The Competent Authorities will inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed between the Parties.

4.13. The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non compliance with GMP and which could affect the protection of public health, is communicated to each other with the appropriate degree of urgency.

Exchange of information between authorities and approximation of quality requirements

4.14. In accordance with the general provisions of this Protocol, the Parties shall exchange any information necessary for the mutual recognition of inspections.

4.15. In addition, the relevant Competent Authorities shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and will endeavour to proceed towards their approximation.

Inspectors training

4.16. In accordance with the general provisions of this Protocol, training sessions for inspectors, organised by the Competent Authorities, shall be accessible to inspectors of the other Party. The Parties will keep each other informed of these sessions.

Joint inspections

4.17. In accordance with the general provisions of this Protocol, and by mutual agreement between the Parties, joint inspections may be authorised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Parties.

Contact points

4.18. For the purpose of this Protocol, the contact points for the alert system, any technical question, such as exchange of inspection reports, inspectors training sessions, technical requirements are:

(a) for the Community:

— the Director of the European Agency for the Evaluation of Medicinal Products;

b) for the Czech Republic:

— in the case of a human medicinal product: the Director of the State Institute for Drug Control;

— in the case of a veterinary medicinal product: the Director of the Institute for State Control of Veterinary Immunologicals and Medicaments.

Divergence of views

4.19. Both Parties shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Association Council.

5. SAFEGUARD CLAUSES

5.1. Where a party establishes in writing and in an objective and reasoned manner that the other Party is failing to comply with the conditions of this Annex, it may consult the Association Council. The Association Council may decide on measures to be taken.

5.2. Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception. Should such an inspection take place, inspection costs may be recovered.

Declaration on exchange of information

The Parties see the merit of adopting a further Annex to the Protocol, concerned with exchange of information referred to in Article 12 thereof. The objective is to prevent any potential new technical barrier through an extension to the Czech Republic of some of the principles contained in 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 ([1]). To that end, a simplified procedure will be prepared as a new Annex to the Protocol.

Declaration by the Community on the attendance of Czech representatives at committee meetings

In order to ensure a better understanding of the practical aspects of the application of the *acquis communautaire*, the Community declares that the Czech Republic is invited, under the following conditions, to the meetings of the committees established or referred to under the Community law on machinery, lifts, personal protective equipment, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances, simple pressure vessels and pressure equipment.

This participation shall be limited to meetings or parts thereof during which the application of the *acquis* is discussed; it shall not entail attendance at meetings intended to prepare and issue opinions on implementation or management powers delegated to the Commission by the Council.

This invitation may be extended, on a case-by-case basis, to groups of experts convened by the Commission.

([1]) OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).