ASSOCIATION BETWEEN THE EUROPEAN UNION AND THE CZECH REPUBLIC

– The Association Council –

Brussels, 24 October 2003
(OR. en)

UE-CZ 1720/1/03
REV 1

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject :	Decision No .../2003 of the EU-Czech Republic Association Council on the addition of annexes to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products

DECISION No …/2003 OF THE EU-CZECH REPUBLIC ASSOCIATION COUNCIL

of

on the addition of annexes to the Protocol to
the Europe Agreement on Conformity
Assessment and Acceptance
of Industrial Products

THE ASSOCIATION COUNCIL,

Having regard to the Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Czech Republic of the other part. [1]

Having regard to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA) [2], and in particular to Article 14(b) thereof.

Whereas the said Protocol entered into force on 1 July 2001. [3]

[1] OJ L 360, 31.12.1994, p. 2.
[2] OJ L 135, 17.5.2001, p. 3.
[3] OJ L 156, 13.6.2001, p. 32.

Whereas Article 14 of the said Protocol provides that the Association Council may decide to add annexes to the PECA.

Whereas extension of the PECA to cover additional sectors will further eliminate technical barriers to trade between the parties.

Whereas it is considered that the Czech Republic has now aligned its legislation, administrative structures and procedures in the areas concerned,

HAS DECIDED AS FOLLOWS:

Article 1

Following the alignment of the relevant Czech legislation administrative structures and procedures, the following new Annexes are hereby added to the abovementioned Protocol.

Mutual recognition of results of conformity assessment:

Non-Automatic Weighing Instruments (NAWI)
Radio Communication and Telecommunication Terminal Equipment (R & TTE)
Medical Devices
Construction Products
Good Laboratory Practice (GLP)

Mutual acceptance of industrial products

Metrology: Measuring Instruments
Metrology: Pre-Packaging.

The text of these Annexes is attached.

Article 2

This Decision shall enter into force on the first day of the second month following its adoption by the Association Council.

Done at Brussels,

ANNEX I

ANNEXES ON MUTUAL RECOGNITION
OF RESULTS OF CONFORMITY ASSESSMENT

(continuing from existing annexes)

11. Non-Automatic Weighing Instruments

12. Radio Communication and Telecommunication Terminal Equipment

13. Medical Devices

14. Construction Products

15. Good Laboratory Practice (GLP)

ANNEX ON MUTUAL RECOGNITION
OF RESULTS OF CONFORMITY ASSESSMENT:

NON-AUTOMATIC WEIGHING INSTRUMENTS

SECTION I
COMMUNITY AND NATIONAL LAW

Community law: Council Directive 90/384/EEC of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments (OJ L 189, 20.7.1990, p. 1. Directive as amended by Council Directive 93/68/EEC (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. 102/2001 Coll. (part 41/21.3.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No 226/2003 Coll. (part 79/31.7.2003),

Act No. 64/1986 Coll. (part 23/3.11.1986), 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), Act No. 71/2000 Coll. (part 24/3.4.2000), Act No. 145/2000 Coll. (part 46/12.6.2000),

Act No. 102/2001 Coll. (part 41/21.3.2001), Act No. 321/2001 Coll. (part 122/7.9.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No 226/2003 Coll. (part 79/31.7.2003),

Government Order No. 326/2002 Coll. (part 119/19.7.2002), that lays down the technical requirements for non-automatic weighing instruments.

SECTION II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Service public fédéral Economie, PME, Classes Moyennes et Energie

  Federale Overheidsdienst Economie, KMO, Middenstand en Energie
- Denmark: Erhvervs- og boligstyrelsen
- Germany: Bundesministerium für Wirtschaft und Arbeit
- Greece: Ministry of Development, Directorate of Technical Control
- Spain: Ministerio de Fomento, Centro Español de Metrología
- France: Ministère de l'Économie, des Finances et de l'Industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie, Sous-Direction de la Métrologie
- Ireland: Department of Enterprise, Trade and Employment
- Italy: Ministero delle Attività Produttive
- Luxembourg: Ministère de l'Économie
- Netherlands: Ministerie van Economische Zaken
- Austria: Bundesministerium für Wirtschaftliche Angelegenheiten
- Portugal: Servicio de Metrologia Legal, Instituto Português da Qualidade
- Finland: Kauppa- ja teollisuusministerio / Handels- och industriministeriet
- Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
- United Kingdom: Department of Trade and Industry, National Weights and Measures Laboratory
- 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 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 designated/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:

RADIO COMMUNICATION AND TELECOMMUNICATION
TERMINAL EQUIPMENT

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	European Parliament and Council Directive 1999/5/EC of 9 March 1999 on the approximation of the laws of the Member States relating to radio communication and telecommunication terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10).
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. 102/2001 Coll. (part 41/21.3.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No 226/2003 Coll. (part 79/31.7.2003), Act No. 64/1986 Coll. (part 23/03.11.1986), 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), Act No. 71/2000 Coll. (part 24/3.4.2000), Act No. 145/2000 Coll. (part 46/12.6.2000), Act No. 102/2001 Coll. (part 41/21.3.2001), Act No. 321/2001 Coll. (part 122/7.9.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No 226/2003 Coll. (part 79/31.7.2003),

Act No. 151/2000 Coll. (part 47/13.6.2000), on Telecommunications and on Amendments to Other Acts, as amended by Act No. 274/2001 Coll. (part 104/02.8.2001) and Act No. 205/2002 Coll. (part 82/24.5.2002).

Government Order No. 426/2000 Coll., that lays down technical requirements for radio equipment and telecommunications terminal equipment (part 119/13.12.2000), as amended by Government Order No. 483/2002 Coll. (part 168/15.11.2002) and Government Order No. 251/2003 (part 85/6.8.2003).

SECTION II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Service public fédéral Economie, PME, Classes Moyennes et Energie
  Federale Overheidsdienst Economie, KMO, Middenstand en Energie
- Denmark: IT- og Telestyrelsen

- Germany: Bundesministerium für Wirtschaft und Arbeit
- Greece: Ministry of Development
- Spain: Ministerio de Industria y Energía
  Subdirección General de Seguridad y Calidad Industrial
  For EMC aspects of telecommunications and radio equipment: Ministerio de Fomento. Subdirección General de Promoción y Normalización de Servicios de Telecomunicaciones
- France: Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction générale des stratégies industrielles
- Ireland: Department of Enterprise, Trade and Employment
- Italy: Ministero delle Attività Produttive
- Luxembourg: Ministère des Transports
- Netherlands: Minister van Verkeer en Waterstaat
- Austria: Bundesministerium für wirtschaftliche Angelegenheiten
- 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:
  Liikenneministeriö/Trafikministeriet
- Sweden: Under the authority of the Government of Sweden :
  Styrelsen för ackreditering och teknisk kontrol (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 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 designated by the Czech Republic in accordance with the Czech national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV

SPECIFIC ARRANGEMENTS

1. Market Surveillance authorities

Each Party shall notify to the other Party the authorities established within its territory which are to carry out the surveillance tasks related to the operation of the respective legislation listed in Section I.

2. Notification of interface regulations

Each Party shall notify to the other Party the interfaces which they have regulated in their respective territory. When classifying equipment the Community shall take due account of the interfaces regulated in the Czech Republic.

3. Application of essential requirements

Where the Commission considers adopting a Decision to apply a requirement contained in article 3.3 of Directive 99/5/EC, the Czech Republic shall give its opinion on the issue in its capacity of observer in the TCAM before the formal opinion of the Committee is requested.

4. Notification of apparatus causing damage

Where a Party considers that "apparatus declared to be compliant with the respective legislation causes serious damage to a network or harmful radio interference or harm to the network or its functioning" and has authorised the operator "to refuse connection, to disconnect such apparatus or to withdraw it from service", the Party shall notify this authorisation to the other Party.

5. 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 the present 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 the present 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 European Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The European 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.

C. Safeguard clause relating to compliant radio products not intended for the use in a spectrum of one of the Parties

1. Where a Member State or the Czech Republic takes a measure to "adopt any appropriate measures with a view to:

   prohibiting or restricting the placing on its market, and/or

   requiring the withdrawal from its market,

   of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands", the Party shall inform the other Party, giving the reasons thereof.

2. Where the other Party considers that the measure may be unjustified, and when the divergence of views can not be resolved to the satisfaction of both Parties, they may consult the Association Council on the measure, giving their reasons.

3. Where, after such consultation, the Association Council finds that the measure is:

   (a) justified, it shall immediately inform all competent national authorities of both Parties;

   (b) unjustified, it shall immediately inform the competent authority in the Party which took the measure and request its withdrawal.

ANNEX ON MUTUAL RECOGNITION
OF RESULTS OF CONFORMITY ASSESSMENT:
MEDICAL DEVICES

SECTION I
COMMUNITY AND NATIONAL LAW

Community law: Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1).

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1), as last 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. 123/2000 Coll. on Medical Devices, and Amendments to Some Related Acts (part 36/12.5.2000), as amended by Act No. 274/2003 Coll. (part 92/27.8.2003),

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 24/03.4.2000), Act No. 102/2001 Coll. (part 41/21.3.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No. 226/2003 Coll. (part 79/31.7.2003),

Act No. 64/1986 Coll. (part 23/3.11.1986), of the Czech National Council, on the Czech Trade Inspection, as amended by Act No. 40/1992 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), Act No. 71/2000 Coll. (part 24/3.4.2000), Act No. 145/2000 Coll. (part 46/12.6.2000), Act No. 102/2001 Coll. (part 41/21.3.2001), Act No. 321/2001 Coll. (part 122/07.9.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No. 226/2003 Coll. (part 79/31.7.2003).

Government Order No. 181/2001 Coll. (part 69/8.6.2001), that lays down the technical requirements for medical devices, as amended by Government Order No. 336/2001 Coll. (part 129/20.9.2001) and Government Order No. 251/2003 (part 85/6.8.2003).

Government Order No. 191/2001 Coll. (part 72/15.6.2001), that lays down the technical requirements for active implantable medical devices as amended by Government Order No. 337/2001 Coll. (part 129/20.9.2001) and Government Order No. 251/2003 Coll. (part 85/6.8.2003).

SECTION II

NOTIFYING AUTHORITIES

European Community:

Belgium:	Ministère de la Santé Publique, de l'Environment et de l'Integration Sociale. Inspection Pharmaceutique/Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie
Denmark:	Indenrigs- og Sundhedsministeriet.
Germany:	Bundesministerium für Gesundheit und Soziale Sicherung.
Greece:	Υπουργείο Υγείας (Ministry of Health).
Spain:	Ministerio de Ciencia y Tecnología.
France:	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DIGITIP), Sous-direction de la chimie, de la pharmacie et des biotechnologies.
Ireland:	Department of Health.
Italy:	Ministero della Sanità.

Luxembourg:	Ministère de la Santé.
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: 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 Health.
• 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 designated 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. Registration of the person responsible for placing devices on the market

Any manufacturer who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC and in the relevant Czech national law shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in these provisions. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. Labelling of medical devices

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices as specified in Annex I, point 13.3(a) to Directive 93/42/EEC and in the relevant Czech national law. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

3. Information exchanges

In accordance with Article 12 of this Protocol, the Parties shall in particular exchange the information referred to in the relevant Community law and Czech national law, in particular:

– data relating to registration of manufacturers and devices,

– data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused,

– data obtained in accordance with the vigilance procedure.

4. Safeguard clause

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:
CONSTRUCTION PRODUCTS:

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ L 040 , 11.2.1989 p. 12), as amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1) and all of its implementing Commission Decisions.
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 24/03.4.2000), Act No. 102/2001 Coll. (part 41/21.3.2001), Act No. 205/2002 Coll. (part 82/24.5.2002) and Act No. 226/2003 Coll. (part 79/31.7.2003). Act No. 64/1986 Coll. (part 23/3.11.1986), 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),
Act No. 71/2000 Coll. (part 24/03.4.2000), Act
No. 145/2000 Coll. (part 46/12.6.2000), Act No. 102/2001
Coll. (part 41/21.3.2001), Act No. 321/2001 Coll.
(part 122/07.9.2001), Act No. 205/2002 Coll.
(part 82/24.5.2002) and Act No. 226/2003 Coll.
(part 79/31.7.2003).

Government Order No. 190/2002 Coll.
(part 79/21.5.2002), that lays down the technical
requirements for construction products bearing the
CE marking, as amended by Government Order
No. 251/2003 Coll. (part 85/6.8.2003).

And implementing practice.

SECTION II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère des Communications et de l'Infrastructure / Ministerie van Verkeer & Infrastructuur
- Denmark: Økonomi- og Erhvervsministeriet, Erhvervs- og Boligstyrelsen
- Germany: Bundesministerium für Verkehr, Bau-und Wohnungswesen
- Greece: Ministry for Environment Physical Planning and Public Works
- Spain: Ministerio de Fomento.
  Ministerio de Ciencia y Tecnología
- France: Ministère de l'Equipement, des transports et du logement, Direction générale de l'urbanisme, de l'habitat et de la construction.
  Ministère de l'Economie des Finances et de l'Industrie, Direction générale de l'Industrie des technologies et de l'information et des Postes (DIGITIP), SQUALPI
- Ireland: Department of the Environment and Local Government
- Italy: Ministero delle Attività Produttive
- Luxembourg: Ministère de l'Économie-Service de l'Energie de l'État

- Netherlands: Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer. Directoraat Generaal van de Volkshuisvesting
- Austria: Bundesministerium für Wirtschaft und Arbeit
- Portugal: Ministério da Economia. Direcçao-General da Indústria/Instituto Português da Qualidade (IPQ)
- Finland: Ympäristöministeriö/Miljöministeriet
- Sweden: Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
- United Kingdom: Department of Transport, Local Government 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 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 products

1. Where a Party has taken a measure to deny free access to its market for 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 the present 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:
GOOD LABORATORY PRACTICE

SECTION I
COMMUNITY AND NATIONAL LAW

Community law: Good Laboratory Practice

Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 15, 17.1.1987, p. 29) as last amended by Commission Directive 1999/11/EC of 8 March 1999 (OJ L 77, 23.3.99, p. 8).

Council Decision 89/569/EEC of 28 July 1989 on the acceptance by the European Economic Community of an OECD decision / recommendation on compliance with principles of good laboratory practice (OJ L 315, 28.10.1989, p. 1).

Monitoring of Good Laboratory Practice

Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP) (OJ L 145, 11.6.88, p. 35), as last amended by Commission Directive1999/12/EC of 8 March 1999 (OJ L 77, 23.3.1999, p. 22).

Medicinal Products for Human Use

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).

Veterinary Medicinal Products

Directive 2001/82/ECof the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

Chemical substances (except medicinal products for human or veterinary use, cosmetic products, foodstuffs, animal feedingstuffs, pesticides, radioactive substances)

Council Directive 92/32/EEC (OJ L 154, 5.6.1992, p. 1) amending for the seventh time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Existing chemicals

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 084, 05/04/1993, p.1).

Dangerous preparations

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30/07/1999, p. 1).

Cosmetics

Council Directive 93/35/EEC of 14 June 1993 (OJ L 151, 23.6.1993, p. 32) amending for the 6th time Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

Feed additives

Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (OJ L 64, 7.3.1987, p. 19).
Commission Directive 94/40/EEC of 22 July 1994 amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition (OJ L 208, 11.8.1994, p. 15).

Pesticides

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

Foodstuffs

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23).
Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24/11/1993, p. 14).

National law: Good Laboratory Practice and Monitoring of Good Laboratory Practice

Act No. 157/1998 Coll. (Part 54, 13.7.1998), on chemicals and chemical preparations and amendment some other Acts, as amended by Act. No. 352/1999 Coll. (Part 111, 30.12.1999), Act No. 132/2000 Coll. (Part 39, 17.5.2000), Act No. 258/2000 Coll. (Part 74, 11.8.2000), Act No. 458/2000 Coll. (Part 131, 29.12.2000) and Act No. 185/2001 Coll. (Part 71, 14.6.2001).

Decree of the Ministry of Environment No. 283/2001 Coll. (Part 106, 7.8.2001), establishing the principles of good laboratory practice, the procedure for verification of their compliance, the procedure for granting certificates and the procedure for monitoring of compliance with the good laboratory practice principles.

Decree of the Ministry of Health and the Ministry of Agriculture No. 504/2000 Coll. (Part 147, 30.12.2000) laying down the good laboratory practice in the field of pharmaceuticals.

Methodical document No. 11 Bulletin of Ministry of Environment (Part 12, 1.1.2001), National program of GLP; Monitoring of compliance with good laboratory practice principles, conducting of inspections of test facilities and study audits.

Documents of good laboratory practice, Official Journal of SUKL No. 8/2000 (SLP-2).

Monitoring procedures for good laboratory practice (GLP) and guidance for the conduct of test facility inspections and study audits, Official Journal of SUKL No. 12/2001 (SLP 3).

National GLP programme – Components of procedures for good laboratory practice monitoring, Official Journal of SUKL No. 12/2001 (SLP-4).

Medicinal Products

Act No. 79/1997 Coll. (Part 26, 15.4.1997), on pharmaceuticals and on amendments to some Acts as amended by Acts No. 149/2000 Coll. (Part 47, 13.6.2000), No. 153/2000 Coll. (Part 49, 21.6.2000), No. 258/2000 Coll. (Part 74, 11.8.2000), No. 102/2001 Coll. (Part 41, 21.3.2001), No. 138/2002 Coll. (Part 57, 15.4.2002), No. 309/2002 Coll. (Part 114, 12.7.2002), and No. 320/2002 Coll. (Part 117, 18.7.2002).

Chemical substances (except medicinal products for human or veterinary use, cosmetic products, foodstuffs, animal feedingstuffs, pesticides, radioactive substances)

Act No. 157/1998 Coll. (Part 54, 13.7.1998), on chemicals and chemical preparations and amendment some other Acts, as amended by Act. No. 352/1999 Coll. (Part 111, 30.12.1999), Act No. 132/2000 Coll. (Part 39, 17.5.2000), Act No. 258/2000 Coll. (Part 74, 11.8.2000), Act No. 458/2000 Coll. (Part 131, 29.12.2000) and Act No. 185/2001 Coll. (Part 71, 14.6.2001).

Pesticides

Act No. 147/1996 Coll. (Part 43, 31.5.1996), on phytosanitary care and amendment some connected Acts, as amended by Act No. 409/2000 Coll. (Part 115, 29.11.2000) and by Act No. 314/2001 Coll. (Part 121, 6.9.2001).

Decree No. 91/2002 Coll. (Part 40, 20.3.2002), on preparations for plant protection.

Biocides

Act No. 120/2002 Coll. (Part 52, 9.4.2002), on conditions of placing of biocidal products and active substances on the market and amendment some connected Acts.

Cosmetics

Act No. 258/2000 Coll. (Part 74, 11.8.2000), on protection of public health and amendment some connected Acts, as amended by Act No. 254/2001 Coll. (Part 98, 25.7.2001), Act No. 274/2001 Coll. (Part 104, 02.8.2001), Act No. 13/2002 Coll. (Part 7, 16.1.2002), Act No. 76/2002 Coll. (Part 34, 1.3.2002), Act No. 86/2002 Coll. (Part 38, 12.3.2002) and Act No. 120/2002 Coll. (Part 52, 9.4.2002).

SECTION II

NOTIFIED TEST FACILITIES

1. For the purpose of this Annex, the term "notified test facilities" means the test facilities recognised under each Party's GLP monitoring programme.

2. Each Party shall provide the other Party at least annually with a list of the test facilities which, in the light of the results of the inspections and study audits conform to the GLP principles as well as of the dates of inspection or study audit, their GLP compliance status, and the area of expertise in accordance with point 4 of the Appendix to Annex III of the OECD Decision-Recommendation of 2 October 1989 C(89)87(Final).

3. Each Party shall notify without delay the other Party when a listed test facility under its jurisdiction fails to conform to the GLP principles to an extent which may jeopardise the integrity or authenticity of any such studies it conducts. The test facility will be deleted from the list established in accordance with the preceding paragraph.

SECTION III

NOTIFYING AUTHORITIES

For the purpose of this Annex, the term "notifying authorities" means the GLP monitoring authorities of the Parties.

European Community

Belgium

Institut Scientifique de la Santé Publique – Louis Pasteur Bureau d'Assurance de Qualité Rue Juliette Wytsman 14 B-1050 Bruxelles	All products
Wetenschappelijk Instituut Volksgezondheid (WIV) Bureau Kwaliteitszorg Juliette Wytsmanstraat 14 B 1050 Brussel	

Denmark

Erhvervs- og Boligstyrelsen Dahlerups Pakhus Langelinie Allé 17 DK-2100 København	Industrial chemicals and pesticides
Lægemiddelstyrelsen Axel Heidesgade 1 DK-2300 København S	Pharmaceuticals

Germany	
Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit Kennedyallee 5 D-53175 Bonn	All products
Greece	
General Chemical State Laboratory An. Tsoha 16 GR-11521 Athens	All products
Spain	
Ministerio de Sanidad y Consumo Agencia Española de Medicamento Subdirección General de Seguridad de los Medicamentos Paseo del Prado 18-20 E-28014 Madrid	Pharmaceuticals and cosmetics

Ministerio de Agricultura, Pesca y Alimentación Secretaria General de Agricultura y Alimentación Dirección General de Agricultura Subdirección General de Medios de Producción Agricólas Avda. Ciudad de Barcelona, 118 E-28007 Madrid	Foodstuffs
Ministerio de Industria y Energía Subdirección General de Seguridad Industrial Paseo de la Castellana 160 PLA 12 E-28046 Madrid	Industrial chemicals
France	
Secrétariat du Groupe Interministeriel des Produits Chimiques Le Bervil 12 rue Villiot DiGITIP 2 F-75572 Paris CEDEX 12	Industrial chemicals, pesticides and products other than medicinal and cosmetic products
Agence française de sécurité sanitaire des produits de santé (AFSSAPS) 143 Boulevard Anatole France F-93285 Saint-Denis	Pharmaceuticals other than veterinary products and cosmetics

Agence française de sécurité sanitaire des aliments (AFSSA/ANMV) BP 90203 La Haute Marche - Javené 35302 Fougères cedex	Foodstuffs, food additives and veterinary medicinal products
<u>Ireland</u>	
The Irish National Accreditation Board Wilton Park House Wilton Place Dublin 2 Ireland	All products
<u>Italy</u>	
Ministero della Sanita Dipartimento della Prevenzione GLP Compliance Monitoring Unit Via della Sierra Nevada 60 I-00144 Roma	All products

Luxembourg

Ministère de l'Economie 19-21 Boulevard Royal L–2449 Luxembourg	All products

Netherlands

Ministerie van Volksgezondheid, Welzijn en Sport Inspectorate for Health Protection, Commodities and Veterinary Public Health. GLP Department P.O. Box 16.108 2500 BC s'Gravenhage Netherlands	All products

Austria

Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft Abteilung I/3 Stubenbastei 5 A-1010 Wien	All products

Portugal	
Instituto Português da Qualidade Ministério da Indústria e Comércio Rua C à Av. dos Très Vales P-2825 Monte da Caparica	Industrial chemicals and pesticides
Instituto Nacional de Farmacia e do Medicamento. Parque de Saúde de Lisboa Avenida do Brasil 53 P-1700 Lisboa	Pharmaceuticals and veterinary drugs
Finland	
Sosiaali- ja terveydenhuollon tuotevalvontakeskus Kemikaaliosasto Säästöpankinranta 2 A PL 210 FIN-00531 Helsinki	All products
Sweden	
Läkemedelsverket Box 26 S-751 03 Uppsala	Pharmaceuticals and hygiene and cosmetic products

Styrelsen för ackreditering och teknisk kontroll (SWEDAC) Box 2231 S-103 15 Stockholm	All other products
United Kingdom Department of Health GLP Monitoring Authority Hannibal House Market Towers 1 Nine Elms Lane London SW8 5NQ United Kingdom	All products
Czech Republic Státní ústav pro kontrolu léčiv - SUKL (State Institute for Drug Control) Šrobárova 48 100 41 Praha 10 Czech Republic	Pharmaceuticals
National GLP Monitoring Authority T. G. Masaryk Water Research Institute ASLAB Podbabska 30 160 62 Prague 6 Czech Republic	All other products

SECTION IV

SPECIFIC ARRANGEMENTS

1. Scope and coverage

1.1. The provisions of this Annex apply to the non-clinical testing of chemicals (including pharmaceuticals) according to Good Laboratory Practice (GLP), being either substances or preparations, covered by the legislative, regulatory and administrative requirements listed in section I.

1.2. Unless specific definitions are given, the definition of terms in the OECD Principles of Good Laboratory Practice as contained in Annex II to OECD Council Decision of 12 May 1981 C(81)30(Final), the Guides for Compliance Monitoring Procedures for Good Laboratory Practice as contained in Annex I to Council Decision-Recommendation of 2 October 1989 C(89)87(Final), the GLP Consensus Document "The Application of the GLP Principles to Field Studies" (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 6), and all amendments made thereto, shall apply.

1.3. The Parties recognise the equivalence of each other's GLP compliance programmes that are in accordance with the legislative, regulatory, and administrative requirements listed in Section I, which requirements are consistent with the OECD Decision-Recommendation of 2 October 1989 C(89)87(Final). The Parties mutually accept the conclusions of study audits and test facility inspections on the GLP compliance status performed by the competent authorities referred to in Section III.

1.4. Test facility inspections and/or study audits shall be carried out in accordance with the legislative, regulatory, and administrative requirements of the Party under the jurisdiction of which the studies and data generated therefrom are produced.

1.5. Each Party recognises studies and data generated therefrom produced by a test facility of the other Party as studies and data generated therefrom produced by the test facilities complying with the GLP principles under its own jurisdiction, provided that the test facility is included in the list established in accordance with Section II.

2. Safeguard clause procedure

2.1. Each Party may request further test facility inspections or study audits if there is a documented doubt as to whether a study was conducted in accordance with GLP.

2.2. The Party from which the data are originating shall consider the matter and the evidence brought to its knowledge. It shall report to the other Party the results of its investigations.

2.3. In case of agreement, the Party from which the data are originating shall take appropriate measures to rectify the situation of the test facility.

2.4. If, in exceptional cases, doubts persist and the requesting Party can justify a special concern, it may designate one or more experts of its authorities listed in Section III to participate in a laboratory inspection or an audit of a study conducted jointly by the authorities of the Parties upon decision of the Association Council.

3. Cooperation

3.1. Each Party may, on request, participate as an observer in an inspection of a test facility conducted by the competent authorities of the other Party with the consent of the test facility concerned in order to maintain a continuing understanding of the other Party's inspection procedures.

3.2. The Parties shall supply each other with additional information on a test facility inspection or study audit in response to a reasonable request from the other Party.

ANNEX II

ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

1. Metrology - measuring instruments

2. Metrology - pre-packaging

ANNEX ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS:

METROLOGY – MEASURING INSTRUMENTS

SECTION I

COMMUNITY AND NATIONAL LAW

Community law: Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC, amended by:

Council Directive 85/1/EEC

Council Directive 89/617/EEC

European Parliament and Council Directive 1999/103/EC.

Council Directive 71/316/EEC on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control, amended by:

Council Directive 72/427/EEC

Council Directive 83/575/EEC

Council Directive 87/354/EEC

Council Directive 87/355/EEC

Council Directive 88/665/EEC.

Council Directive 75/410/EEC on the approximation of the laws of the Member States relating to continuous totalizing weighing machines.

Council Directive 78/1031/EEC on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines.

Council Directive 75/33/EEC on the approximation of the laws of the Member States relating to cold-water meters.

Council Directive 79/830/EEC on the approximation of the laws of the Member States relating to hot-water meters.

Council Directive 71/319/EEC on the approximation of the laws of the Member States relating to meters for liquids other than water.

Council Directive 71/348/EEC on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water.

Council Directive 77/313/EEC on the approximation of the laws of the Member States relating to measuring systems for liquids other than water

Adaptation to technical progress:

Commission Directive 82/625/EEC.

Council Directive 71/318/EEC on the approximation of the laws of the Member States relating to gas volume meters

Commission Directive 74/331/EEC

Commission Directive 78/365/EEC

Commission Directive 82/623/EEC.

Council Directive 76/891/EEC on the approximation of the laws of the Member States relating to electrical energy meters

Commission Directive 82/621/EEC.

Directive 73/362/EEC on the approximation of the laws of the Member States relating to material measures of length

Council Directive 78/629/EEC

Commission Directive 85/146/EEC.

Council Directive 76/765/EEC on the approximation of the laws of the Member States relating to alcohol meters and alcohol hydrometers

Commission Directive 82/624/EEC.

Council Directive 76/766/EEC on the approximation of the laws of the Member States relating to alcohol tables.

Council Directive 71/317/EEC on the approximation of the laws of the Member States relating to 5 to 50 kg medium accuracy rectangular bar weights and 1 gramme to 10 kg medium accuracy cylindrical weights.

Council Directive 74/148/EEC on the approximation of the laws of the Member States relating to relating to weights from 1 milligramme to 50 kg of above-medium accuracy.

Council Directive 77/95/EEC on the approximation of the laws of the Member States relating to taximeters.

Council Directive 86/217/EEC on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles.

Council Directive 71/347/EEC on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain.

Council Directive 71/349/EEC on the approximation of the laws of the Member States relating to the calibration of the tanks of vessels.

National law:

Act No. 505/1990 Coll. (part 83/17.12.1990), on Metrology, as amended by Act No. 119/2000 Coll. (part 35/10.5.2002), Act No. 137/2002 Coll. (part 57/15.4.2002) and Act No. 226/2003 Coll. (part 79/31.7.2003).

DECREE No. 262/2000 Coll. (part 125/30.7.2002), of the Ministry of Industry and Trade ensuring uniformity and accuracy of measuring instruments and measurements, as amended by DECREE No. 344/2002 Coll. (part 125/30.7.2002).

DECREE No. 345/2002 Coll. (part 125/30.7.2002), of the Ministry of Industry and Trade, that specifies measuring instruments for mandatory verification and measuring instruments subject to type approval.

DECREE No. 264/2000 Coll. (part 77/17.8.2000), of the Ministry of Industry and Trade, that relates to basic units of measurement and other units and to their indications.

DECREE No. 332/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that lays down some procedures for type approval and verification of specified measuring instruments bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 333/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that relates to hot-water meters bearing EEC mark, as amended by DECREE No 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 334/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that relates to cold-water meters bearing EEC mark, as amended by DECREE No 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 335/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that lays down requirements for taximeters bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 336/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that relates to gas volume meters bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 338/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that lays down requirements for electrical energy meters bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 339/2000 Coll. (part 91/26.9.2000), of the Ministry of Industry and Trade, that lays down requirements for material measures of length bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 21/2001 Coll. (part 6/16.1.2001), of the Ministry of Industry and Trade, that lays down requirements for meters for liquids other than water bearing the EEC mark and for ancillary equipment for these meters, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 22/2001 Coll. (part 6/16.1.2001), of the Ministry of Industry and Trade, that relates to requirements for measuring systems for liquids other than water bearing the EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 249/2001 Coll. (part 97/24.7.2001), of the Ministry of Industry and Trade that lays down requirements for automatic checkweighing and weight grading instruments bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 250/2001 Coll. (part 97/24.7.2001), of the Ministry of Industry and Trade, that lays down requirements for continuous totalising weighing instruments bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 29/2002 Coll. (part 12/29.1.2002) of the Ministry for Industry and Trade, that lays down requirements for measuring instruments of the standard mass per storage volume of grain bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 30/2002 Coll. (part 12/29.1.2002) of the Ministry for Industry and Trade, that lays down methods for the calibration of the tanks used as measuring instruments placed on vessels and bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 31/2002 Coll. (part 12/29.1.2002) of the Ministry of Industry and Trade, that lays down requirements for alcoholmeters and alcohol hydrometers bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 32/2002 Coll. (part 12/29.1.2002) of the Ministry of Industry and Trade, that lays down requirements for weights of from 1 mg to 50 kg of above-medium accuracy bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

DECREE No. 33/2002 Coll. (part 12/29.1.2002) of the Ministry of Industry and Trade, that lays down requirements for 5 to 50 kg medium accuracy rectangular bar weights and 1 g to 10 kg medium accuracy cylindrical weights bearing EEC mark, as amended by DECREE No. 260/2003 Coll. (part 88/14.8.2003).

SECTION II

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 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.

ANNEX ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS:

METROLOGY – PRE-PACKAGING

SECTION I

Community law:	Council Directive 75/106/EEC on the approximation of the laws of the Member States relating to the making-up by volume of certain pre-packaged liquids, amended by:
	Council Directive 79/1005/EEC
	Council Directive 85/10/EEC
	Council Directive 88/316/EEC
	Council Directive 89/676/EEC

Adaptation to technical progress:

Commission Directive 78/891/EEC.

Council Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers.

Council Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products

Adaptation to technical progress:

Commission Directive 78/891/EEC.

Council Directive 80/232/EEC on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products, amended by:

Council Directive 86/96/EEC

Council Directive 87/356/EEC.

National law:	Act No. 505/1990 Coll. (part 83/17.12.1990), on Metrology, as amended by Act No. 119/2000 Coll. (part 35/10.5.2002), Act No. 137/2002 Coll. (part 57/15.4.2002) and Act No 226/2003 Coll. (part 79/31.7.2003). DECREE No. 328/2000 Coll. (91/26.9.2000), of the Ministry of Industry and Trade that relates to the method of making-up by weight or by volume of certain prepackaged products. DECREE No. 329/2000 Coll. (91/26.9.2000), of the Ministry of Industry and Trade that relates to the method of making-up by volume of certain prepackaged liquid products. DECREE No. 330/2000 Coll. (91/26.9.2000), of the Ministry of Industry and Trade, that lays down ranges of nominal quantities and nominal capacities permitted for certain types of prepackaged products. DECREE No. 331/2000 Coll. (91/26.9.2000), of the Ministry of Industry and Trade, that lays down the requirements for bottles used as measuring containers for prepackages.

SECTION II

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 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.