Proposal for a

COUNCIL DECISION

concerning the Community position within the Association Council established by the Europe Agreement between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part, on the addition of annexes to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA)

(presented by the Commission)
EXPLANATORY MEMORANDUM

The Europe Agreement\(^1\) (EA) establishing an Association between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part, came into force on 1 February 1995. A Protocol\(^2\) to the EA on Conformity Assessment and Acceptance of Industrial Products (PECA) was signed on 26 February 2001 and entered into force on 1 July 2001.

The PECA facilitates trade through the elimination of technical barriers to trade in the (industrial) sectors which it covers. Annexes to the PECA specify these particular sectors (e.g. hot-water boilers, gas appliances) and list the relevant Community and Czech legislation, notifying bodies and any specific arrangements, for example safeguard clauses.

Following analysis by the Commission services, it is now judged that the Czech Republic has now aligned its legislation, administrative structures and procedures to such an extent that it is now possible to consider the addition of seven new annexes to the existing ten which make up its PECA. Five of the annexes concern the mutual recognition of results of conformity assessment - Non-Automatic Weighing Instruments (NAWI), Radio Communication and Telecommunication Terminal Equipment (R&TTE), Medical Devices, Construction Products and Good Laboratory Practice (GLP) Two of the new sectors concern the mutual acceptance of industrial products - Metrology: Measuring Instruments and Metrology: Pre-Packaging.

Article 14 of the PECA empowers the Association Council to add new annexes. Article 3(3) of the Decision concluding the PECA\(^3\) specifies that the position to be taken by the Community in the Association Council in such cases shall be determined by the Council, acting by qualified majority on a proposal by the Commission.

The attached Proposal has no financial implications.

For the reasons set out above, the Council is invited to adopt the annexed decision.

\(^2\) OJ L 135, 17.05.2001.
\(^3\) OJ L 135, 17.05.2001, p. 2.
Proposal for a

COUNCIL DECISION

calling for the Community position within the Association Council established by the
Europe Agreement between the European Communities and their Member States, of the
one part, and the Czech Republic, of the other part, on the addition of annexes to the
Protocol to the Europe Agreement on Conformity Assessment and Acceptance of
Industrial Products (PECA)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision of 4 April 2001 on the conclusion of a Protocol on
Conformity Assessment and Acceptance of Industrial Products with the Czech Republic and
in particular Article 3(3) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The Europe Agreement between the European Communities and their Member States,
on the one part, and the Czech Republic, on the other part, entered into force on
1 February 1995.

(2) The Protocol to the Europe Agreement on Conformity Assessment and Acceptance of
Industrial Products (PECA), signed in Brussels on 26 February 2001, entered into
force on 1 July 2001.

(3) Article 14 of the Protocol on Conformity Assessment and Acceptance of Industrial
Products foresees that the Association Council can decide to accept add new annexes
to the PECA.

(4) The position of the Community should be established with respect to the addition of
annexes to the PECA on Non-Automatic Weighing Instruments (NAWI), Radio
Communication and Telecommunication Terminal Equipment (R&TTE), Medical
Devices, Construction Products, Good Laboratory Practice (GLP) Metrology:
Measuring Instruments and Metrology: Pre-Packaging.

6 OJ L 156, 13.06.2001, p. 32.
HAS DECIDED AS FOLLOWS:

Sole Article

The position to be taken by the Community within the Association Council established by the Europe Agreement between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part, on the addition of annexes to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA) is contained in the attached draft decision of the Association Council.

Done at Brussels,

For the Council
The President
ANNEX

DRAFT DECISION NO. …/03 OF THE ASSOCIATION COUNCIL ESTABLISHED BY THE EUROPE AGREEMENT BETWEEN THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, OF THE ONE PART, AND THE CZECH REPUBLIC, OF THE OTHER PART

OF …. 2003

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\(^7\) establishing an association between the European Communities and their Member States, of the one part, and the Czech Republic of the other part,

Having regard to the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products\(^8\), and in particular to Article 14 (b) thereof

Whereas the Protocol on Conformity Assessment and Acceptance of Industrial Products (PECA) entered into force on 1 July 2001\(^9\)

Whereas Article 14 of the said protocol foresees that the Association Council can 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 PECA.

Mutual recognition of results of conformity assessment:

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\(^8\) OJ L 135, 17.5.2001.
\(^9\) OJ L 156, 13.06.2001, p. 32.
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, …. 2003
ANNEXE 2
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


SECTION II

NOTIFYING AUTHORITIES
European Community:

- Belgium: Ministère des Affaires économiques / Ministerie van Economische Zaken
- Denmark: Erhvervsfremme Styrelsen

10 Footnote (Point of Information, not to be included in final text agreed by Association Council Decision):
In a parallel, but separate process a different amendment is being made to Article 8 (Rule of Origin) of the PECA. That change requires minor technical adjustments in the Czech Republic’s Act 22/1997 and implementing legislation. The Commission has been consulted on these technical amendments to Act 22. The Czech Republic will supply the updated legislative reference numbers – for insertion in the text before final approval of the Association Council Decision.
- Germany: Bundesministerium für Wirtschaft und Technologie
- Greece: Ministry of Development, Directorate of Technical Control
- Spain: Ministerio de Fomento, Centro Español de Metrologia
- 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 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/authorized 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:


National law:


SECTION II
NOTIFYING AUTHORITIES

European Community:

- Austria: Bundesministerium für wirtschaftliche Angelegenheiten
- Belgium: Ministère des Affaires Economiques
  Ministerie van Economische Zaken
- Denmark: Telestyrelsen
- Finland: Kauppa-ja teollisuusministeriö/Handels-och industriministeriet
  For EMC aspects of telecommunications and radio equipment:
  Liikenneministeriö/Trafikministeriet
- France: Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction générale des stratégies industrielles
- Germany: Bundesministerium für Wirtschaft und Technologie
- Greece: Ministry of Development
- Ireland: Department of Enterprise, Trade and Employment
- Italy: Ministero delle Attività Produttive
- Luxembourg: Ministère des Transports
- Netherlands: Minister van Verkeer en Waterstaat
- Portugal: Under the authority of the Government of Portugal:
  Instituto Português da Qualidade.
- 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.
- 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 of the European 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 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 authorized 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 the present 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


SECTION II
NOTIFYING AUTHORITIES

European Community:

- Denmark: Sundhedsministeriet.
- Germany: Bundesministerium für Gesundheit.
- 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.


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


• 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


Government Order No. 190/2002 Coll. (part 79/21.05.2002), that lays down the technical requirements for construction products bearing the CE marking, as amended by ........

And implementing practice.

SECTION II

NOTIFYING AUTHORITIES

European Community

- Austria: Bundesministerium für Wirtschaft und Arbeit
• Belgium: Ministère des Communications et de l'Infrastructures / Ministerie van Verkeer & Infrastructuur

• Denmark: Økonomi- og Erhvervsministeriet, Erhvervs- og Boligstyrelsen

• Finland: Ympäristöministeriö/Miljöministeriet

• 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.

• Germany: Bundesministerium für Verkehr, Bau-und Wohnungswesen

• Greece: Ministry for Environment Physical Planning and Public Works

• 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

• Portugal: Ministério da Economia. Direcção-General da Indústria/Instituto Português da Qualidade (IPQ)

• Spain: Ministerio de Fomento.

Ministerio de Ciencia y Tecnología.

• 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


Monitoring of Good Laboratory Practice


Medicinal Products for Human Use


Veterinary Medicinal Products


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


**Existing chemicals**


**Dangerous preparations**


**Cosmetics**


**Feed additives**


**Pesticides**


**Foodstuffs**


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


Decree of the Ministry of Environment No. 283/2001 Coll. (Part 106, 07.08.2001), 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 (good laboratory practice principles).


Methodical document No. 11 Bulletin of Ministry of Environment (Part 12, 01.01.2001), National program of GLP; Monitoring of compliance with good laboratory practice principles, conducting of inspections of test facilities and study audits.


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).


Medicinal Products

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


Pesticides


Decree No. 91/2002 Coll. (Part 40, 20.03.2002), on preparations for plant protection.

Biocides

Act No. 120/2002 Coll. (Part 52, 09.04.2002), on conditions of placing of biocidal products and active substances on the market and amendment some connected Acts.

Cosmetics


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

Wetenschappelijk Instituut Volksgezondheid (WIV)
Bureau Kwaliteitszorg
Juliette Wytsmanstraat 14
B 1050 Brussel

Denmark

Erhvervs- og Boligstyrelsen
Dahlerups Pakhus
Langelinie Allé 17
DK-2100 København

Lægemiddelstyrelsen
Frederikssundsvej 378
DK-2700 Brønshøj

Germany

Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit
Kennedyallee 5
D-53175 Bonn

All products

Industrial chemicals and pesticides

Pharmaceuticals

All products
Greece
General Chemical State Laboratory
An. Tsoha 16
GR-11521 Athens

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

Ministerio de Agricultura, Pesca y Alimentación
Secretaría General de Agricultura y Alimentación
Dirección General de Agricultura
Subdirección General de Medios de Producción Agrícolas
Avda. Ciudad de Barcelona, 118
E-28007 Madrid

Ministerio de Industria y Energía
Subdirector General de Seguridad Industrial
Paseo de la Castellana 160
PLA 12
E-28046 Madrid

France
Secrétariat du Groupe Interministériel des Produits Chimiques
Le Bervil
12 rue Villiot DiGITIP 2
F-75572 Paris CEDEX 12

Agence française de sécurité sanitaire des produits de santé (AFSSAPS)
143 Boulevard Anatole France
F-93285 Saint-Denis

Agence française de sécurité sanitaire des aliments (AFSSA/ANMV)
BP 90203
La Haute Marche - Javené
35302 Fougères cedex

Ireland
The Irish National Accreditation Board
Wilton Park House
Wilton Place
Dublin 2
Ireland

Italy
Ministero della Sanita
Dipartimento della Prevenzione
GLP Compliance Monitoring Unit
Via della Sierra Nevada 60
I-00144 Roma

Luxembourg
Ministère de l’Economie
19-21 Boulevard Royal
L–2449 Luxembourg

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

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

Portugal
Instituto Português da Qualidade
Ministério da Indústria e Comércio
Rua C à Av. dos Très Vales
P-2825 Monte da Caparica

Instituto Nacional de Farmacia e do Medicamento.
Parque de Saúde de Lisboa
Avenida do Brasil 53
P-1700 Lisboa

Finland
Sosiaali- ja terveydenhuollon tuotevalvontakeskus
Kemikaaliosasto
Säästöpankinranta 2 A

All products

All products

All products

All products

Industrial chemicals and pesticides

Pharmaceuticals and veterinary drugs

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.
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:


Adaptation to technical progress:

Commission Directive 82/625/EEC.


Adaptations to technical progress:

Commission Directive 74/331/EEC


Adaptation to technical progress:

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

Adaptations to technical progress:

Commission Directive 85/146/EEC.


Adaptation to technical progress:

Commission Directive 82/624/EEC.


laws of the Member States relating to relating to weights from 1 milligramme to 50 kilogramme of above medium accuracy.


National law:


DECREE No. 345/2002 Coll. (part 125/30.07.2002), 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 77/17.08.2000), 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 91/26.09.2000), 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. 333/2000 Coll. (part 91/26.09.2000), of the Ministry of Industry and Trade, that relates to hot-water meters bearing EEC mark, as amended by ………

DECREE No. 334/2000 Coll. (part 91/26.09.2000), of the Ministry of Industry and Trade, that relates to cold-water meters bearing EEC mark, as amended by ………

DECREE No. 335/2000 Coll. (part 91/26.09.2000), of the Ministry of Industry and Trade, that lays down requirements
for taximeters bearing EEC mark, as amended by …….


DECREE No. 338/2000 Coll. (part 91/26.09.2000), of the Ministry of Industry and Trade, that lays down requirements for electrical energy meters bearing EEC mark, as amended by ……..

DECREE No. 339/2000 Coll. (part 91/26.09.2000), of the Ministry of Industry and Trade, that lays down requirements for material measures of length bearing EEC mark, as amended by ……..

DECREE No. 21/2001 Coll. (part 6/16.01.2001), 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. 22/2001 Coll. (part 6/16.01.2001), 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. 249/2001 Coll. (part 97/24.07.2001), 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. 250/2001 Coll. (part 97/24.07.2001), of the Ministry of Industry and Trade, that lays down requirements for continuous totalising weighing instruments bearing EEC mark, as amended by ……..

DECREE No. 29/2002 Coll. (part 12/29.01.2002) 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. 30/2002 Coll. (part 12/29.01.2002) 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. 31/2002 Coll. (part 12/29.01.2002) of the Ministry of Industry and Trade, that lays down requirements for alcoholmeters and alcohol hydrometers bearing EEC mark, as amended by ……..

DECREE No. 32/2002 Coll. (part 12/29.01.2002) 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. 33/2002 Coll. (part 12/29.01.2002) 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 ........
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


Adaptation to technical progress:

Commission Directive 78/891/EEC.


Adaptation to technical progress:

Commission Directive 78/891/EEC.


National law:

ACT No. 505/1990 Coll. (part 83/17.12.1990), on Metrology, as amended by ACT No. 119/2000 Coll. (part 35/10.05.2002),
ACT No. 137/2002 Coll. (part 57/15.04.2002) and ……...


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.

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