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1 Annex

DECISION OF THE COUNCIL NO 02 OF 2009

ADOPTED AT THE FIFTH MEETING ON 16 JUNE 2009

AMENDMENTS TO ARTICLE 53 AND ANNEX I TO THE CONVENTION

MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

THE COUNCIL,

Having regard to Article 15 of the EFTA Convention concerning mutual recognition of conformity assessment.

Having regard to the Member States' endeavour to regularly update the Convention in order to take account of developments under the Agreement on the European Economic Area and the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (the EC – Swiss MRA).

Having regard to the need to amend Paragraph 4 of Article 53 to the Convention in order for the Committee established under Annex I to make certain technical amendments to the Annex.

Having regard to the recommendation to amend Annex I in order to align it to the EC – Swiss MRA to facilitate future updates and to avoid having to regularly include Conformity Assessment Bodies into the Annex.

Having regard to the Joint Declaration under the EFTA Convention on the parallel application of Annex I (consolidated version) on mutual recognition in relation to conformity assessment with the EC – Swiss MRA.

Having regard to Protocol 12 of the EEA Agreement in which it is foreseen that the European Community concludes mutual recognition agreements with third countries on the basis that the third countries concerned will conclude parallel agreements with the EEA EFTA Member States.

In accordance with Article 59 concerning amendments to the provisions of the EFTA Convention,

DECIDES:

1. The first sentence of Paragraph 4 of Article 53 of the Convention shall be replaced by the following:

“The Committee established under Annex I may decide to amend Article 3 of that Annex as well as the Appendix thereto.”

2. Annex I of the Convention shall be replaced by the Annex to this Decision.

3. This Decision shall enter into force on the first day of the second month following the deposit of the instruments of acceptance by all Member States with the Depositary, which shall notify all other Member States, according to Article 59 of the Convention.

4. The Secretary-General of the European Free Trade Association shall deposit the text of this Decision with the Depositary.

ANNEX TO COUNCIL DECISION NO 02/2009

Annex I of the Convention shall be replaced by the following:

“ANNEX I

Mutual recognition in relation to conformity assessment (Article 15)

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1. Basic provisions
2. Appendix 1: Designating Authorities

ARTICLE 1

Purpose

1. Switzerland and the EEA EFTA States hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the recognised conformity assessment bodies as referred by Article 6 and of the manufacturer's declarations of conformity certifying conformity to the requirements of each other in the areas covered by Article 3.
2. In order to avoid duplication of procedures when Swiss and European Economic Area requirements are deemed equivalent, Switzerland and the EEA EFTA States shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies as referred to in Article 6 and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3. Reports, certificates, authorisations and manufacturer's declarations of conformity shall, in particular, indicate conformity with the legislation applied in the European Economic Area. Conformity marks required by the legislation of one of the Member States must be affixed to products placed on the market of that Member State.
3. The Committee established under Article 10 shall specify the cases in which paragraph 2 shall apply.

ARTICLE 2

Definitions

1. For the purposes of this Annex:

"EEA EFTA States" shall mean those members of the European Free Trade Association that participate in the European Economic Area, i.e. the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway;

"Conformity assessment" shall mean systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

"Conformity assessment body" shall mean a public or private law body whose activities include performance of all or any stage of the conformity assessment process;

"Designating authority" shall mean an authority with the legal power to designate, suspend, withdraw designation or remove suspension of Conformity assessment bodies under its jurisdiction.
2. The definitions laid down by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) may be used to establish the meaning of the general terms relating to conformity assessment contained in this Convention.

ARTICLE 3

Scope and Subject matter

1. The scope of this Annex is identical to that of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment¹ as last amended by Joint Committee Decision 2/2008 on 16 May 2008.²
2. Should the subject matter of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment be amended, then the Parties to this Convention shall consider amending this Annex accordingly.

ARTICLE 4

Legislation

1. For Switzerland, relevant legislative, regulatory and administrative provisions under this Annex are listed in the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment.
2. For the EEA EFTA States, relevant legislative, regulatory and administrative provisions under this Annex are listed in the Agreement on the European Economic Area.
3. When the European Community and Switzerland have both concluded that their respective legislation is equivalent, the Swiss legislation is also deemed to be equivalent to the EEA legislation.³

ARTICLE 5⁴

Origin

The provisions of the Annex shall apply to products covered by this Annex, irrespective of their origin.

ARTICLE 6

Recognised conformity assessment bodies

The conformity assessment bodies that are notified or accepted under the Agreement

¹ OJ L 114, 30.4.2002, p. 369.

² OJ L 158, 19.6.2009, p.1.

³ Concerning the deemed equivalent legislation, please refer to Paragraph 2 of Article 1 of the EC-Swiss MRA.

⁴ As amended by Decision of the Committee established under Annex I, No. 1 of 2007 (23 April 2007).

between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment or under the Agreement on the European Economic Area are recognised under this Annex. Information on these conformity assessment bodies shall be made available on the website of the EFTA Secretariat.⁵

ARTICLE 7

Designating authorities

1. The Member States hereby undertake to ensure that their Designating authorities have the necessary power and competence to designate or withdraw designation, suspend or remove suspension of the recognised conformity assessment bodies defined in Article 6.
2. Designating authorities for each of the product sectors covered are listed in Appendix 1 to this Annex.

ARTICLE 8

Verification of compliance of conformity assessment bodies

1. Each Member State shall, in exceptional circumstances, have the right to contest the technical competence of the recognised conformity assessment bodies defined in Article 6. For this purpose, it shall submit in writing an objective and reasoned argument to the other Member States.
2. In the event of a disagreement between the Member States, confirmed by the Committee referred in Article 10, a verification of the technical competence of the conformity assessment body in question shall be undertaken in accordance with requirements jointly by the Member States, with the participation of the competent authorities concerned. The result of that verification shall be discussed by the Committee with a view to resolving the issue as soon as possible.
3. Each Member State shall ensure that the conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.
4. Unless otherwise decided by the Committee, the disputed body shall be suspended by the competent designating authority from the time that the disagreement has been established until agreement has been reached by the Committee.

⁵ <http://www.efta.int/mra/recognised-cabs>

ARTICLE 9

Implementation of the Annex

1. The Member States shall co-operate with a view to ensuring the satisfactory application of this Annex.
2. The designating authorities shall ascertain by appropriate means whether the conformity assessment bodies under their jurisdiction are observing the general principles of designation according to the applicable provisions referred to in Article 4.
3. The recognised conformity assessment bodies shall be required by the designating authorities to co-operate appropriately in order to ensure that the conformity assessment procedures provided for in Article 4 are applied in a consistent and correct manner.

ARTICLE 10

Committee

1. For the management and monitoring of the smooth functioning of this Annex, the Committee established in accordance with paragraph 3 of Article 43 of the Convention shall issue recommendations and take decisions in the circumstances provided for in this Annex. It may call on the assistance of experts, advisers or sectoral working groups. The Committee shall act by mutual agreement.
2. The Committee shall establish its own rules of procedure, which shall contain, *inter alia*, provisions on the convening of meetings, the appointment of the chairman and the chairman's term of office.
3. The Committee shall meet when necessary. Each Member State may request the convening of a meeting.
4. The Committee may decide to amend Paragraph 1 of Article 3 of this Annex and the Appendix thereto.
5. The Chairman of the Committee shall notify the Council without delay of all decisions of the Committee.

ARTICLE 11

Information exchange

1. The Member States shall exchange relevant information regarding implementation and application of this Annex.

2. Each Member State shall inform the other Member States of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Annex, and shall notify the other Member States in writing of the new provisions at least 60 days before their entry into force.

3. Where the legislation of one of the Member States stipulates that a specific item of information must be made available to the competent authority by a person established in its territory, that authority may also approach the competent authority of the other Member States or enter into direct contact with the manufacturer or, if appropriate, the latter's agent in the territory of the other Member States, in order to obtain that information.

4. Each Member State shall immediately notify the other Member States of safeguard measures taken in its territory.

ARTICLE 12

Dispute settlement

Each Member State may refer any dispute relating to the interpretation or application of this Annex to the Committee referred to in Article 10. The Committee shall endeavour to settle the dispute, and must be supplied with any information which may facilitate a thorough examination of the situation, with a view to finding an acceptable solution. For that purpose, the Committee shall consider every possible means of maintaining the smooth functioning of this Annex.

ARTICLE 13

Agreements with third States

The Member States hereby agree that mutual recognition agreements concluded by either Member State with a third State shall in no circumstances entail an obligation upon the other Member States in terms of the acceptance of manufacturer's declarations of conformity, as well as of reports, certificates, authorisations and marks issued by Conformity assessment bodies in that third State, unless there is an explicit agreement between the Member States.

ARTICLE 14

Suspension

Where a Member State establishes that another Member State is failing to comply with the conditions of this Annex or is subject to a suspension of application of parallel conditions under an agreement with the European Community, it may, after consulting the Committee, suspend the application of this Annex in full or in part.

ARTICLE 15

Acquired rights

The Member States shall continue to recognize reports, certificates, authorizations and conformity marks and manufacturers' declarations of conformity issued in accordance with this Annex, provided that:

- (a) the request for conformity evaluation was made before the notice of suspension of this Annex or notice of withdrawal from this Convention;
and
- (b) the reports, certificates, authorizations and conformity marks and manufacturer's declarations of conformity were issued before the suspension or withdrawal took effect.

APPENDIX 1

Designating Authorities⁶

This Appendix lists the Designating Authorities of the Member States for the following product sectors:

1. Machinery
2. Personal protective equipment
3. Toys
4. Medical devices
5. Gas appliances and boilers
6. Pressure vessels
7. Telecommunications terminal equipment
8. Equipment and protective systems intended for use in potentially explosive atmospheres
9. Electrical equipment and electromagnetic compatibility
10. Construction plant and equipment
11. Measuring instruments and prepackages
12. Motor vehicles
13. Agricultural and forestry tractors
14. Good laboratory practice (GLP)
15. Medicinal products GMP Inspection and Batch Certification
16. Construction products

⁶ The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

1. MACHINERY

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Labour and Social Inclusion

Switzerland: State Secretariat for Economic Affairs (SECO)

2. PERSONAL PROTECTIVE EQUIPMENT

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police;
For personal protective marine equipment:
Ministry of Trade and Industry

Switzerland: State Secretariat for Economic Affairs (SECO)

3. TOYS

EEA EFTA States

Iceland: Ministry of Business Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Children and Equality

Switzerland: Federal Office of Public Health

4. MEDICAL DEVICES

EEA EFTA States

Iceland: Ministry of Health and Social Security
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Health and Care Services

Switzerland: Swissmedic, Swiss Agency for Therapeutic Products

5. GAS APPLIANCES AND BOILERS

Provisions covered by Article 1 paragraph 1 (hot water boilers)

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Local Government and Regional Development

Switzerland: Federal Office for the Swiss Agency for the Environment

Provisions covered by Article 1 paragraph 2 (appliances burning gaseous fuel)

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police

Switzerland: State Secretariat for Economic Affairs (SECO)

6. PRESSURE VESSELS

Provisions covered by Article 1 paragraph 1 (transportable pressure equipments)

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police

Switzerland: Swiss Federal Roads Authority (FEDRO)
and Federal Office for transports

Provisions covered by Article 1 paragraph 2 (pressure equipments and simple pressure vessels)

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police

Switzerland: State Secretariat for Economic Affairs (SECO)

7. RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT

EEA EFTA States

Iceland: Ministry of Communications
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Transport and Communications

Switzerland: Federal Office for Communications

8. EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

EEA EFTA States

Iceland: Ministry of Social Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police

Switzerland: Federal Office of Energy

9. ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

EEA EFTA States

Iceland: Ministry of Business Affairs
Ministry of Transport and Communication
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Justice and the Police
Ministry of Transport and Communications (for EMC aspects of radio and telecommunications terminal equipment)

Switzerland: Federal Office of Energy
Federal Office of Communications (for EMC aspects of radio and telecommunications terminal equipment)

10. CONSTRUCTION PLANT AND EQUIPMENT

EEA EFTA States

Iceland: Ministry of Industry
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Local Government and Regional Development

Switzerland: Federal Office for the Swiss Agency for the Environment

11. MEASURING INSTRUMENTS AND PREPACKAGES

Provisions covered by Article 1 paragraph 1

EEA EFTA States

Iceland: Ministry of Commerce
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Trade and Industry

Switzerland: Federal Office of Metrology (METAS)

Provisions covered by Article 1 paragraph 2

EEA EFTA States

Iceland: Ministry of Business Affairs

Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Trade and Industry

Switzerland: Federal Office of Metrology (METAS)

12. MOTOR VEHICLES

EEA EFTA States

Iceland: Ministry of Communications
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Transport and Communications

Switzerland: Federal Roads Authority Office

13. AGRICULTURAL OR FORESTRY TRACTORS

EEA EFTA States

Iceland: Ministry of Communications
Liechtenstein: The Government of Liechtenstein
Norway: Ministry of Transport and Communications

Switzerland: Federal Roads Authority Office

14. GOOD LABORATORY PRACTICE (GLP)

For the purpose of this Sectoral Chapter, "Designating Authorities" means the official GLP Monitoring Authorities of the Member States.

EEA EFTA States

Iceland: Ministry of Business Affairs
Liechtenstein: The Government of Liechtenstein
Norway: Norwegian Accreditation

Switzerland: For environmental studies on all products
Federal Office for the Environment

For health studies on pharmaceutical products
Swissmedic, Swiss Agency for Therapeutic Products

For health studies on all products except pharmaceuticals:
Federal Office of Public Health

15. MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

For the purpose of this Chapter "Conformity Assessment Bodies" means the official GMP inspection services of each Member State.

EEA EFTA States

Iceland: Icelandic Medicines Control Agency

Liechtenstein: Amt für Gesundheit

Norway: Norwegian Medicines Agency

Switzerland: Swissmedic, Swiss Agency for Therapeutic Products,
(for all products for human and veterinary use – except immunological products for veterinary use)

Institute for Virology and Immunoprophylaxis
(for immunobiological products for veterinary use)

16. CONSTRUCTION PRODUCTS

EEA EFTA States

Iceland: Ministry of Business Affairs

Liechtenstein: The Government of Liechtenstein

Norway: National Office of Building Technology and Administration

Switzerland: Federal Office for Building and Logistics”