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VEDLEGG 10

Annex I. Mutual recognition in relation to conformity assessment (Art. 15)

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Article 1

Purpose

Switzerland and the EEA EFTA States hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the bodies listed in Appendix 1 and of the manufacturer's declarations of conformity certifying conformity to the requirements of each other in the areas covered by Article 3.

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 the bodies listed in Appendix 1 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.

The Committee referred to in Article 10 (hereinafter the «Committee») shall specify the cases in which paragraph 2 above shall apply.

Article 2

Definitions

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.

The definitions laid down by ISO/IEC Guide 2 (1996 edition) and in European standard EN 45020 (1993 edition) in relation to «General terms and their definitions concerning standardisation and related activities» may be used to establish the meaning of the general terms relating to conformity assessment contained in this Convention.

Article 3

Scope

This Annex covers the obligatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Appendix 1.

Appendix 1 defines the product sectors covered by this Annex. The Appendix is divided into sectoral chapters and these are subdivided in principle as follows: Section I legislative, regulatory and administrative provisions; Section II Conformity assessment bodies; Section III Designating authorities; Section IV special rules relating to the designation of conformity assessment bodies; Section V any additional provisions.

Appendix 2 sets out general rules applicable to the designation of conformity assessment bodies.

Article 4

Origin

This Annex shall cover products originating in the Member States [\[1\]](#), without prejudice to the special provisions laid down in Appendix 1.

In the event that such products are also covered by agreements on mutual recognition in relation to conformity assessment between Switzerland and the European Community, this Annex shall also cover products originating in the European Community.

Origin shall be determined in accordance with the rules governing non-preferential origin applicable in each of the Member States or, where appropriate, in the European Community. In the event of divergent rules, the rules of the Member State in which the goods will be placed on the market shall apply.

Proof of origin may be provided by presentation of a certificate of origin. This certificate shall not be required in the case of imports covered by a movement certificate EUR 1 or by an invoice declaration issued in accordance with Annex A to this Convention, provided

that that document indicates as the country of origin one of the Member States or the European Community.

Article 5

Conformity assessment bodies

The Member States hereby recognise that the bodies listed in Appendix 1 fulfil the conditions of eligibility to assess conformity.

Article 6

Designating authorities

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 bodies listed in Appendix 1. For the designation of Conformity assessment bodies, the authorities shall observe the general principles for designation set out in Appendix 2, subject to the provisions of the respective Section IV in Appendix 1. These authorities shall observe the same principles when withdrawing designation, suspending or removing suspension.

The decision to include Conformity assessment bodies in or remove them from Appendix 1 shall be taken on a proposal from one of the Member States in accordance with the procedure set out in Article 11.

In the event of the suspension or withdrawal of the suspension by a Designating authority of a conformity assessment body listed in Appendix 1 under its jurisdiction, the Member State concerned shall immediately notify the other Member States and the Chairman of the Committee. Reports, certificates, authorisations and conformity marks issued by the Conformity assessment body while under suspension need not be recognised by the Member States.

Article 7

Verification of designation procedures

The Member States shall exchange information concerning the procedures used to ensure that the Conformity assessment bodies under their jurisdiction listed in Appendix 1 comply with the general principles of designation outlined in Appendix 2 subject to the provisions of the respective Section IV in Appendix 1.

The Member States shall compare methods used to verify conformity of the bodies with the general principles of designation outlined in Appendix 2, subject to the provisions of the respective Section IV in Appendix 1. Existing systems for the accreditation of Conformity assessment bodies in the Member States may be used for the purpose of such comparisons.

Verification shall be carried out in accordance with the procedure implemented by the Committee.

Article 8

Verification of compliance of conformity assessment bodies

Each Member State shall, in exceptional circumstances, have the right to contest the technical competence of the Conformity assessment bodies proposed by the other Member States or listed in Appendix 1 under the jurisdiction of the other Member States. For this purpose, it shall submit in writing an objective and reasoned argument to the other Member States and to the Chairman of the Committee.

In the event of a disagreement between the Member States, confirmed in the Committee, 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 in the Committee with a view to resolving the issue as soon as possible.

Each Member State shall ensure that the Conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.

Unless otherwise decided by the Committee, the disputed body shall be suspended by the competent Designating authority from the time disagreement has been established until agreement has been reached in the Committee.

Article 9

Implementation of the Annex

The Member States shall co-operate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Appendix 1.

The Designating authorities shall ascertain by appropriate means whether the Conformity assessment bodies under their jurisdiction listed in Appendix 1 are observing the general principles of designation listed in Appendix 2, subject to the provisions listed in the respective Section IV in Appendix 1.

The Conformity assessment bodies listed in Appendix 1 shall co-operate in an appropriate way in the framework of the co-ordination and comparison work conducted by the Member States in respect of the sectors covered by Appendix 1 in order to ensure that the conformity assessment procedures provided for in the laws and regulations covered by this Annex are applied in a consistent manner.

Article 10

Committee

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.

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.

The Committee shall meet as and when necessary and at least once a year. Each Member State may request the convening of a meeting.

The Committee may consider any matter related to this Annex. In particular, it shall be responsible for:

- the inclusion of Conformity assessment bodies in Appendix 1;
- the removal of Conformity assessment bodies from Appendix 1;
- drawing up the procedure for carrying out the verifications provided for in Article 7;
- drawing up the procedure for carrying out the verifications provided for in Article 8;
- examining any legislative, regulatory and administrative provisions notified by one of the Member States pursuant to Article 12 in order to assess their repercussions on the Annex and to amend the appropriate sections in Appendix 1.

The Committee may, on a proposal from one of the Member States, modify the Appendices to this Annex.

The Chairman of the Committee shall notify the Council without delay of all decisions of the Committee.

Article 11

Inclusion of Conformity assessment bodies in Appendix 1 and their removal

The Committee shall decide to include a Conformity assessment body in Appendix 1 or to remove it from Appendix 1 in accordance with the following procedure:

- a Member State wishing to add to or remove from Appendix 1 any Conformity assessment body shall notify the Chairman of the Committee and the other Member States of the proposal for a decision to that effect, adding the appropriate information to its request;
- if the other Member States agree to the proposal or raise no objection within 60 days of the notification of the proposal, the proposed decision shall be adopted by the Committee;
- if another Member State raises objections within that 60-day period, the procedure provided for in paragraph 2 of Article 8 shall be applied;
- the Chairman of the Committee shall notify the Member States without delay of all decisions of the Committee. They shall take effect from the date fixed in the decision;
- if the Committee decides to include a Conformity assessment body in Appendix 1, the Member States shall recognise the reports, certificates, authorisations and conformity marks issued by that body with effect from the date of entry into force of the decision. If the Committee decides to remove a body from Appendix 1, the Member States shall recognise the reports, certificates, authorisations and conformity marks issued by that body until the date on which that decision takes effect.

Article 12

Information exchange

The Member States shall exchange all relevant information regarding implementation and application of the legislative, regulatory and administrative provisions listed in Appendix 1.

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 of the new provisions at least 60 days before their entry into force.

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.

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

Article 13

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 14

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. The Committee may modify Article 4 of this Annex in order to take account of such agreements with third States.

Article 15

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 Appendix 1 in full or in part.

Article 16

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:

the request for conformity evaluation to be started was made before the notice of suspension of this Annex or notice of withdrawal from this Convention; and

the reports, certificates, authorizations and conformity marks and manufacturer's declarations of conformity were issued before the suspension or withdrawal took effect.

Appendix 1

Product sectors

This Appendix is divided up into the following Chapters by sector:

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

Chapter 1

Machinery

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1) (EEA Agreement, Annex II, Chapter XXIV, point 1 as replaced by Decision No 94/1999)
Switzerland	Federal Law of 19 March 1976 on the safety of technical installations and equipment (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Ordinance of 12 June 1995 on the safety of technical installations and equipment (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Labour and Government Administration
Switzerland:	Federal Office for Economic Development and Employment

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex VII to Directive 98/37/EC (EEA Agreement, Annex II, Chapter XXIV, point 1 as replaced by Decision No 94/1999).

Section V

Supplementary provisions

Second-hand machinery

The legislative, regulatory and administrative provisions listed in Section I shall not apply to second-hand machinery.

The principle contained in paragraph 2 of Article 1 of the Annex shall apply, however, to machinery legally placed on the market and/or put into service in one of the Member States and exported as second-hand machinery to the market of another Member State.

The other provisions relating to second-hand machinery, e.g. those relating to safety in the place of work in force in the importing state, shall remain applicable.

Chapter 2

Personal protective equipment

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC) (EEA Agreement, Annex II, Chapter XXII, point 1), as last amended by Directive 96/58/EC of the European Parliament and of the Council of 3 September 1996 (OJ L 236, 18.9.1996, p. 44) (EEA Agreement, Annex II, Chapter XXII, point 1, third indent as added by Decision No 68/97)
	Ordinance of 12 June 1995 on the safety of technical installations and equipment (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	The Government of Liechtenstein The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.
Norway:	Ministry of Labour and Government Administration; For personal protective marine equipment: Ministry of Trade and Industry

*Section IV***Special rules relating to the designation of conformity assessment bodies**

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex V to Directive 89/686/EEC (EEA Agreement, Annex II, Chapter XXII, point 1).

Chapter 3**Toys***Section I***Legislative, regulatory and administrative provisions****Provisions covered by Article 1 paragraph 1**

EEA EFTA States	Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (88/378/EEC) (OJ L 187, 16.7.1988, p. 1) (EEA Agreement, Chapter XXIII, point 1), as subsequently amended and incorporated into the EEA Agreement
Switzerland	Federal Law of 9 October 1992 on foodstuffs and commodities (RS 817.0), as subsequently amended
	Ordinance of 1 March 1995 on commodities (RS 817.04), as subsequently amended
	Ordinance of 26 May 1995 on the safety of toys (RS 817.044.1), as subsequently amended

*Section II***Conformity assessment bodies**

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

*Section III***Designating authorities****EEA EFTA States:**

Iceland:	Ministry of Industry and Commerce
Liechtenstein:	The Government of Liechtenstein The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.
Norway:	Ministry of Children and Family Affairs
Switzerland:	Swiss Federal Office of Public Health

Section IV

Special rules relating TO the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex III to Directive 88/378/EEC (EEA Agreement, Chapter XXIII, point 1).

Section V

Supplementary provisions

Information concerning the certificate and the technical file<?17641

In accordance with Article 10(4) of Directive 88/378/EEC (EEA Agreement, Chapter XXIII, point 1), the authorities listed in Section III may obtain on request a copy of the certificate and, on reasoned request, a copy of the technical file and the reports on the examinations and tests carried out.

2. Notification of grounds for refusal by approved bodies

In accordance with Article 10(5) of Directive 88/378/EEC (EEA Agreement, Chapter XXIII, point 1), the Swiss bodies shall inform the Swiss Federal Office of Public Health when refusing to issue an EC type-examination certificate. The Federal Office shall likewise notify the EEA EFTA States thereof.

Chapter 4

Medical devices

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) (EEA Agreement, Annex II, Chapter X, point 7), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1) (EEA Agreement, Annex II, Chapter X, point 7, second indent as added by Decision No 7/94)
	Council Directive of 14 June 1993 concerning medical devices (93/42/EEC) (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision 7/94), as last amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 (OJ L 331, 7.12.1998, p.1.) (EEA Agreement, Annex II, Chapter XXX, point 2 as inserted by Decision No 166/99)
Switzerland	Federal Law of 19 March 1976 on the safety of technical installations and equipment (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Federal Law of 24 June 1902 concerning the electrical weak and heavy

	current installations (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901)
	Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 18 June 1993 (RO 1993 3149)
	Federal Law of 22 March 1991 on radiation protection (RO 1994 1933)
	Ordinance of 24 January 1996 on medical devices (RO 1996 987), as last amended on 17 June 1996 (RO 1996 1868)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Health and Social Security
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Health and Social Affairs
Switzerland:	Swiss Federal Office of Public Health

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 to the Annex and those in Annex XI to Directive 93/42/EEC (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision 7/94), in respect of the bodies designated under that Directive, and in Annex VIII to Directive 90/385/EEC (EEA Agreement, Annex II, Chapter X, point 7), in respect of the bodies designated thereunder.

Section V

Supplementary provisions

Registration of the person responsible for placing devices on the market

Any manufacturer who places on the market of one of the Member States the medical devices referred to in Article 14 of Directive 93/42/EEC (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision 7/94) shall inform the competent authorities of the Member State in which he has his registered place of business of the particulars

referred to in that Article. The Member States shall mutually 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 Member States.

2. Labelling of medical devices

Manufacturers of the Member States shall indicate their name or trade name and address on the label of medical devices as specified in Annex 1, point 13.3(a) to Directive 93/42/EEC (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision 7/94). 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 Member States on the label, outer packaging or instructions for use.

3. Information exchanges

In accordance with Article 9 of the Annex, the Member States shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC (EEA Agreement, Annex II, Chapter X, point 7) and in Article 10 of Directive 93/42/EEC (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision 7/94).

Chapter 5

Gas appliances and boilers

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 1

EEA EFTA States	Council Directive of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (92/42/EEC) (OJ L 167, 22.06.1992, p. 17) (EEA Agreement, Annex II, Chapter V, point 3 as inserted by Decision No 7/94), as subsequently amended and incorporated into the EEA Agreement
Switzerland	Ordinance of 16 December 1985 on Air Pollution Control (OAPC) (Annexes 3 and 4) (RS 814.318.142.1), as subsequently amended

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (90/396/EEC) (EEA Agreement, Annex II, Chapter V, point 2), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1) (EEA Agreement, Annex II, Chapter V, point 2, first indent as added by Decision 7/94)
Switzerland	Federal Law of 19 March 1976 on the safety of technical installations and equipment (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Ordinance of 12 June 1995 on the safety of technical installations and equipment (RO 1995 2770), as last amended on 17 June 1996 (RO

	1996 1867)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

Provisions covered by Article 1 paragraph 1

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	<p>For hot water boilers:</p> <p>Ministry of Local Government and Regional Development;</p> <p>For gas appliances/burning gaseous fuels:</p> <p>Ministry of Labour and Government Administration</p>
Switzerland:	Federal Office of Environment, Forests and Landscape

Provisions covered by Article 1 paragraph 2

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	<p>For hot water boilers:</p> <p>Ministry of Local Government and Regional Development;</p> <p>For gas appliances/burning gaseous fuels:</p> <p>Ministry of Labour and Government Administration</p>
Switzerland:	Federal Office for Economic Development and Employment

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 to the Annex and those in Annex V to Directive 92/42/EEC (EEA Agreement, Annex II, Chapter V, point 3 as inserted by Decision No 7/94), in respect of the bodies designated under that Directive, and in Annex V to Directive 90/396/EEC (EEA Agreement, Annex II, Chapter V, point 2), in respect of the bodies designated thereunder.

Chapter 6

Pressure vessels

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 1

EEA EFTA States	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders (84/525/EEC) (OJ L 300, 19.11.1984, p.1) (EEA Agreement, Annex II, Chapter VIII, point 3), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders (84/526/EEC) (OJ L 300, 19.11.1984, p.20) (EEA Agreement, Annex II, Chapter VIII, point 4), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders (84/527/EEC) (OJ L 300, 19.11.1984, p.48) (EEA Agreement, Annex II, Chapter VIII, point 5), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 25 June 1987 on the approximation of the laws of the Member States relating to simple pressure vessels (87/404/EEC) (OJ L 220, 8.8.1987, p.48) (EEA Agreement, Annex II, Chapter VIII, point 6), as subsequently amended and incorporated into the EEA Agreement
	Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1) (EEA Agreement, Annex II, Chapter VIII, point 2, fourth indent as added by Decision No 82/98), as subsequently amended and incorporated into the EEA Agreement
Switzerland	Directives 84/525/EEC, 84/526/EEC and 84/527/EEC: no related legislation
	Directive 87/404/EEC:
	Federal Law of 20 March 1981 on accident insurance (RS 832.20), as subsequently amended
	Ordinance of 19 March 1938 on installation and operation of pressure

	vessels (RS 832.312.12), as subsequently amended
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Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	The Government of Liechtenstein The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.
Norway:	Ministry of Labour and Government Administration
Switzerland:	Federal Office for Economic Development and Employment

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall comply with the general principles contained in Appendix 2 to the Annex and those in Annex III to Directive 87/404/EEC (EEA Agreement, Annex II, Chapter VIII, point 6).

Section V

Supplementary provisions

Recognition of certificates by Switzerland

Where the provisions of Swiss legislation listed in Section I lay down a conformity assessment procedure, Switzerland shall recognise certificates issued by a body designated by the EEA EFTA States listed in Section II which certifies that the product conforms to standard EN 286.

Chapter 7

Telecommunications terminal equipment

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA	Directive 98/13/EC of the European Parliament and of the Council of
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States	12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity (OJ L 074, 12.3.1998, p. 1) (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99)
	Commission Decision of 9 July 1997 on a common technical regulation for terminal equipment to be connected to public circuit switched data networks and ONP leased circuits using a CCITT Recommendation X.21 type interface (97/544/EC) (OJ L 223, 13.8.1997, p. 18) (EEA Agreement, Annex II, Chapter XVIII, point 4p as inserted by Decision No 61/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for Data Terminal Equipment (DTE) to connect to Packet Switched Public Data Networks (PSPDNs) offering CCITT Recommendation X.25 interfaces (97/545/EC) (OJ L 223, 13.8.1997, p. 21) (EEA Agreement, Annex II, Chapter XVIII, point 4q as inserted by Decision No 61/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the general terminal attachment requirements for digital enhanced cordless telecommunications (DECT) (edition 2) (97/523/EC) (OJ L 215, 7.8.1997, p. 48) (EEA Agreement, Annex II, Chapter XVIII, point 4zb as inserted by Decision No 116/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the telephony application requirements for digital enhanced cordless telecommunications (DECT) (edition 2) (97/524/EC) (OJ L 215, 07.08.1997, p. 50) (EEA Agreement, Annex II, Chapter XVIII, point 4zc as inserted by Decision No 116/98)
	Commission Decision of 28 November 1995 on a common technical regulation for attachment requirements for terminal equipment for digital European cordless telecommunications (DECT), public access profile (PAP) applications (95/525/EC) (OJ L 300, 13.12.1995, p. 35) (EEA Agreement, Annex II, Chapter XVIII, point 4k as inserted by Decision No 3/97) In the meantime this Commission Decision has been repealed. This will be taken into account at the next update of this Chapter.
	Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital unstructured ONP leased lines (Amendment 1) (97/520/EC) (OJ L 215, 07.08.1997, p. 41) (EEA Agreement, Annex II, Chapter XVIII, point 4y as inserted by Decision No 115/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital structured ONP leased lines (97/521/EC) (OJ L 215, 07.08.1997, p. 44) (EEA Agreement, Annex II, Chapter XVIII, point z as inserted by Decision No 115/98)
	Commission Decision of 9 July 1997 on a common technical regulation

	for the attachment requirements for the terminal equipment interface for connection to 64 kbit/s digital unrestricted ONP leased lines (Amendment 1) (97/522/EC) (OJ L 215, 07.08.1997, p. 46) (EEA Agreement, Annex II, Chapter XVIII, point 4za as inserted by Decision No 115/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to Open Network Provision (ONP) two-wire analogue leased lines (97/486/EC) (OJ L 208, 02.08.1997, p. 44) (EEA Agreement, Annex II, Chapter XVIII, point 4r as inserted by Decision No 62/98)
	Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to Open Network Provision (ONP) four-wire analogue leased lines (97/487/EC) (OJ L 208, 02.08.1997, p. 47) (EEA Agreement, Annex II, Chapter XVIII, point 4s as inserted by Decision No 62/98)
	Commission Decision of 28 November 1995 on a common technical regulation for Integrated Services Digital Network (ISDN)+ Telephony 3.1 kHz teleservice, attachment requirements for handset terminals (95/526/EC) (OJ L 300, 13.12.1995, p.38) (EEA Agreement, Annex II, Chapter XVIII, point 4l as inserted by Decision No 3/97) In the meantime this Commission Decision has been repealed. This will be taken into account at the next update of this Chapter.
	Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment for digital enhanced cordless telecommunications (DECT) generic access profile (GAP) applications (97/525/EC) (OJ L 215, 07.08.1997, p. 52) (EEA Agreement, Annex II, Chapter XVIII, point 4zd as inserted by Decision No 116/98)
	Commission Decision of 19 September 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 34 Mbit/s digital unstructured and structured leased lines (97/639/EC) (OJ L 271, 03.10.1997, p. 16) (EEA Agreement, Annex II, Chapter XVIII, point 4t as inserted by Decision No 62/98)
	Commission Decision of 31 October 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 140 Mbit/s digital unstructured and structured leased lines (97/751/EC) (OJ L 305, 08.11.1997, p. 66) (EEA Agreement, Annex II, Chapter XVIII, point 4zh as inserted by Decision No 65/99)
	Commission Decision of 17 June 1998 on a common technical Regulation for the pan-European integrated services digital (ISDN) basic access (Amendment 1) (notified under document number C(1998) 1607) (98/515/EC) (OJ L 232, 19.08.98, p.7) (EEA Agreement, Annex II, Chapter XVIII, point 4zi as inserted by Decision No 107/99)
	Commission Decision of 17 June 1998 on a common technical

	Regulation for the pan-European integrated services digital network (ISDN) primary rate access (Amendment 1) (notified under document number C(1998) 1613) (98/520/EC) (OJ L 232, 19.08.98, p.19) (EEA Agreement, Annex II, Chapter XVIII, point 4zn as inserted by Decision No 107/99)
	Commission Decision of 17 June 1998 on a common technical Regulation for public land-based enhanced radio message system (ERMES) receiver requirements (second edition) (notified under document number C(1998) 1615) (98/522/EC) (OJ L 232, 19.08.98, p.25) (EEA Agreement, Annex II, Chapter XVIII, point 4zp as inserted by Decision No 109/99)
	Council Decision of 20 July 1998 on a common technical Regulation for the attachment requirements for connection to the analogue public switched telephone networks (PSTNs) of terminal equipment (excluding terminal equipment supporting the voice telephony justified case service) in which network addressing, if provided, is by means of dual tone multi-frequency (DTMF) signalling (98/482/EC) (OJ L 216, 04.08.98, p.8) (EEA Agreement, Annex II, Chapter XVIII, point 4zu as inserted by Decision No 111/99)
	Commission Decision of 4 September 1998 on a common technical regulation for telephony application requirements for public pan-European cellular digital land-based mobile communications, phase II (edition 2) (notified under document number C(1998) 2561) (98/542/EC) (OJ L 254, 16.09.98, p.28) (EEA Agreement, Annex II, Chapter XVIII, point 4zs as inserted by Decision No 110/99)
	Commission Decision of 3 September 1998 on a common technical Regulation for the terrestrial flight telecommunications system (TFTS) (notified under document number C(1998)2378) (98/535/EC) (OJ L 251, 11.09.98, p.36) (EEA Agreement, Annex II, Chapter XVIII, point 4zze as inserted by Decision No 29/2000)
	Commission Decision of 17 June 1998 on a common technical Regulation for low data rate land mobile satellite earth stations (LMES) operating in the 11/12/14 GHz frequency bands (notified under document number C(1998) 1608) (98/516/EC) (OJ L 232, 19.08.1998, p.10) (EEA Agreement, Annex II, Chapter XVIII, point 4zj as inserted by Decision No 108/99)
	Commission Decision of 17 June 1998 on a common technical Regulation for satellite news gathering transportable earth stations (SNG TES) operating in the 11-12/13-14 GHz frequency bands (notified under document number C(1998) 1609) (98/517/EC) (OJ L 232, 19.08.1998, p. 12) (EEA Agreement, Annex II, Chapter XVIII, point 4zk as inserted by Decision No 108/99)
	Commission Decision of 17 June 1998 on a common technical Regulation for ISDN packet mode using ISDN primary rate access (notified under document number C(1998) 1610) (98/518/EC) (OJ L 232, 19. 08.1998, p. 14) (EEA Agreement, Annex II, Chapter XVIII, point 4zl as inserted by Decision No 107/99)

	Commission Decision of 17 June 1998 on a common technical Regulation for very small aperture terminals (VSATs) operating in the 11/12/14 GHz frequency bands (notified under document number C(1998) 1612) (98/519/EC) (OJ L 232, 19.08.98, p.17) (EEA Agreement, Annex II, Chapter XVIII, point 4zm as inserted by Decision No 108/99)
	Commission Decision of 17 June 1998 on a common technical Regulation for ISDN packet mode using ISDN basic access (notified under document number C(1998) 1614) (98/521/EC) (OJ L 232, 19.08.98, p.22) (EEA Agreement, Annex II, Chapter XVIII, point 4zo as inserted by Decision No 107/99)
	Commission Decision of 3 September 1998 on a common technical Regulation for Satellite Personal Communications Networks (S-PCN) Mobile Earth Stations (MESs), including handheld earth stations, for S-PCN operating in the 1,6/2,4 GHz frequency bands under the Mobile Satellite Service (MSS) (notified under document number C(1998) 2375) (98/533/EC) (OJ L 247, 05.09.98, p.11) (EEA Agreement, Annex II, Chapter XVIII, point 4zq as inserted by Decision No 108/99)
	Commission Decision of 3 September 1998 on a common technical Regulation for Satellite Personal Communications Networks (S-PCN) Mobile Earth Stations (MESs), including handheld earth stations, for S-PCN operating in the 2,0 GHz frequency bands under the Mobile Satellite Service (MSS) (notified under document number C(1998) 2376) (98/534/EC) (OJ L 247, 05.09.98, p.13) (EEA Agreement, Annex II, Chapter XVIII, point 4zr as inserted by Decision No 108/99)
	Commission Decision of 4 September 1998 on a common technical regulation for the telephony application requirements for mobile stations intended to be used with phase II public digital cellular telecommunications networks operating in the DCS 1800 band (edition 2) (notified under document number C(1998) 2562) (98/543/EC) (OJ L 254, 16.09.98, p.32) (EEA Agreement, Annex II, Chapter XVIII, point 4zt as inserted by Decision No 110/99)
	Commission Decision of 16 September 1998 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications, Phase II (Edition 2) (notified under document number C(1998) 2720) (98/574/EC) (OJ L 278, 15.10.98, p.30) (EEA Agreement, Annex II, Chapter XVIII, point 4zv as inserted by Decision No 112/99)
	Commission Decision of 16 September 1998 on a common technical regulation for the general attachment requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the GSM 1800 band (Edition 2) (notified under document number C(1998) 2721) (98/575/EC) (OJ L 278, 15.10.98, p.35) (EEA Agreement, Annex II, Chapter XVIII, point 4zw as inserted by Decision No 112/99)
	Commission Decision of 16 September 1998 on a common technical regulation for the attachment requirements for terminal equipment to connect to public switched telephone networks (PSTNs) and

	incorporating an analogue handset function (notified under document number C(1998) 2722) (98/576/EC) (OJ L 278, 15.10.98, p.40) (EEA Agreement, Annex II, Chapter XVIII, point 4zx as inserted by Decision No 112/99)
	Commission Decision of 16 September 1998 on a common technical regulation for very small aperture terminals (VSATs) satellite earth stations operating in the 4 GHz and 6 GHz frequency bands (notified under document number C(1998) 2723) (98/577/EC) (OJ L 278, 15.10.98, p.43) (EEA Agreement, Annex II, Chapter XVIII, point 4zy as inserted by Decision No 112/99)
	Commission Decision of 16 September 1998 on a common technical regulation for low data rate land mobile satellite earth stations (LMES) operating in the 1,5/1,6 GHz frequency bands (notified under document number C(1998) 2724) (98/578/EC) (OJ L 278, 15.10.98, p.46) (EEA Agreement, Annex II, Chapter XVIII, point 4zz as inserted by Decision No 112/99)
	Commission Decision of 30 November 1998 on a common technical Regulation for land mobile satellite earth stations (LMES) operating in the 1,5/1,6 GHz frequency bands (notified under document number C(1998) 3695) (98/734/EC) (OJ L 351, 29.12.1998, p.37) (EEA Agreement, Annex II, Chapter XVIII, point 4zza as inserted by Decision No 164/99)
Switzerland	Federal Law of 30 April 1997 on Telecommunications (LTC; RO 1997 2187)
	Ordinance of the Federal Council of 6 October 1997 on Telecommunications Equipment (OIT; RO 1997 2853)
	Ordinance of the Federal Office for Communications (OFCOM) of 9 December 1997 on Telecommunications Equipment; (RO 1998 485)
	Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 1998 488), as last amended on 9 March 1999 (RO 1999 1191)
	Technical standards declared to be obligatory:
	10.1 based on CTR1 (97/544/EC)
	10.2 based on CTR2 edition 2 (97/545/EC)
	10.3 based on CTR3 amendment 1(98/515/EC)
	10.4 based on CTR4 amendment 1 (98/520/EC)
	10.6 based on CTR6 edition 2 (97/523/EC)
	10.7 based on CTR7 edition 2 (98/522/EC)
	10.8 based on CTR8 (95/526/EC)
	10.10 based on CTR10 edition 2 (97/524/EC)
	10.11 based on CTR11 (95/525/EC)
	10.12 based on CTR12 amendment 1 (97/520/EC)
	10.13 based on CTR13 (97/521/EC)
	10.14 based on CTR14 amendment 1 (97/522/EC)

	10.15 based on CTR15 (97/486/EC)
	10.17 based on CTR17 (97/487/EC)
	10.19 based on CTR19 edition 2 (98/574/EC)
	10.20 based on CTR20 edition 2 (98/542/EC)
	10.21 based on CTR21 (98/482/EC)
	10.22 based on CTR22 (97/525/EC)
	10.23 based on CTR23 (98/535/EC)
	10.24 based on CTR24 (97/639/EC)
	10.25 based on CTR25 (97/751/EC)
	10.26 based on CTR26 (98/578/EC)
	10.27 based on CTR27 (98/516/EC)
	10.28 based on CTR28 (98/519/EC)
	10.30 based on CTR30 (98/517/EC)
	10.31 based on CTR31 edition 2 (98/575/EC)
	10.32 based on CTR32 edition 2 (98/543/EC)
	10.33 based on CTR33 (98/521/EC)
	10.34 based on CTR34 (98/518/EC)
	10.38 based on CTR38 (98/576/EC)
	10.41 based on CTR41 (98/533/EC)
	10.42 based on CTR42 (98/534/EC)
	10.43 based on CTR43 (98/577/EC)
	10.44 based on CTR44 (98/734/EC)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Transport and Communication
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Transport and Communications
Switzerland:	Federal Office for Communications

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex V to Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99).

Section V

Supplementary provisions

Administrative Decision

The Member States shall mutually recognise the administrative Decision (Art. 11(6), Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99), Art. 31 of the Federal Law of 30 April 1997 on telecommunications (LTC; RO 1977 2187) and Art. 8ff of the Ordinance of the Federal Council of 6 October 1997 on telecommunications equipment (OIT; RO 1997 2853)) approving connection of the terminal equipment concerned to the public telecommunications network.[\[2\]](#)

2. Notification of the manufacturer's or supplier's declaration

When placing on the market of one of the Member States the telecommunications equipment referred to in Article 3(1) of Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99), the person responsible shall notify the manufacturer's or supplier's declaration to the notified body of the Member State where the equipment is first placed on the market.

3. Test laboratories

Each Member State shall notify the other Member States of the test laboratories designated to carry out the tests pertaining to the procedures referred to in Article 10 of Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99). The criteria fixed by the relevant harmonised standards for the designation of such laboratories shall be applied.

4. Exchanges of information between Conformity assessment bodies

4.1 In accordance with Annex I, point 7f of Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99), the Conformity assessment bodies listed in Section II of this Appendix shall make available to the other bodies the relevant information concerning type-examination certificates issued and withdrawn.

4.2 In accordance with Annex III, point 6, and Annex IV, point 6 of Directive 98/13/EC (EEA Agreement, Annex II, Chapter XVIII, point 4zg, as inserted by Decision No 32/99), the Conformity assessment bodies listed in Section II of this Appendix shall make available to the other bodies the relevant information concerning quality system approvals issued and withdrawn.

Chapter 8

Equipment and protective systems intended for use in potentially explosive atmospheres

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Directive of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC) (OJ L 100, 19.04.1994, p.1) (EEA Agreement, Annex II, Chapter X, point 7a as inserted by Decision No 14/94)
	Council Directive of 18 December 1975 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres (76/117/EEC) (OJ L 24, 30.01.1976, p. 45) (EEA Agreement, Annex II, Chapter X, point 2)
	Council Directive of 6 February 1979 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection (79/196/EEC) (EEA Agreement, Annex II, Chapter X, point 3), as last amended by Commission Directive 97/53/EC of 11 September 1997 (OJ L 257, 20.09.1997, p. 27) (EEA Agreement, Annex II, Chapter X, point 3, fifth indent as added by Decision No 57/98)
	Council Directive of 15 February 1982 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to firedamp (82/130/EEC) (EEA Agreement, Annex II, Chapter X, point 4), as last amended by Commission Directive 98/65/EC of 3 September 1998 (OJ L 257, 19/09/1998, p. 29) (EEA Agreement, Annex II, Chapter X, point 4, fourth indent as added by Decision No 48/99)
Switzerland	Federal Law of 24 June 1902 concerning the electrical weak an heavy current installations (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901)
	Ordinance of 2 March 1998 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 1998 963)
	Federal Law of 19 March 1976 on the safety of technical installations and equipment (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Ordinance of 12 June 1995 on the safety of technical installations and equipment (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Social Affairs
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Labour and Government Administration
Switzerland:	Swiss Federal Office of Energy

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex XI to Directive 94/9/EC (EEA Agreement, Annex II, Chapter X, point 7a as inserted by Decision No 14/94).

Section V

Supplementary provisions

Information exchange

The Conformity assessment bodies listed in Section II shall provide the EEA EFTA States, the competent Swiss authorities and/or the other Conformity assessment bodies with the information provided for in Article 9(2) of Directive 76/117/EEC (EEA Agreement, Annex II, Chapter X, point 2).

2. Technical documentation

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing products on the market to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Member States for a period of at least ten years after the last date of manufacture of the product.

The Member States hereby undertake to forward all relevant technical documents at the request of the authorities of the other Member States.

Chapter 9

Electrical equipment and Electromagnetic Compatibility

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (73/23/EEC) (EEA Agreement, Annex II, Chapter X, point 1), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p. 1) (EEA Agreement, Annex II, Chapter X, point 1, first indent as added by Decision No 7/94)
	Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC) (EEA Agreement, Annex II, Chapter X, point 6), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p. 1) (EEA Agreement, Annex II, Chapter X, point 6, second indent as added by Decision No 7/94)
Switzerland	Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901)
	Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185)
	Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 5 December 1995 (RO 1995 1024)
	Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016)
	Ordinance of 9 April 1997 on electromagnetic compatibility (RO 1997 1008)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Industry and Commerce, Ministry of Transport and Communication
Liechtenstein:	The Government of Liechtenstein The Government of Liechtenstein is entitled to appoint appropriate

	specific national administration bodies as designators of conformity assessment bodies at a future date.
Norway:	Ministry of Labour and Government Administration
Switzerland:	Swiss Federal Office of Energy

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex II to Directive 89/336/EEC (EEA Agreement, Annex II, Chapter X, point 6).

Section V

Supplementary provisions

Technical documentation

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing products on the market to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Member States for a period of at least ten years after the last date of manufacture of the product.

The Member States hereby undertake to forward all relevant documents at the request of the authorities of the other Member States.

2. Standardisation bodies

In accordance with Article 11 of Directive 73/23/EEC (EEA Agreement, Annex II, Chapter X, point 1), the Member States shall notify each other of the bodies responsible for drawing up the standards referred to in Article 5 of this Directive.

3. Competent bodies

The Member States shall inform each other of and mutually recognise the bodies made responsible for drawing up technical reports and/or certificates pursuant to Article 8(2) of Directive 73/23/EEC (EEA Agreement, Annex II, Chapter X, point 1) and Article 10(2) of Directive 89/336/EEC (EEA Agreement, Annex II, Chapter X, point 6).

4. Special measures

In accordance with Article 6(2) of Directive 89/336/EEC (EEA Agreement, Annex II, Chapter X, point 6), each Member State shall inform the other Member States of the special measures taken pursuant to paragraph 1 of that Article.

5. Competent authorities

In accordance with Article 10(6) of Directive 89/336/EEC (EEA Agreement, Annex II, Chapter X, point 6), each Member State shall notify the other Member States of the competent authorities referred to in that Article.

Chapter 10

Construction plant and equipment

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 1

EEA EFTA States	Council Directive of 19 December 1978 on the approximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment (79/113/EEC) (OJ L 33, 08.02.1979, p. 15) (EEA Agreement, Annex II, Chapter VI, point 1), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for construction plant and equipment (84/532/EEC) (OJ L 300, 19.11.1984, p. 111) (EEA Agreement, Annex II, Chapter VI, point 2), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of compressors (84/533/EEC) (OJ L 300, 19.11.1984, p. 123) (EEA Agreement, Annex II, Chapter VI, point 3), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes (84/534/EEC) (OJ L 300, 19.11.1984, p. 130) (EEA Agreement, Annex II, Chapter VI, point 4), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of welding generators (84/535/EEC) (OJ L 300, 19.11.1984, p. 142) (EEA Agreement, Annex II, Chapter VI, point 5), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of power generators (84/536/EEC) (OJ L 300, 19.11.1984, p. 149) (EEA Agreement, Annex II, Chapter VI, point 6), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of powered hand-held concrete-breakers and picks (84/537/EEC) (OJ L 300, 19.11.1984, p. 156) (EEA Agreement, Annex II, Chapter VI, point 7), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 22 December 1986 on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders (86/662/EEC) (OJ L 384, 31.1.1986, p. 1) (EEA Agreement, Annex II, Chapter VI, point 10), as subsequently amended and incorporated into the EEA Agreement

	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers (84/538/EEC) (OJ L 300, 19.11.1984, p. 171) (EEA Agreement, Annex II, Chapter VII, point 1), as subsequently amended and incorporated into the EEA Agreement
Switzerland	No legislation

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Industry and Commerce
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Local Government and Regional Development
Switzerland:	Federal Office of Environment, Forests and Landscape

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex II to Council Directive 84/532/EEC (EEA Agreement, Annex II, Chapter VI, point 2), as amended by Council Directive 88/665/EEC (EEA Agreement, Annex II, Chapter VI, point 2, first indent).

Chapter 11

Measuring Instruments and prepackages

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 1

EEA EFTA States	Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain (71/347/EEC) (OJ L 239, 25.10.1971, p. 1) (EEA Agreement, Annex II, Chapter IX, point 5), as subsequently
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	amended and incorporated into the EEA Agreement
	Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to the calibration of the tanks of vessels (71/349/EEC) (OJ L 239, 25.10.1971, p. 15) (EEA Agreement, Annex II, Chapter IX, point 7), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 17 December 1974 on the approximation of the laws of the Member States relating to cold-water meters (75/33/EEC) (OJ L 14, 20.01.1975, p.1) (EEA Agreement, Annex II, Chapter IX, point 7), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholometers and alcohol hydrometers (76/765/EEC) (OJ L 262, 27.09.1976, p.143) (EEA Agreement, Annex II, Chapter IX, point 17), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters (77/95/EEC) (OJ L 26,31.01.1977, p.59) (EEA Agreement, Annex II, Chapter IX, point 20), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 5 December 1978 on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines (78/1031/EEC) (OJ L 364, 27.12.1978, p.1) (EEA Agreement, Annex II, Chapter IX, point 22), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 11 September 1979 on the approximation of the laws of the Member States relating to hot-water meters (79/830/EEC) (OJ L 259, 15.10.1979, p.1) (EEA Agreement, Annex II, Chapter IX, point 23), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (86/217/EEC) (OJ L 152, 06.06.1986, p.48) (EEA Agreement, Annex II, Chapter IX, point 26), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments (90/384/EEC) (OJ L 189, 20.07.1990, p.1) (EEA Agreement, Annex II, Chapter IX, point 27), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids (75/106/EEC) (OJ L 42, 15.02.1975, p.1) (EEA Agreement, Annex II, Chapter IX, point 12), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 19 December 1974 on the approximation of the

	laws of the Member States relating to bottles used as measuring containers (75/107/EEC) (OJ L 42, 15.02.1975, p.14) (EEA Agreement, Annex II, Chapter IX, point 13), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (76/211/EEC) (OJ L 46, 21.02.1976, p.1) (EEA Agreement, Annex II, Chapter IX, point 15), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products (80/232/EEC) (OJ L 51, 25.02.1980, p.1) (EEA Agreement, Annex II, Chapter IX, point 25), as subsequently amended and incorporated into the EEA Agreement
Switzerland	Ordinance of 21 May 1986 on measuring instruments for thermal energy (RS 941.231), as subsequently amended
	Ordinance of 15 July 1970 concerning the binding declarations in trade with measurable goods (RS 941.281), as subsequently amended
	Ordinance of 25 October 1972 on declarations (RS 941.281.1), as subsequently amended
	Ordinance of 3 December 1973 on volume measures (RS 941.211), as subsequently amended
	Ordinance of 17 December 1984 on the qualification of measuring instruments (RS 941.210)
	Ordinance of 15 August 1986 on weighing instruments (RS 941.221.1)

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (80/181/EEC) (EEA Agreement, Annex II, Chapter IX, point 24), as last amended by Council Directive 89/617/EEC of 27 November 1989 (OJ L 357, 7/12/1989, p. 28) (EEA Agreement, Annex II, Chapter IX, point 24, third indent)
	Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control (71/316/EEC) (EEA Agreement, Annex II, Chapter IX, point 1), as last amended by Council Directive 88/665/EEC of 21 December 1988 (OJ L 382, 31/12/1988, p. 42) (EEA Agreement, Annex II, Chapter IX, point 1, seventh indent)
	Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 to 10 kilogramme medium accuracy cylindrical weights (71/317/EEC) (OJ L 202, 6/9/1971, p. 14) (EEA Agreement, Annex II, Chapter IX, point 2)
	Council Directive of 26 July 1971 on the approximation of the laws of

	the Member States relating to gas volume meters (71/318/EEC) (EEA Agreement, Annex II, Chapter IX, point 3), as last amended by Commission Directive 82/623/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 5) (EEA Agreement, Annex II, Chapter IX, point 3, third indent)
	Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to meters for liquids other than water (71/319/EEC) (OJ L 202, 6/9/1971, p. 32) (EEA Agreement, Annex II, Chapter IX, point 4)
	Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water (71/348/EEC) (OJ L 239, 25/10/1971, p. 9) (EEA Agreement, Annex II, Chapter IX, point 6)
	Council Directive of 19 November 1973 on the approximation of the laws of the Member States relating to material measures of length (73/362/EEC) (EEA Agreement, Annex II, Chapter IX, point 9), as last amended by Commission Directive 85/146/EEC of 31 January 1985 (OJ L 54, 23/2/1985, p. 29) (EEA Agreement, Annex II, Chapter IX, point 9, second indent)
	Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to weights of from 1 mg to 50 kg of above-medium accuracy (74/148/EEC) (OJ L 84, 28/3/1974, p. 3) (EEA Agreement, Annex II, Chapter IX, point 10)
	Council Directive of 24 June 1975 on the approximation of the laws of the Member States relating to continuous totalising weighing machines (75/410/EEC) (OJ L 183, 14/7/1975, p. 25) (EEA Agreement, Annex II, Chapter IX, point 14)
	Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (76/766/EEC) (OJ L 262, 27/9/1976, p. 149) (EEA Agreement, Annex II, Chapter IX, point 18)
	Council Directive of 4 November 1976 on the approximation of the laws of the Member States relating to electrical energy meters (76/891/EEC) (EEA Agreement, Annex II, Chapter IX, point 19), as last amended by Commission Directive 82/621/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 1) (EEA Agreement, Annex II, Chapter IX, point 19, first indent)
	Council Directive of 5 April 1977 on the approximation of the laws of the Member States relating to measuring systems for liquids other than water (77/313/EEC) (EEA Agreement, Annex II, Chapter IX, point 21), as last amended by Commission Directive 82/625/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 10) (EEA Agreement, Annex II, Chapter IX, point 21, first indent)
Switzerland	Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 18 June 1993 (RO 1993 3149)
	Ordinance of 23 November 1994 on units of measurement (RO 1994 3109)

	Ordinance of 8 April 1991 on measuring instruments for length (RO 1991 1306)
	Ordinance of 1 December 1986 on measuring instruments for liquids other than water (RO 1987 216)
	Ordinance of 15 August 1986 on weights (RO 1986 2022), as last amended on 21 November 1995 (RO 1995 5646)
	Ordinance of 4 August 1986 on measuring instruments for gas quantities (RO 1986 1491)
	Ordinance of 4 August 1986 on measuring instruments for electrical energy and power (RO 1986 1496)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the Conformity assessment bodies.

Section III

Designating authorities

Provisions covered by Article 1 paragraph 1

EEA EFTA States:

Iceland:	Ministry of Industry and Commerce
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Trade and Industry
Switzerland:	Swiss Federal Office of Metrology

Provisions covered by Article 1 paragraph 2

EEA EFTA States:

Iceland:	Ministry of Industry and Commerce
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Trade and Industry
Switzerland:	Swiss Federal Office of Metrology

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, Designating authorities shall comply with the general principles contained in Appendix 2 and those in Annex V to Directive 90/384/EEC (EEA Agreement, Annex II, Chapter IX, point 27), as regards the products covered by that Directive.

Section V

Supplementary provisions

Information exchange

The Conformity assessment bodies listed in Section II shall periodically provide the EEA EFTA States and the competent Swiss authorities with the information provided for in point 1.5 of Annex II to Directive 90/384/EEC (EEA Agreement, Annex II, Chapter IX, point 27).

The Conformity assessment bodies listed in Section II may request the information provided for in point 1.6 of Annex II to Directive 90/384/EEC (EEA Agreement, Annex II, Chapter IX, point 27).

2. Prepackages

Switzerland shall recognise checks carried out in accordance with the provisions of legislation applied in the EEA EFTA States listed in Section I by an EEA EFTA State body listed in Section II in the case of EEA EFTA States prepackages placed on the market in Switzerland.

As regards statistical checking of the quantities declared on prepackages, the EEA EFTA States shall recognise the Swiss method laid down in Articles 24 to 40 of the Ordinance on declarations (RS 941.281.1) as equivalent to the EEA EFTA States method laid down in Annex II of Directives 75/106/EEC (EEA Agreement, Annex II, Chapter IX, point 12) and 76/211/EEC (EEA Agreement, Annex II, Chapter IX, point 15), as amended by Directive 78/891/EEC (EEA Agreement, Annex II, Chapter IX, point 15, first indent). Swiss producers whose prepackages conform to legislation applied in the EEA EFTA States and have been checked according to the Swiss method shall affix the «e» mark on their products exported to the EEA EFTA States.

Chapter 12

Motor vehicles

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (70/156/EEC) (EEA Agreement, Annex II, Chapter I, point 1), as last amended by Commission Directive 98/14/EC of 6 February 1998 (OJ L 91,25/03/1998, p.1) (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99)
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	<p>Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (70/157/EEC) (EEA Agreement, Annex II, Chapter I, point 2), as last amended by Commission Directive 96/20/EC of 27 March 1996 (OJ L 92, 13/4/1996, p. 23) (EEA Agreement, Annex II, Chapter I, point 2, tenth indent as added by Decision No 73/96)</p>
	<p>Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles (70/220/EEC) (EEA Agreement, Annex II, Chapter I, point 3), as last amended by Directive 96/69/EC of the European Parliament and of the Council of 8 October 1996 (OJ L 282, 1/11/1996, p. 64) (EEA Agreement, Annex II, Chapter I, point 3, fourteenth indent as added by Decision No 74/97)</p>
	<p>Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to liquid fuel tanks and rear protective devices for motor vehicles and their trailers (70/221/EEC) (EEA Agreement, Annex II, Chapter I, point 4), as last amended by Commission Directive 97/19/EC of 18 April 1997 (OJ L 125, 16/05/1997, p.1) (EEA Agreement, Annex II, Chapter I, point 4, fourth indent as added by Decision No 39/98)</p>
	<p>Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to the space for mounting and the fixing of rear registration plates on motor vehicles and their trailers (70/222/EEC) (OJ L 76, 6/4/1970, p. 25) (EEA Agreement, Annex II, Chapter I, point 5)</p>
	<p>Council Directive of 8 June 1970 on the approximation of the laws of the Member States relating to the steering equipment for motor vehicles and their trailers (70/311/EEC) (EEA Agreement, Annex II, Chapter I, point 6), as last amended by Commission Directive 92/62/EEC of 2 July 1992 (OJ L 199, 18/7/1992, p. 33) (EEA Agreement, Annex II, Chapter I, point 6, second indent as added by Decision No 7/94)</p>
	<p>Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers (70/387/EEC) (OJ L 176, 10/8/1970, p. 5) (EEA Agreement, Annex II, Chapter I, point 7)</p>
	<p>Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to audible warning devices for motor vehicles (70/388/EEC) (OJ L 176, 10/8/1970, p. 12) (EEA Agreement, Annex II, Chapter I, point 8)</p>
	<p>Council Directive of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles (71/127/EEC) (EEA Agreement, Annex II, Chapter I, point 9), as last amended by Commission Directive 88/321/EEC of 16 May 1988 (OJ L 147, 14/6/1988, p. 77) (EEA Agreement, Annex II, Chapter I, point 9, seventh indent)</p>

	<p>Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and of their trailers (71/320/EEC) (EEA Agreement, Annex II, Chapter I, point 10), as last amended by Commission Directive 98/12/EC of 27 January 1998 (OJ L 081, 18/03/1998, p. 1) (EEA Agreement, Annex II, Chapter I, point 10, eighth indent as added by Decision No 16/99)</p>
	<p>Council Directive of 20 June 1972 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles (72/245/EEC) (EEA Agreement, Annex II, Chapter I, point 11), as last amended by Commission Directive 95/54/EC of 31 October 1995 (OJ L 266, 8/11/1995, p. 1) (EEA Agreement, Annex II, Chapter I, point 11, second indent as added by Decision No 72/96)</p>
	<p>Council Directive of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles (72/306/EEC) (EEA Agreement, Annex II, Chapter I, point 12), as last amended by Commission Directive 97/20/EC of 18 April 1997 (OJ L 125, 16/05/1997, p.21) (EEA Agreement, Annex II, Chapter I, point 12, second indent as added by Decision No 28/98)</p>
	<p>Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of the seats) (74/60/EEC) (EEA Agreement, Annex II, Chapter I, point 13), as last amended by Commission Directive 78/632/EEC of 19 May 1978 (OJ L 206, 29/7/1978, p. 26) (EEA Agreement, Annex II, Chapter I, point 13, first indent)</p>
	<p>Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to devices to prevent the unauthorised use of motor vehicles (74/61/EEC) (EEA Agreement, Annex II, Chapter I, point 14), as last amended by Commission Directive 95/56/EC of 8 November 1995 (OJ L 286, 29/11/1995, p. 1) (EEA Agreement, Annex II, Chapter I, point 14, first indent as added by Decision No 74/96)</p>
	<p>Council Directive of 4 June 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact) (74/297/EEC) (EEA Agreement, Annex II, Chapter I, point 15), as last amended by Commission Directive 91/662/EEC of 6 December 1991 (OJ L 366, 31/12/1991, p. 1) (EEA Agreement, Annex II, Chapter I, point 15, first indent as added by Decision No 7/94)</p>
	<p>Council Directive of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seats and of their anchorages) (74/408/EEC) (EEA Agreement, Annex II, Chapter I, point 16), as last amended by Commission Directive 96/37/EC of 17 June 1996 (OJ L 186,</p>

	<p>25/7/1996, p. 71) (EEA Agreement, Annex II, Chapter I, point 16, second indent as added by Decision No 62/97)</p>
	<p>Council Directive of 17 September 1974 on the approximation of the laws of the Member States relating to the external projections of motor vehicles (74/483/EEC) (EEA Agreement, Annex II, Chapter I, point 17), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 26 June 1975 on the approximation of the laws of the Member States relating to the reverse and speedometer equipment of motor vehicles (75/443/EEC) (EEA Agreement, Annex II, Chapter I, point 18), as last amended by Commission Directive 97/39/EC of 24 June 1997 (OJ L 177, 05/07/1997, p.15) (EEA Agreement, Annex II, Chapter I, point 18, first indent as added by Decision No 55/98)</p>
	<p>Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment (76/114/EEC) (EEA Agreement, Annex II, Chapter I, point 19), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p.43.)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts (76/115/EEC) (EEA Agreement, Annex II, Chapter I, point 20), as last amended by Commission Directive 96/38/EC of 17 June 1996 (OJ L 187, 26/7/1996, p. 95) (EEA Agreement, Annex II, Chapter I, point 20, fourth indent as added by Decision No 63/97)</p>
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on motor vehicles and their trailers (76/756/EEC) (EEA Agreement, Annex II, Chapter I, point 21), as last amended by Commission Directive 97/28/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 1) (EEA Agreement, Annex II, Chapter I, point 21, seventh indent as added by Decision No 29/98)</p>
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers (76/757/EEC) (EEA Agreement, Annex II, Chapter I, point 22), as last amended by Commission Directive 97/29/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 11) (EEA Agreement, Annex II, Chapter I, point 22, third indent as added by Decision No 70/98)</p>
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to rear position (side) lamps and stop lamps</p>

	for motor vehicles and their trailers (76/758/EEC) (EEA Agreement, Annex II, Chapter I, point 23), as last amended by Commission Directive 97/30/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 25) (EEA Agreement, Annex II, Chapter I, point 23, fourth indent as added by Decision No 40/98)
	Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers (76/759/EEC) (EEA Agreement, Annex II, Chapter I, point 24), as last amended by Commission Directive 89/277/EEC of 28 March 1989 (OJ L 109, 20/4/1989, p. 25) (EEA Agreement, Annex II, Chapter I, point 24, third indent)
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers (76/760/EEC) (EEA Agreement, Annex II, Chapter I, point 25), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to motor-vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such headlamps (76/761/EEC) (EEA Agreement, Annex II, Chapter I, point 26), as last amended by Commission Directive 89/517/EEC of 1 August 1989 (OJ L 265, 12/9/1989, p. 15) (EEA Agreement, Annex II, Chapter I, point 26, third indent)</p>
	<p>Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps (76/762/EEC) (EEA Agreement, Annex II, Chapter I, point 27), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 17 May 1977 on the approximation of the laws of the Member States relating to motor-vehicle towing-devices (77/389/EEC) (EEA Agreement, Annex II, Chapter I, point 28), as last amended by Commission Directive 96/64/EC of 2 October 1996 (OJ L 258, 11/10/1996, p. 26) (EEA Agreement, Annex II, Chapter I, point 28, first indent as added by Decision No 75/97)</p>
	<p>Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers (77/538/EEC) (EEA Agreement, Annex II, Chapter I, point 29), as last amended by Commission Directive 89/518/EEC of 1 August 1989 (OJ L 265, 12/9/1989, p. 24) (EEA Agreement, Annex II,</p>

	Chapter I, point 29, third indent
	<p>Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers (77/539/EEC) (EEA Agreement, Annex II, Chapter I, point 30), as last amended by Commission Directive 97/32/EC (OJ L 177, 30/06/1997, p. 63) (EEA Agreement, Annex II, Chapter I, point 30, third indent as added by Decision No 42/98)</p>
	<p>Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to parking lamps for motor vehicles (77/540/EEC) (EEA Agreement, Annex II, Chapter I, point 31), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles (77/541/EEC) (EEA Agreement, Annex II, Chapter I, point 32), as last amended by Commission Directive 96/36/EC of 17 June 1996 (OJ L 178, 17/7/1996, p. 15) (EEA Agreement, Annex II, Chapter I, point 32, sixth indent as added by Decision No 76/97)</p>
	<p>Council Directive of 27 September 1977 on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers (77/649/EEC) (EEA Agreement, Annex II, Chapter I, point 33), as last amended by Commission Directive 90/630/EEC of 30 October 1990 (OJ L 341, 6/12/1990, p. 20) (EEA Agreement, Annex II, Chapter I, point 33, third indent as added by Decision No 7/94)</p>
	<p>Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (identification of controls, tell-tales and indicators) (78/316/EEC) (EEA Agreement, Annex II, Chapter I, point 34), as last amended by Commission Directive 94/53/EC of 15 November 1994 (OJ L 299, 22/11/1994, p. 26)</p> <p>Commission Directive 94/53/EC has not yet been incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles (78/317/EEC) (OJ L 81, 28/3/1978, p. 27) (EEA Agreement, Annex II, Chapter I, point 35)</p>
	<p>Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles (78/318/EEC) (EEA Agreement, Annex II, Chapter I, point 36), as last amended by Commission Directive 94/68/EC of 16 December 1994 (OJ L 354, 31/12/1994, p. 1) (EEA Agreement, Annex II, Chapter I, point 36, first indent as added by Decision No 40/95)</p>

	<p>Council Directive of 12 June 1978 on the approximation of the laws of the Member States relating to heating systems for the passenger compartment of motor vehicles (78/548/EEC) (OJ L 168, 26/6/1978, p. 40) (EEA Agreement, Annex II, Chapter I, point 37)</p>
	<p>Council Directive of 12 June 1978 on the approximation of the laws of the Member States relating to the wheel guards of motor vehicles (78/549/EEC) (EEA Agreement, Annex II, Chapter I, point 38), as last amended by Commission Directive 94/78/EC of 21 December 1994 (OJ L 354, 31/12/1994, p. 10) (EEA Agreement, Annex II, Chapter I, point 38, first indent as added by Decision No 41/95)</p>
	<p>Council Directive of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles (78/932/EEC) (EEA Agreement, Annex II, Chapter I, point 39), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)</p> <p>Council Directive 87/354/EEC has not yet been fully incorporated in the EEA. The incorporation will be completed at the next update of Chapter I, Motor Vehicles, of Annex II of the EEA Agreement.</p>
	<p>Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the fuel consumption of motor vehicles (80/1268/EEC) (EEA Agreement, Annex II, Chapter I, point 42), as last amended by Commission Directive 93/116/EC of 17 December 1993 (OJ L 329, 30/12/1993, p. 39) (EEA Agreement, Annex II, Chapter I, point 42, second indent as added by Decision No 7/94)</p>
	<p>Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the engine power of motor vehicles (80/1269/EEC) (EEA Agreement, Annex II, Chapter I, point 43), as last amended by Commission Directive 97/21/EC of 18 April 1997 (OJ L 125, 16/05/1997, p. 31) (EEA Agreement, Annex II, Chapter I, point 43, third indent as added by Decision No 43/98)</p>
	<p>Council Directive of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (96/53/EC) (OJ L 235, 17/09/1996, p. 59) (EEA Agreement, Annex XIII, Chapter II, point 15a as inserted by Decision No 24/97)</p>
	<p>Council Directive of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles (88/77/EEC) (EEA Agreement, Annex II, Chapter I, point 44), as last amended by Council Directive 96/1/EC of 22 January 1996 (OJ L 40, 17/2/1996, p. 1) (EEA Agreement, Annex II, Chapter I, point 44, second indent as added by Decision No 75/96)</p>
	<p>Council Directive of 13 April 1989 on the approximation of the laws of the Member States relating to the lateral protection (side guards) of certain motor vehicles and their trailers (89/297/EEC) (OJ L 124,</p>

	5/5/1989, p. 1) (EEA Agreement, Annex II, Chapter I, point 45)
	Council Directive of 18 July 1989 on the approximation of the laws of the Member States relating to the tread depth of tyres of certain categories of motor vehicles and their trailers (89/459/EEC) (OJ L 226, 3/8/1989, p. 4) (EEA Agreement, Annex XIII, Chapter II, point 17)
	Council Directive of 27 March 1991 on the approximation of the laws of the Member States relating to the spray-suppression systems of certain categories of motor vehicles and their trailers (91/226/EEC) (OJ L 103, 23/4/1991, p. 5) (EEA Agreement, Annex II, Chapter I, point 45a as inserted by Decision No 7/94)
	Council Directive of 10 February 1992 on the installation and use of speed limitation devices for certain categories of motor vehicles in the Community (92/6/EEC) (OJ L 57, 2/3/1992, p. 27) (EEA Agreement, Annex XIII, Chapter II, point 17b as inserted by Decision No 7/94)
	Council Directive of 31 March 1992 on the masses and dimensions of motor vehicles of category M1 (92/21/EEC) (EEA Agreement, Annex II, Chapter I, point 45b as inserted by Decision No 7/94), as last amended by Commission Directive 95/48/EC of 20 September 1995 (OJ L 233, 30/9/1995, p. 73) (EEA Agreement, Annex II, Chapter I, point 45b, first indent as inserted by Decision No 76/96)
	Council Directive of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers (92/22/EEC) (OJ L 129, 14/5/1992, p. 11) (EEA Agreement, Annex II, Chapter I, point 45c)
	Council Directive of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting (92/23/EEC) (OJ L 129, 14/5/1992, p. 95) (EEA Agreement, Annex II, Chapter I, point 45d as inserted by Decision No 7/94)
	Council Directive of 31 March 1992 relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles (92/24/EEC) (OJ L 129, 14/5/1992, p. 154) (EEA Agreement, Annex II, Chapter I, point 45e as inserted by Decision No 7/94)
	Council Directive of 17 December 1992 relating to the external projections forward of the cab's rear panel of motor vehicles of category N (92/114/EEC) (OJ L 409, 31/12/1992, p. 17) (EEA Agreement, Annex II, Chapter I, point 45g as inserted by Decision No 7/94)
	Directive of the European Parliament and of the Council of 30 May 1994 relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles (94/20/EC) (OJ L 195, 29/7/1994, p. 1) (EEA Agreement, Annex II, Chapter I, point 45r as inserted by Decision No 30/94)
	Directive of the European Parliament and of the Council of 24 October 1995 relating to the burning behaviour of materials used in the interior construction of certain categories of motor vehicle (95/28/EC) (OJ L 281, 23/11/1995, p. 1) (EEA Agreement, Annex II, Chapter I, point 45t as inserted by Decision No 1/97)

	Directive 96/27/EC of the European Parliament and of the Council of 20 May 1996 on the protection of occupants of motor vehicles in the event of a side impact and amending Directive 70/156/EEC (OJ L 169, 8/7/1996, p. 1) (EEA Agreement, Annex II, Chapter I, point 45u as inserted by Decision No 60/97)
	Directive 96/79/EC of the European Parliament and of the Council of 16 December 1996 on the protection of occupants of motor vehicles in the event of a frontal impact and amending Directive 70/156/EEC (OJ L 018, 21/01/1997 p. 7) (EEA Agreement, Annex II, Chapter I, point 45v as inserted by Decision No 44/98)
	Directive 97/27/EC of the European Parliament and of the Council of 22 July 1997 relating to the masses and dimensions of certain categories of motor vehicles and their trailers and amending Directive 70/156/EEC (OJ L 233, 25/08/1997, p. 1 and OJ L 263, 25/09/1997, p. 30) (EEA Agreement, Annex II, Chapter I, point 45w as inserted by Decision No 56/98)
Switzerland	Ordinance of 19 June 1995 on the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as last amended on 21 April 1997 (RO 1997 1280)
	Ordinance of 19 June 1995 on type approval of road vehicles (RO 1995 3997)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the authorities responsible for type-approval, technical services and testing bodies.

EEA EFTA States:

Iceland:	Ministry of Justice
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Transport and Communications
Switzerland:	<p>Authority responsible for type-approval</p> <p>Swiss Federal Roads Office</p> <p>Section des homologations</p> <p>CH-3003 Berne</p>

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Justice
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Transport and Communication
Switzerland:	Swiss Federal Roads Office

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in Section I.

Section V

Supplementary provisions

The provisions of this section shall apply exclusively to relations between Switzerland and the EEA EFTA States.

Information exchange

The competent type-approval authorities in Switzerland and the EEA EFTA States shall in particular exchange the information referred to in Article 4(5) and (6) of Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94) and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99).

In the event of refusal by Switzerland or the EEA EFTA States to grant type-approval in accordance with Article 4(2) of Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99), their competent authorities shall notify each other of their decision and give the reasons for it.

2. Recognition of vehicle type-approval

Switzerland shall also recognise vehicle type-approval granted before the entry into force of the Annex in accordance with Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99), by the authorities responsible for type-approval listed in Section II of this Chapter where that approval is still valid in the EEA EFTA States.

The EEA EFTA States shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99).

Recognition of Swiss-issued type-approval shall be suspended should Switzerland fail to adapt its legislation to all the type-approval legislation in force in the EEA EFTA States.

3. Vehicle type-approval safeguard clauses

Registration and entry into service

Each EEA EFTA State and Switzerland shall register, permit the sale or entry into service of new vehicles on grounds relating to their construction and functioning if, and only if, they are accompanied by a valid certificate of conformity. In the case of incomplete vehicles, each EEA EFTA State and Switzerland may not prohibit the sale of such vehicles but may refuse their permanent registration and entry into service so long as they are not completed.

Each EEA EFTA State and Switzerland shall permit the sale or entry into service of components or separate technical units if, and only if, they comply with the requirements of the relevant separate Directive or the requirements of the Swiss legislation equivalent to the relevant separate Directive.

If a EEA EFTA State or Switzerland finds that vehicles, components or separate technical units of a particular type are a serious risk to road safety although they are accompanied by a valid certificate of conformity or are properly marked, it may, for a maximum period of six months, refuse to register such vehicles or may prohibit the sale or entry into service in its territory of such vehicles, components or separate technical units. It shall forthwith notify the EEA EFTA States concerned and Switzerland thereof, stating the reasons on which its decision is based. If the EEA EFTA State or Switzerland which granted type-approval disputes the risk to road safety notified to it, the EEA EFTA States or Switzerland concerned shall endeavour to settle the dispute. The Committee shall be kept informed and shall, where necessary, hold appropriate consultations for the purpose of reaching a settlement.

Measures related to the conformity of production

When a EEA EFTA State or Switzerland grants type-approval, it shall take the necessary measures in accordance with Annex X to Framework Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99), in relation to that approval to verify, if need be in co-operation with the approval authorities of the other EEA EFTA States or Switzerland, that adequate arrangements have been made to ensure that vehicles, systems, components or separate technical units produced, conform to the approved type.

When a EEA EFTA State or Switzerland has granted a type approval, it shall take the necessary measures in accordance with Annex X to Framework Directive 70/156/EEC

(EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99), in relation to that approval to verify, if need be in co-operation with the approval authorities of the other EEA EFTA States or Switzerland, that the arrangements referred to in paragraph 1 continue to be adequate and that vehicles, systems, components or separate technical units produced, continue to conform to the approved type. Verification to ensure that products conform to the approved type shall be limited to the procedures set out in Section 2 of Annex X to Framework Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99), and in those separate directives that contain specific requirements. *Nonconformity with the approved type*

There shall be failure to conform to the approved type where deviations from the particulars in the type-approval certificate and/or the information package are found to exist and where these deviations have not been authorised under Article 5 (3) or (4), by the EEA EFTA States or Switzerland which granted the type-approval. A vehicle shall not be considered to deviate from the approved type where tolerances are permitted by separate Directives and these tolerances are respected.

Where a EEA EFTA State or Switzerland has granted type-approval and finds that vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the type it has approved, it shall take the necessary measures to ensure that vehicles, components or separate technical units produced again conform to the approved type. The approval authorities of that EEA EFTA State or Switzerland shall notify those of the other EEA EFTA States and/or Switzerland of the measures taken which may extend to withdrawal of type-approval.

If a EEA EFTA State or Switzerland demonstrates that vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, it may request the EEA EFTA State or Switzerland which granted the type-approval to verify that vehicles, components or separate technical units produced conform to the approved type. Such action shall be taken as soon as possible and in any case within six months of the date of the request.

In the case of:

a vehicle type-approval where the nonconformity of a vehicle arises exclusively from the nonconformity of a system, component or separate technical unit, or

a multi-stage type-approval where the nonconformity of a completed vehicle arises exclusively from the nonconformity of a system, component or separate technical unit being part of the incomplete vehicle, or of the incomplete vehicle itself, the vehicle-approval authority shall request the EEA EFTA State(s) or Switzerland which granted any relevant system, component, separate technical unit or incomplete vehicle type-approval(s) to take the necessary action to ensure that vehicles produced again conform to the approved type. Such action shall be taken

as soon as possible and in any case within six months of the date of the request, if necessary in conjunction with the EEA EFTA State or Switzerland making the request. Where a failure to conform is established, the approval authorities of the EEA EFTA State or Switzerland which granted the system, component or separate technical unit type-approval or the approval of the incomplete vehicle shall take the measures set out in paragraph 2 of Article 11 of Directive 70/156/EEC (EEA Agreement, Annex II, Chapter I, point 1), as amended by Directive 92/53/EEC (EEA Agreement, Annex II, Chapter I, point 1, eighth indent as added by Decision No 7/94), and as last adapted to technical progress by Commission Directive 98/14/EC (EEA Agreement, Annex II, Chapter I, point 1, fourteenth indent as added by Decision No 16/99).

The approval authorities of the EEA EFTA States or Switzerland shall inform each other within one month of any withdrawal of type-approval and of the reasons for such a measure.

If the EEA EFTA State or Switzerland which granted type-approval disputes the failure to conform notified to it, the EEA EFTA States concerned and Switzerland shall endeavour to settle the dispute. The Committee shall be kept informed and shall, where necessary, hold appropriate consultations for the purpose of reaching a settlement.

Chapter 13

Agricultural or forestry tractors

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors (74/150/EEC) (EEA Agreement, Annex II, Chapter II, point 1), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 1, sixth indent as added by Decision No 28/99)
	Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to certain parts and characteristics of wheeled agricultural or forestry tractors (74/151/EEC) (EEA Agreement, Annex II, Chapter II, point 2), as last amended by Commission Directive 98/38/EC of 3 June 1998, (OJ L 170, 16/06/1998, p. 13) (EEA Agreement, Annex II, Chapter II, point 2, fourth indent as added by Decision No 46/99)
	Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to the maximum design speed of and load platforms for wheeled agricultural or forestry tractors (74/152/EEC) (EEA Agreement, Annex II, Chapter II, point 3), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement,

	Annex II, Chapter II, point 3, third indent as added by Decision No 28/99)
	Council Directive of 25 June 1974 on the approximation of the laws of the Member States relating to rear-view mirrors for wheeled agricultural or forestry tractors (74/346/EEC) (EEA Agreement, Annex II, Chapter II, point 4), as last amended by Commission Directive 98/40/EC of 6 June 1998, (OJ L 171, 16/06/1998, p. 28) (EEA Agreement, Annex II, Chapter II, point 4, fourth indent as added by Decision No 47/99)
	Council Directive of 25 June 1974 on the approximation of the laws of the Member States relating to the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (74/347/EEC) (EEA Agreement, Annex II, Chapter II, point 5), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 5, third indent as added by Decision No 28/99)
	Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to the steering equipment of wheeled agricultural or forestry tractors (75/321/EEC) (EEA Agreement, Annex II, Chapter II, point 6), as last amended by Commission Directive 98/39/EC of 5 June 1998 (OJ L 170, 16/06/1998, p. 15) (EEA Agreement, Annex II, Chapter II, point 6, fourth indent as added by Decision No 46/99)
	Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to wheeled agricultural or forestry tractors (75/322/EEC) (EEA Agreement, Annex II, Chapter II, point 7), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 7, second indent as added by Decision No 28/99)
	Council Directive of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors (76/432/EEC) (EEA Agreement, Annex II, Chapter II, point 8), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 8, third indent as added by Decision No 28/99)
	Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors (76/763/EEC) (EEA Agreement, Annex II, Chapter II, point 9), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 9, second indent as added by Decision No 28/99)
	Council Directive of 29 March 1977 on the approximation of the laws of the Member States relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (77/311/EEC) (EEA

	Agreement, Annex II, Chapter II, point 10), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 10, third indent as added by Decision No 28/99)
	Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors (77/536/EEC) (EEA Agreement, Annex II, Chapter II, point 11), as last amended by Council Directive 89/680/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 26) (EEA Agreement, Annex II, Chapter II, point 11, third indent as added by Decision No 28/99)
	Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors (77/537/EEC) (EEA Agreement, Annex II, Chapter II, point 12), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 12, second indent as added by Decision No 28/99)
	Council Directive of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors (78/764/EEC) (EEA Agreement, Annex II, Chapter II, point 13), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 13, sixth indent as added by Decision No 28/99)
	Council Directive of 17 October 1978 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on wheeled agricultural and forestry tractors (78/933/EEC) (EEA Agreement, Annex II, Chapter II, point 14), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 14, second indent as added by Decision No 28/99)
	Council Directive of 17 May 1979 on the approximation of the laws of the Member States relating to the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (79/532/EEC) (EEA Agreement, Annex II, Chapter II, point 15), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 15, second indent as added by Decision No 28/99)
	Council Directive of 17 May 1979 on the approximation of the laws of the Member States relating to the coupling device and the reverse of wheeled agricultural or forestry tractors (79/533/EEC) (EEA Agreement, Annex II, Chapter II, point 16), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23

	September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 16, second indent as added by Decision No 28/99)
	Council Directive of 25 June 1979 on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (79/622/EEC) (EEA Agreement, Annex II, Chapter II, point 17), as last amended by Commission Directive 88/413/EEC of 22 June 1988 (OJ L 200, 26/7/1988, p. 32) (EEA Agreement, Annex II, Chapter II, point 17, third indent)
	Council Directive of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors (80/720/EEC) (EEA Agreement, Annex II, Chapter II, point 18), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 18, third indent as added by Decision No 28/99)
	Council Directive of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of wheeled agricultural and forestry tractors and their protection (86/297/EEC) (EEA Agreement, Annex II, Chapter II, point 19), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 19, first indent as added by Decision No 28/99)
	Council Directive of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors (86/298/EEC) (EEA Agreement, Annex II, Chapter II, point 20), as last amended by Council Directive 89/682/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 29) (EEA Agreement, Annex II, Chapter II, point 20, first indent as added by Decision No 28/99)
	Council Directive of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors (86/415/EEC) (EEA Agreement, Annex II, Chapter II, point 21), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 21, first indent as added by Decision No 28/99)
	Council Directive of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors (87/402/EEC) (EEA Agreement, Annex II, Chapter II, point 22), as last amended by Council Directive 89/681/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 27) (EEA Agreement, Annex II, Chapter II, point 22, first indent)
	Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to certain components and characteristics of wheeled agricultural or forestry tractors (89/173/EEC)

	(EEA Agreement, Annex II, Chapter II, point 23), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) (EEA Agreement, Annex II, Chapter II, point 1, first indent as added by Decision No 28/99)
Switzerland	Ordinance of 19 June 1995 on the technical requirements for agricultural tractors (RO 1995 4171)
	Ordinance of 19 June 1995 on type approval of road vehicles (RO 1995 3997)

Section II

Conformity assessment bodies

The Committee shall draw up and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the authorities responsible for type-approval, technical services and testing bodies.

EEA EFTA States:

Iceland:	Ministry of Justice
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	Ministry of Transport and Communications
Switzerland	<p>Authority responsible for type approval</p> <p>Swiss Federal Roads Office</p> <p>CH-3003 Berne</p>

Section III

Designating authorities

EEA EFTA States:

Iceland:	Ministry of Justice
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	<p>For type approval, certain parts and characteristics, maximum design speed of and load platforms, rear-view mirrors, vision and windscreen wipers, steering equipment, suppression of radio interference produced by sparkignition engines, braking devices, measures to be taken against emission of pollutants from diesel engines, installation of lighting and light-signalling devices, component type-approval of lighting and light-signalling, coupling device and the reverse,</p>

	installation, location, operation and identification of the controls, certain components and characteristics of wheeled tractors:
	Ministry of Transport and Communications
	For passenger seats, driver-perceived noise level, roll-over protection structures, drivers seat, operating space, access to the driving position and the doors and windows, power take-offs, rear-mounted roll-over protection structures of narrow-track tractors, roll-over protection structures mounted in front of the drivers seats on narrow-track tractors:
	Ministry of Labour and Government Administration
Switzerland:	Swiss Federal Roads Office

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of Conformity assessment bodies, the Designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in Section I.

Section V

Supplementary provisions

Information exchange

The competent EEA EFTA State's and Swiss authorities shall notify each other of conforming (Art. 5 and 6, Directive 74/150/EEC) (EEA Agreement, Annex II, Chapter II, point 1) or non-conforming (Art. 8, Directive 74/150/EEC) (EEA Agreement, Annex II, Chapter II, point 1) vehicles, devices and systems placed on the market.

Chapter 14

Good laboratory practice (GLP)

Scope and coverage

The provisions of this Chapter shall apply to the testing of chemicals according to GLP, being either substances or preparations, covered by the legislative, regulatory and administrative provisions listed in Section I. For the purposes of this Chapter the provisions of Article 4 of the Annex concerning origin do not apply.

Unless specific definitions are given, the definition of terms in the «OECD Principles of Good Laboratory Practice» (Appendix II to OECD Council Decision of 12 May 1981 C(81)30(Final)), the «Guides for Compliance Monitoring Procedures for Good Laboratory Practice» (Appendix I to Council Decision-Recommendation of 2 October 1989 C(89)87(Final)) and GLP Consensus documents, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and all amendments made thereto, shall apply.

The Member States recognise the equivalence of each other's compliance monitoring programmes on Good Laboratory Practice that are in accordance with the OECD

decisions and recommendations mentioned above and the legislative, regulatory and administrative procedures and principles listed in Section IV.

The Member States mutually accept studies and data generated therefrom, produced by the test facilities of the other Member States listed in Section II provided they participate in the Good Laboratory Practice compliance monitoring programme of that Member State in accordance with the principles and provisions stated above.

The Member States mutually accept the conclusions of study audits and test facility inspections performed by the monitoring authorities referred to in Section III.

Section I

Legislative, regulatory and administrative provisions

With regard to the testing of chemicals according to GLP, the relevant parts of the legislative, regulatory and administrative provisions listed below shall apply.

Provisions covered by Article 1 paragraph 1

EEA EFTA States	<i>Feed additives:</i>
	Council Directive of 18.4.83 on the fixing of guidelines for the assessment of certain products used in animal nutrition (83/228/EEC) (OJ L 126, 13/05/1983, p. 23) (EEA Agreement, Annex I, Chapter II, point 16), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 16.2.87 fixing guidelines for the assessment of additives in animal nutrition (87/153/EEC) (OJ L 64, 07/02/1987, p. 19) (EEA Agreement, Annex I, Chapter II, point 2), as subsequently amended and incorporated into the EEA Agreement
	<i>Foodstuffs:</i>
	Council Directive of 14.6.89 on the official control of foodstuffs (89/397/EEC) (OJ L 186 of 30.06.1989, p. 23) (EEA Agreement, Annex II, Chapter XII, point 50), as subsequently amended and incorporated into the EEA Agreement
	Council Directive of 29.10.93 on the subject of additional measures concerning the official control of foodstuffs (93/99/EEC) (OJ L 290 of 24.11.1993, p. 14) (EEA Agreement, Annex XII, Chapter II, point 54n as inserted by Decision No 7/94), as subsequently amended and incorporated into the EEA Agreement
	<i>Cosmetics:</i>
	Council Directive of 14.6.93 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (93/35/EEC) (OJ L 151, 23.06.1993, p. 32) (EEA Agreement, Annex II, Chapter XVI, point 1, twenty-third indent as added by Decision No 7/94) as subsequently amended and incorporated into the EEA Agreement
Switzerland	No GLP-relevant legislation

Provisions covered by Article 1 paragraph 2

EEA EFTA States	<i>New and Existing Chemicals:</i>
	Council Directive of 18.12.86 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 (87/18/EEC) (OJ L 15, 17.01.1987, p. 29) (EEA Agreement, Annex II, Chapter XV, point 8)
	Council Directive of 30.4.92 amending for the seventh time Directive 67/548/EEC (EEA Agreement, Annex II, Chapter XV, point 1) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (92/32/EEC) (OJ L 154, 5/6/1992, p. 1) (EEA Agreement, Annex II, Chapter XV, point 1, tenth indent as added by Decision No 7/94)
	Council Directive of 7.6.88 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (88/379/EEC) (OJ L 187, 16/7/1988, p. 14) (EEA Agreement, Annex II, Chapter XV, point 10)
	Council Regulation of 23.3.93 on the evaluation and control of the risks of existing substances (No 793/93/EEC) (OJ L 84, 5/4/1993, p. 1) (EEA Agreement, Annex II, Chapter XV, point 12e)
	<i>Medicinal products:</i>
	Council Directive of 22.12.86 amending Directive 75/318/EEC (EEA Agreement, Annex II, Chapter XIII, point 2) on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (87/19/EEC) (OJ L 15, 17/1/1987, p. 31) (EEA Agreement, Annex II, Chapter XIII, point 2, second indent)
	Council Directive of 22.12.86 amending Directive 65/65/EEC (EEA Agreement, Annex II, Chapter XIII, point 1) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (87/21/CEE) (OJ L 15 of 17/1/1987, p. 36) (EEA Agreement, Annex II, Chapter XIII, point 1, third indent)
	Commission Directive of 19.7.91 modifying the Appendix to Council Directive 75/318/EEC (EEA Agreement, Annex II, Chapter XIII, point 2) on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (91/507/EEC) (OJ L 270 of 26/9/1991, p. 32) (EEA Agreement, Annex II, Chapter XIII, point 2, fourth indent as added by Decision No 7/94)
	<i>Veterinary Drugs:</i>
	Council Directive of 22.12.86 amending Directive 81/852/EEC (EEA

	Agreement, Annex II, Chapter XIII, point 6) on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (87/20/EEC) (OJ L 15 of 17/1/1987, p. 34) (EEA Agreement, Annex II, Chapter XIII, point 6, first indent)
	Commission Directive of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC (EEA Agreement, Annex II, Chapter XIII, point 6) on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (92/18/EEC) (OJ L 97 of 10/04/92, p.1) (EEA Agreement, Annex II, Chapter XIII, point 6, second indent as added by Decision No 7/94)
	<i>Plant Protection Products:</i>
	Council Directive of 15.7.91 concerning the placing of plant protection products on the market (91/414/EEC) (OJ L 230 of 19/8/1991, p. 1) (EEA Agreement, Annex II, Chapter II, point 1)
	Commission Directive of 27.7.93 amending Council Directive 91/414 concerning the placing of plant protection products on the market (93/71/EEC) (OJ L 221 of 31/8/1993, p. 27) (EEA Agreement, Annex II, Chapter XV, point 12a as inserted by Decision No 7/94)
	Commission Directive of 14.7.95 amending Council Directive 91/414/EEC concerning the placing on the market of plant protection products (95/35/EC) (OJ L 172 of 22/7/1995, p. 6) (EEA Agreement, Annex II, Chapter XV, point 12a, fifth indent as added by Decision No 15/96)
Switzerland	Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 21 December 1995 (RO 1997 1155)
	Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 4 November 1998 (RO 1999 39)
	Federal law of 21 March 1969 on trade in toxic substances (RO 1972 430) as last amended on 21 December 1995 (RO 1997 1155)
	Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 4 November 1998 (RO 1999 56)
	Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on 23 November 1995

Section II

Conformity assessment bodies

For the purpose of this Sectoral Chapter, «Conformity Assessment Bodies» means the test facilities recognised under each Member State's GLP monitoring programme.

On the basis of information provided by the Member States according to Section V of this Chapter, the Committee shall establish and keep up to date, according to the procedure described in Article 11 of the Annex, a list of the test facilities that have been found to be in conformity with the GLP principles.

Section III

Designating authorities

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 Industry and Commerce
Liechtenstein:	<p>The Government of Liechtenstein</p> <p>The Government of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.</p>
Norway:	The Norwegian Metrology Accreditation Service
Switzerland:	<p>Federal Office of Environment,</p> <p>Forests and Landscape</p>
CH-3003 Berne	<p>Environmental studies on all products</p> <p>Intercantonal Office for the</p> <p>Control of Medicines</p> <p>Erlachstrasse 8</p>
P.O. Box	<p>Health studies on pharmaceutical</p>
CH-3000 Berne 9	<p>products</p> <p>Federal Office of Public Health</p>
Chemicals division	<p>Health studies on all products</p>
CH-3003 Berne	<p>except pharmaceuticals</p>

Section IV

Special principles for designating conformity assessment bodies

For the purpose of this Sectoral Chapter, «designation of conformity assessment bodies» means the procedure by which the GLP Monitoring Authorities recognise that test facilities comply with the GLP principles. To this end they shall apply the principles and procedures of their provisions listed below, that are recognised to be equivalent and in conformity with the aforementioned OECD Council Acts C(81)30 Final and C(89)87 (Final):

EEA EFTA States	Council Directive of 18.12.86 on the harmonisation of laws, regulations and administrative provisions relating to the application of the
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	principles of good laboratory practice and the verification of their applications for tests on chemical substances (87/18/EEC) (OJ L 15, 17/1/1987, p. 29) (EEA Agreement, Annex II, Chapter XV, point 8)
	Council Directive of 9.6.88 on the inspection and verification of Good Laboratory Practice (GLP) (88/320/EEC) (OJ L 145, 11/6/1988, p. 35) (EEA Agreement, Annex II, Chapter XV, point 9)
	Commission Directive of 18.12.89 adapting to technical progress the Appendix of Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP) (90/18/EEC) (OJ L 11, 13/1/1990, p. 37) (EEA Agreement, Annex II, Chapter XV, point 9, first indent)
Switzerland	Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 21 December 1995 (RO 1197 1155)
	Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 4 November 1998 (RO 1999 39)
	Federal law of 21 March 1969 on trade in toxic substances (1972 435) as last amended on 21 December 1995 (RO 1197 1155)
	Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 4 November 1998 (RO 1999 56)
	Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on 23 November 1995
	Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, DFI/IKS, March 1986

Section V

Additional provisions

Information exchange

In accordance with Article 12 of the Annex, the Member States in particular provide each other 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 Good Laboratory Practice, as well as of the dates of inspection or audit and their compliance status.

In accordance with Article 6 of the Annex, the Member States shall inform each other in a timely manner when a test facility coming under the terms of Section II of this sectoral Chapter which states that it applies Good Laboratory Practice fails to conform to such practice to an extent which may jeopardise the integrity or authenticity of any such studies it conducts.

The Member States shall supply each other with any additional information on a test facility inspection or study audit in response to a reasonable request from another Member State.

2. Test Facility Inspections

Each Member State may request further test facility inspection or study audits if there is a documented doubt as to whether a test was conducted in accordance with Good Laboratory Practice.

If, in exceptional cases, doubts persist and the requesting Member State can justify special concern, it may, in accordance with Article 8 of the Annex, designate one or more experts of its authorities listed in Section III to participate in a laboratory inspection or the audit of a study conducted by the authorities of the other Member State.

3. Confidentiality

In conformity with Article 52 of the Convention, the Member States shall keep confidential any information brought to their knowledge pursuant to this Sectoral Chapter or that came to their knowledge in the framework of participation in an inspection or study audit and which falls within the definition of a trade secret or confidential commercial or financial information. They shall treat such information with at least the same confidentiality as that accorded to it by the providing Member State and ensure that any authority to whom the information is transmitted treats it in the same way.

4. Co-operation

Based on Article 9 of the Annex, each Member State may, on request, participate as an observer in an inspection of a test facility conducted by the authorities of another Member State with the consent of the test facility concerned in order to maintain a continuing understanding of the other Member State 's inspection procedures.

Chapter 15

Medicinal products gmp inspection and batch certification

Scope and coverage

The provisions of this Sectoral Chapter cover all medicinal products which are industrially manufactured in Switzerland or the EEA EFTA States, and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Chapter, each Member State shall recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Member States and the relevant manufacturing authorisations granted by the competent authorities of the other Member States.

The manufacturer's certification of the conformity of each batch to its specifications shall be recognised by the other Member States without recontrol at import.

In addition, official batch releases carried out by an authority of the exporting Member State will be recognised by the other Member States.

«Medicinal products» means all products regulated by pharmaceutical legislation in the EEA EFTA States and Switzerland as listed in Section I of this Chapter. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs and, where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products.

«GMP» is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and products specifications. For the purpose of this Chapter it includes the system whereby the manufacturer receives the specification of the product and the process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (Equivalent to «Qualified Person» for certification in the EEA EFTA States).

With respect to medicinal products covered by the legislation of either Switzerland or the EEA EFTA States, the manufacturing company can request, for the purpose of the Annex, an inspection be made by the locally competent inspection service. This provision shall apply i.a. to the manufacture of active pharmaceutical ingredients, intermediate products and investigational medicinal products, as well as to pre-marketing inspections.

Operational arrangements are detailed under Section III, paragraph 3.

Certification of manufacturers

At the request of an exporter, importer or the competent authority of another Member State, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products shall certify that the manufacturer:

is appropriately authorised to manufacture the relevant medicinal product, or to carry out the relevant specified manufacturing operation;

is regularly inspected by the authorities;

complies with the national GMP requirements recognised as equivalent by the Member States, and which are listed in Section I of this Chapter. Should different GMP requirements be used as reference, this is to be mentioned in the certificate.

The certificates shall also identify the site(s) of manufacture (and contract quality control laboratories, if any).

Certificates shall be issued expeditiously, and the time taken should not exceed thirty calendar days. In exceptional cases, i.a. when a new inspection has to be carried out, this period may be extended to sixty days.

Batch certification

Each batch exported shall be accompanied by a batch certificate established by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active ingredients and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specifications and shall be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer shall take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate shall detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It shall contain a statement that the batch processing and packaging records were reviewed and found in conformity with GMP. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the EEA EFTA States the «qualified person»

referred to in Article 21 of Directive 75/319/EEC (EEA Agreement, Annex II, Chapter XIII, point 1, first indent), and in Switzerland the responsible person referred to in Articles 4 and 5 of the Ordinance on immunobiological products, Articles 4 and 5 of the Ordinance on immunobiological products for veterinary use and Article 10 of the Directives of the IOCM on the manufacture of medicinal products.

Official Batch Release

When an official batch release procedure applies, official batch releases carried out by an authority of the exporting Member State (listed in Section II) will be recognised by the other Member States. The manufacturer shall provide the certificate of the official batch release.

For the EEA EFTA States, the official batch release procedure is specified in document «Control/Authority Batch Release of Vaccination and Blood Products of 24 September 1998» and different specific batch release procedures. For Switzerland, the official batch release procedure is specified in Articles 22-27 of the Ordinance on immunobiological products, Articles 20-25 of the Ordinance on immunobiological products for veterinary use and Articles 4-6 of the Directives of the IOCM on the Authority Batch Release.

Section I

With regard to GMP, the relevant parts of the legislative, regulatory and administrative provisions listed below apply. However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, shall be those of the relevant marketing authorisation granted by the competent authority of the importing Member State.

Provisions covered by Article 1 paragraph 2

EEA EFTA States	Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (65/65/EEC) (EEA Agreement, Annex II, Chapter XIII, point 1), as last amended by Council Directive 93/39/EEC of June 14, 1993 (OJ L 214, 24.8.1993, p.22) (EEA Agreement, Annex II, Chapter XIII, point 1, sixth indent as added by Decision No 74/99)
	Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (75/319/EEC) (EEA Agreement, Annex II, Chapter XIII, point 1, first indent) as last amended by Council Directive 93/93/EEC of June 3, 1993 (OJ L 214, 24.8.1993, p.22) (EEA Agreement, Annex II, Chapter XIII, point 1, sixth indent, as added by Decision No 74/99) The reference to this provision in the parallel Switzerland - EC Mutual Recognition Agreement is incorrect. The Parties to the aforementioned Agreement have agreed to correct this mistake at the time of the first update of the Annexes after the entry into force of their Agreement.
	Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products

	(81/851/EEC) (EEA Agreement, Annex II, Chapter XIII, point 5) as last amended by Council Directive 90/676/EEC of December 13, 1990 (OJ L 373, 31.12.1990, p.15) (EEA Agreement, Annex II, Chapter XIII, point 5, first indent)
	Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (91/356/EEC) (OJ L 193, 17.7.1991, p.30) (EEA Agreement, Annex II, Chapter XIII, point 15)
	Commission Directive of July 23, 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (91/412/EEC) (OJ L 228, 17.8.1991, p.70) (EEA Agreement, Annex II, Chapter XIII, point 15a as inserted by Decision No 7/94)
	Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (EEA Agreement, Annex II, Chapter XIII, point 15g as inserted by Decision No 74/99), as last amended by Commission Regulation (EC) No 649/98 of 23 March 1998 (OJ L 88, 24.3.1998, p.7) (EEA Agreement, Annex II, Chapter XIII, point 15g, first indent as added by Decision No 75/99)
	Council Directive of March 31, 1992 on the wholesale distribution of medicinal products for human use (92/25/EEC) (OJ L 113, 30.4.1992, p.1) (EEA Agreement, Annex II, Chapter XIII, point 15b as inserted by Decision No 7/94) and Guide to Good Distribution Practice
	Guide to Good Manufacturing Practice Volume IV of Rules Governing Medicinal Products in the European Community
Switzerland	Federal law of October 6, 1989 on the pharmacopoeia (RO 1990 570)
	Ordinance of August 23, 1989 on immunobiological products (RO 1989 1797), as last amended on 24 February 1993 (RO 1993 963)
	Ordinance of June 22, 1994 on radioprotection (RO 1994 1947)
	Federal Decree of 22 March 1996 on the control of blood, blood products and transplants (RO 1996 2296)
	Ordinance of 26 June 1996 on the control of blood, blood products and transplants (RO 1996 2309)
	Federal Law of 1 July 1966 on epizootics (RO 1966 1621)
	Ordinance of June 27, 1995 on immunobiological products for veterinary use (RO 1995 3805)
	Intercantonal Convention of June 3, 1971 on the control of medicines (RO 1972 1026), as last amended on 1 January 1979 (RO 1979 252)
	Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on May 14, 1998
	Directives of May 18, 1995 of the Intercantonal Office for the Control of Medicines (IOCM) on the manufacture of medicinal products
	IOCM Directives of May 23, 1985 on the manufacture of active

	pharmaceutical ingredients
	IOCM Directives of May 20, 1976 for the wholesale of medicines
	IOCM Directives of November 24, 1994 on the Authority Batch Release
	IOCM Directives of May 19, 1988 on the manufacture and distribution of medicated feeding stuff
	IOCM Directives of November 19, 1998 for the Inspection of Manufacturers of Medicinal Products (Inspection Directives)

Section II

Conformity assessment bodies

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

EEA EFTA States:

Iceland:	State Drug Inspectorate Lyfjaeftirlit ríkisins Eidistorg 15 170 Seltjarnarnes Iceland
Liechtenstein:	Amt für Lebensmittelkontrolle und Veterinärwesen (Office of foodstuff control and veterinary affairs)
	Kontrollstelle für Arzneimittel Postplatz 2 Postfach 37 FL - 9494 Schaan
Norway:	Norwegian Medicines Agency Pharmaceutical Inspectorate Sven Oftedals vei 6 N-0950 Oslo

Switzerland:

Swiss Federal Office of Public Health, Division of Biologicals, Berne (for immunobiological products for human use)

Institute for Virology and Immunoprophylaxis, Research Station of the Swiss Federal Veterinary Office, 3147 Mittelhäusern (for immunobiological products for veterinary use)

Intercantonal Office for the Control of Medicines, 3000 Berne 9 (for all other medicinal products for human and veterinary use)

Section III

Additional provisions

Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing site or, in case analytical operations are contracted out, of the control site. The request may concern a «full inspection report» or a «detailed report» (see item 2 below). Each Member State shall deal with these inspection reports with the degree of confidentiality requested by the providing Member State.

Member States will ensure that inspection reports are forwarded in no more than thirty calendar days, this period being extended to sixty days should a new inspection be carried out.

2. Inspection reports

A «full inspection report» comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A «detailed report» responds to specific queries about a firm by another Member State.

3. GMP Reference

Manufacturers shall be inspected against the applicable GMP of the exporting Member State (see Section I).

With respect to medicinal products covered by the pharmaceutical legislation of the importing Member State but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations shall inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Member State.

For specific products or classes of products (e.g. investigational medicinal products, starting materials not limited to active pharmaceutical ingredients), equivalence of GMP requirements shall be determined according to a procedure established by the Committee.

4. Nature of inspections

Inspections shall routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).

«Product- or process-oriented» inspections (which may be «pre-marketing» inspections as relevant) focus on the manufacture of one or a series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) shall be provided in confidence to the inspectorate.

5. Fees

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees shall not be charged to manufacturers located on the territory of another Member State.

6. Safeguard clause for inspections

Each Member State reserves the right to have its own inspection conducted for reasons identified to another Member State. Such inspections are to be notified in advance to that other Member State and shall, in accordance with Article 8 of the Annex, be carried out jointly by the competent authorities of the two Member States. Recourse to this safeguard clause should be an exception.

7. Exchange of information between authorities and approximation of quality requirements

In accordance with the general provisions of the Annex, the Member States shall exchange any information necessary for the mutual recognition of inspections.

The relevant authorities in Switzerland and in the EEA EFTA States shall also keep each other informed of any new technical guidance or inspection procedure. The Member States shall consult each other before their adoption and shall endeavour to proceed towards their approximation.

8. Inspectors training

In accordance with Article 9 of the Annex, training sessions for inspectors, organised by the authorities, shall be accessible to inspectors of the other Member States. The Member States shall keep each other informed on these sessions.

9. Joint inspections

In accordance with Article 12 of the Annex, and by mutual agreement between the Member States, joint inspections may be organised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Committee.

10. Alert system

Contact points shall be agreed between the Member States to permit authorities and manufacturers to inform the authorities of the other Member States with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

The Member States shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could have public health implications, are communicated to each other with the appropriate degree of urgency.

11. Contact points

For the purpose of the Annex, the contact points for any technical question, such as exchanges of inspection reports, inspectors training sessions, technical requirements, are:

for the EEA EFTA States:

Iceland:	State Drug Inspectorate
	Lyfjaeftirlit ríkisins

	Eidistorg 15
	170 Seltjarnarnes
	Iceland
Liechtenstein:	Amt für Lebensmittelkontrolle und Veterinärwesen (Office of foodstuff control and veterinary affairs)
	Kontrollstelle für Arzneimittel
	Postplatz 2 Postfach 37
	FL - 9494 Schaan
Norway:	Norwegian Medicines Agency
	Pharmaceutical Inspectorate
	Sven Oftedals vei 6
	N-0950 Oslo

for Switzerland:

the official GMP inspection services listed in Section II above.

12. Divergence of views

The Member States shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Committee referred to in Article 10 of the Annex.

Appendix 2

General rules regarding the designation of Conformity assessment bodies

General terms and conditions

Under the Annex, the Designating authorities shall remain solely responsible for the competence and the capacity of the bodies they have designated and shall designate only legally identifiable bodies under their jurisdiction.

Designating authorities shall designate Conformity assessment bodies able to demonstrate by objective means that they understand and have the requisite experience and competence to apply the requirements and certification procedures laid down in the legislative, regulatory and administrative provisions referred to in Appendix 1, that are applicable to the specific product, product category or sector for which they are designated.

Demonstration of technical competence shall cover:

the conformity assessment body's technical knowledge of the relevant products, processes or services which it is willing to treat;

the understanding of the technical standards and/or legislative, regulatory and administrative provisions for which designation is sought;

the physical capability to perform a given conformity assessment activity;

the adequate management of the activity concerned; and

any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed at all times.

The technical competence criteria shall be based as far as possible on internationally accepted documents, such as the EN 45000 series of standards or equivalents as well as on supplemented interpretative documents as appropriate. However these documents clearly need to be interpreted in such a way as to take account of the different types of requirements laid down in the applicable legislative, regulatory and administrative provisions.

The Member States shall encourage harmonisation of designation procedures and co-ordination of conformity assessment procedures through co-operation between Designating authorities and Conformity assessment bodies based on co-ordination meetings, participation in mutual recognition arrangements, and *ad hoc* working party meetings. The Member States shall also encourage accreditation bodies to participate in mutual recognition arrangements. **B. System for verification of Conformity assessment bodies' competence**

In order to verify the technical competence of Conformity assessment bodies, the authorities concerned may use various procedures ensuring an appropriate level of trust between the Member States. If necessary, a Member State shall indicate to the Designating authority possible ways of demonstrating competence.

Accreditation. Accreditation shall constitute a presumption of the technical competence of Conformity assessment bodies in relation to the application of the requirements of the other Member States provided that the competent accreditation body:

complies with the relevant international provisions in force (EN 45000 standards or ISO/IEC guides); and

is signatory to multilateral arrangements under which it is subject to peer evaluation, or

takes part, under the authority of a Designating authority, and in accordance with whatever conditions are decided on, in programmes to conduct comparisons and exchange technical experience, in the interests of ensuring continued trust in the technical competence of the accreditation and conformity-assessment bodies. Such programmes could include joint evaluations, special co-operation exercises or conformity assessment.

Where the criteria applicable Conformity assessment bodies require the latter to assess the conformity of products, processes or services directly to standards or technical specifications, the Designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it enables assessment of those bodies' ability to apply such standards or technical specifications. Designation shall be limited to those activities of the conformity assessment body.

Where the criteria applicable Conformity assessment bodies require the latter to assess the conformity of products, processes or services not directly to standards or technical specifications, but to general (essential)

requirements, the Designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it incorporates elements which will enable assessment of the capacity of the Conformity assessment body (technical knowledge of the product, of its use, etc.) to assess the conformity of the product to those essential requirements. Designation shall be limited to those activities of the Conformity assessment body.

Other means. If there is no accreditation scheme, or on other grounds, the authorities concerned shall require the Conformity assessment bodies to demonstrate their competence by other means, e.g.:

participation in regional or international mutual recognition arrangements or certification systems;

regular peer evaluation, based on clear criteria and conducted with the appropriate expertise;

aptitude tests; or

comparison of Conformity assessment bodies. **C. Evaluation of the verification system**

Once a verification system to evaluate the competence of Conformity assessment bodies has been defined, the other Member States will be invited to check that the system guarantees the conformity of the designation process to its own legal requirements. Such checks shall focus on the appropriateness and effectiveness of the verification system rather than on the Conformity assessment bodies themselves. **D. Formal designation**

When the Member States submit their proposals to the Committee on the inclusion of Conformity assessment bodies in the Appendices, they shall provide the following details in respect of each body:

its name;

its postal address;

its fax number;

the Sectoral Chapter, product categories or products, processes and services covered by the designation;

the conformity assessment procedures covered by the designation;

the methods used to establish the body's competence.

[1]

Fyrstedømmet Liechtenstein er i tollunion med Sveits og vil derfor fortsatt benytte «sveitsisk opprinnelse».

[2]

In the context of this Annex, the expression «public telecommunications network» is to be interpreted for the purpose of Swiss law as «installations provided by a telecommunications services provider».