

II

(Acts whose publication is not obligatory)

COMMISSION

DECISION No 2/2002

of 8 January 2003

of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment on the modification of the Annex 1 of the Agreement

(2003/154/EC)

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition (the Agreement) in relation to Conformity Assessment signed on the 21 of June 1999, and in particular Article 10 (5) thereof,

Whereas the Agreement entered into force on 1 June 2002;

Whereas the text of some sectoral chapters of Annex 1 must be modified to take account of legislative changes and changes to designating authorities in Switzerland and the Community,

DECIDES AS FOLLOWS:

Article 1

The respective Sections of the following sectoral chapters of Annex 1 of the Agreement are deleted and replaced with the text at Attachment A:

- Chapter 1 on machinery; Sections I and III,
- Chapter 2 on personal protective equipment; Sections I and III,
- Chapter 4 on medical devices; Sections I, III, IV and V,
- Chapter 5 on gas appliances and boilers; Sections I and III,
- Chapter 6 on pressure vessels; Sections I, III, IV and V,
- Chapter 7 on telecommunications terminal equipment; Title and Sections I, III, IV and V,
- Chapter 8 on equipment and protective systems intended for use in potentially explosive atmospheres; Sections I and III,
- Chapter 9 on electrical equipment and electromagnetic compatibility; Sections I and III,
- Chapter 10 on construction plant and equipment; Sections I, III and IV,
- Chapter 11 on measuring instruments and prepackages; Sections I, III and V,

- Chapter 12 on motor vehicles; Sections I, III and V,
- Chapter 13 on agricultural and forestry tractors; Sections I, III and V,
- Chapter 14 on good laboratory practice (GLP); 'Scope and Coverage' and Sections I, III and IV,
- Chapter 15 on medicinal products GMP Inspection and Batch Certification; 'Scope and Coverage' and Sections I and II.

Article 2

This Decision, done in duplicate, is signed by the Co-Chairs or other persons authorised to act on behalf of the Parties.

This Decision shall be effective from the date of the later of these signatures.

Signed in Bern, 12 December 2002.

On behalf of the Swiss Confederation

Oscar ZOSSO

Signed in Brussels, 8 January 2003.

On behalf of the European Commission

Paul DE LUSIGNAN

ANNEX

Attachment A

CHAPTER 1

MACHINERY

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(2)*

European Community	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, 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)
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 27 March 2002 (RO 2002 853)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section III

Designating authorities*European Community:*

— Belgium:	Ministère de l'Emploi et du Travail/Ministerie voor Arbeid en Tewerkstelling
— Denmark:	Arbejdsministeriet, Arbejdstilsynet
— France:	Ministère de l'Emploi et de la Solidarité, Direction des relations du travail, Bureau CT 5
— Germany:	Bundesministerium für Arbeit und Sozialordnung
— Greece:	Ministry of Development. General Secretariat of Industry
— Spain:	Ministerio de Ciencia y Tecnología
— Ireland:	Department of Enterprise and Employment
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato
— Luxembourg:	Ministère du Travail (Inspection du travail et des Mines)
— Netherlands:	Minister van Sociale Zaken en Werkgelegenheid
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade
— Finland:	Sosiaali- ja terveystieteiden ministeriö/Social- och hälsovårdsministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
— United Kingdom:	Department of Trade and Industry
Switzerland:	State Secretariat for Economic Affairs

CHAPTER 2

PERSONAL PROTECTIVE EQUIPMENT

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(2)*

European Community	Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, 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)
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 27 March 2002 (RO 2002 853)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section III

Designating authorities*European Community:*

— Belgium:	Ministère de l'Emploi et du Travail/Ministerie voor Arbeid en Tewerkstelling
— Denmark:	Arbejdsministeriet, Arbejdstilsynet
— Finland:	Sosiaali- ja terveystieteiden ministeriö/Social- och hälsovårdsministeriet
— France:	Ministère de l'emploi et de la solidarité, Direction des relations du travail, Bureau CT 5 Ministère de l'Economie, des Finances et de l' Industrie, Direction générale de l'industrie, des technologies de l'information et des postes (DIGITIP) — SQUALPI
— Germany:	Bundesministerium für Arbeit und Sozialordnung
— Greece:	Ministry of Development. General Secretariat of Industry
— Spain:	Ministerio de Ciencia y Tecnología
— Ireland:	Department of Enterprise and Employment
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato
— Luxembourg:	Ministère du Travail (Inspection du Travail et des Mines)
— Netherlands:	Minister van Volksgezondheid, Welzijn en Sport
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
— United Kingdom:	Department of Trade and Industry
Switzerland:	State Secretariat for Economic Affairs

CHAPTER 4

MEDICAL DEVICES

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(2)*

European Community

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

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 (OJ L 6, 10.1.2002, p. 50)

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1)

Switzerland

Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790)

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 18 June 1999 (RO 1999 3071)

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 1993)

Ordinance of 17 October 2001 on medical devices (RO 2001 3487)

Section III

Designating authorities*European Community:*

— Belgium:

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

Ministère des Affaires Economiques/Ministerie van Economische Zaken

— Denmark:

Sundhedsministeriet, Sundhedsstyrelsen

— Germany:

Bundesministerium für Gesundheit

— Greece:

Ministry of Health

— Spain:

Ministerio Sanidad y Consumo

— France:

Agence française de sécurité sanitaire des produits de santé (AFSSAPS)

Ministère de l'Economie, des Finances et de l'Industrie. Direction générale de l'industrie, des technologies de l'information et des postes (DIGITIP) — SIM

— Ireland:

Department of Health

— Italy:

Ministero della Sanità

— Luxembourg:

Ministère de la Santé

— Netherlands:

Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid

— Austria:

Bundesministerium für soziale Sicherheit und Generationen

— Portugal:	Ministerio da Saude
— Finland:	Sosiaali- ja terveystieteiden ministeriö/Social- och hälsovårdsministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
— United Kingdom:	Department of Health, Medical Devices Agency
Switzerland:	Swissmedic, Swiss Agency for Therapeutic Products

Section IV

Special rules relating to the designation of conformity assessment bodies listed in Section II

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and those in Annex XI to Directive 93/42/EEC, in Annex VIII to Directive 90/385/EEC and in Annex IX to Directive 98/79/EC, in respect of the bodies designated under those Directives.

Section V

Additional provisions

1. Registration of the person responsible for placing devices on the market

Any manufacturer who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC or Article 10 of Directive 98/79/EC shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in those Articles. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. Labelling of medical devices

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices specified in Annex 1, point 13.3(a) to Directive 93/42/EEC and *in vitro* diagnostic medical devices specified in Annex 1, point 8.4(a), to Directive 98/79/EC. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

3. Information exchange

In accordance with Article 9 of the Agreement, the Parties shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC, Article 10 of Directive 93/42/EEC and Article 11 of Directive 98/79/EC.

4. European databank

The competent Swiss authorities shall have access to the European databanks established under Article 12 of Directive 98/79/EC and Article 14a of Directive 93/42/EEC. They shall transmit to the Commission and/or body responsible for managing the databank the data provided for in those Articles collected in Switzerland for entry into the European databank.

CHAPTER 5

GAS APPLIANCES AND BOILERS

Section I

Legislation, regulations and administrative provisions

Provisions covered by Article 1(1)

European Community	Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17), as subsequently amended
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(2)

European Community	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels, as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 1993, p. 1)
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 27 March 2002 (RO 2002 853)
	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783)

Section III

Designating authorities*European Community:*

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken
— Denmark:	Økonomi- og Erhvervsministeriet; Danmarks Gasmateriel Prøvning
— Germany:	Bundesministerium für Arbeit und Sozialordnung
— Greece:	Υπουργείο Ανάπτυξης, Γενική Γραμματεία Βιομηχανίας (Ministry of Development, General Secretariat of Industry)
— Spain:	Ministerio de Ciencia y Tecnología
— France:	Ministère de l'Economie, des Finances et de l'Industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI). Sous-direction de la sécurité industrielle
— Ireland:	Department of Enterprise and Employment
— Italy:	Ministero delle Attività Produttive
— Luxembourg:	Ministère du Travail (Inspection du Travail et des Mines)
— Netherlands:	Ministerie van Economische Zaken
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade
— Finland:	Kauppa- ja teollisuusministeriö/Handels- och industriministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontrol (SWEDAC)
— United Kingdom:	Department of Trade and Industry, Department for Environment, Food & Rural Affairs
Switzerland:	Provisions covered by Article 1(1) Swiss Agency for the Environment, Forests and Landscape Provisions covered by Article 1(2) State Secretariat for Economic Affairs

CHAPTER 6

PRESSURE VESSELS

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(1)*

European Community	<p>Council Directive 84/525/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders (OJ L 300, 19.11.1984, p. 1), as subsequently amended</p> <p>Council Directive 84/526/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders (OJ L 300, 19.11.1984, p. 20), as subsequently amended</p> <p>Council Directive 84/527/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders (OJ L 300, 19.11.1984, p. 48), as subsequently amended</p> <p>Council Directive 87/404/EEC of 25 June 1987 on the approximation of the laws of the Member States relating to simple pressure vessels (OJ L 220, 8.8.1987, p. 48), as subsequently amended</p> <p>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 No L 181, 9.7.1997, p. 1), as subsequently amended</p>
Switzerland	<p>No legislation relating to Directives 84/525/EEC, 84/526/EEC and 84/527/EEC: no related legislation.</p> <p>Relating to Directives 87/404/EEC and 97/23/EEC:</p> <p>Federal Law of 20 March 1981 on accident insurance (RS 832.20), as subsequently amended</p> <p>Ordinance of 19 March 1938 on installation and operation of pressure vessels (RS 832.312.12), as subsequently amended</p>

Section III

Designating authorities*European Community:*

— Belgium:	Ministère de l'Emploi et du Travail/Ministerie voor Arbeid en Tewerkstelling
— Denmark:	Arbejdsministeriet, Arbejdstilsynet
— Germany:	Bundesministerium für Arbeit und Sozialordnung
— Greece:	Ministry of Development. General Secretariat of Industry
— Spain:	Ministerio de Ciencia y Tecnología
— France:	Ministère de l'Economie, des Finances et de l'Industrie, Direction de l'action régionale et de la petite et moyenne industrie (DARPMI). Sous-direction de la sécurité industrielle
— Ireland:	Department of Enterprise and Employment
— Italy:	Ministero dell'Industria, del Commercio e dell'Artigianato
— Luxembourg:	Ministère du Travail et de l'Emploi
— Netherlands:	Minister van Sociale Zaken en Werkgelegenheid
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade

— Finland:	Kauppa- ja teollisuusministeriö/Handels- och industriministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
— United Kingdom:	Department of Trade and Industry
Switzerland:	State Secretariat for Economic Affairs

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 Annex 2 and those in Annex III to Directive 87/404/EEC or Annexes IV or V to Directive 97/23/EC.

Section V

Additional provisions

1. 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 designated Community body listed in Section II which certifies that the product conforms to either Directive 87/404/EEC or Directive 97/23/EC.

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 Parties for a period of at least ten years after the last date of manufacture of the product.

The Parties hereby undertake to forward all relevant documents at the request of the authorities of the other Party.

CHAPTER 7

RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT

Section I

Legislation, regulations and administrative provisions

Provisions covered by Article 1(2)

European Community
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10).

Commission Decision of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers (OJ L 97, 19.4.2000, p. 13)

Commission Decision of 22 September 2000 on the application of Article 3(3)(e) of Directive 1999/5/EC to radio equipment covered by the regional arrangement concerning radiotelephone service on inland waterways (OJ L 269, 21.10.2000, p. 50)

Commission Decision of 22 September 2000 on the application of Article 3(3)(e) of Directive 1999/5/EC to marine radio communication equipment intended to be fitted to seagoing non-SOLAS vessels and which is intended to participate in the global maritime distress and safety system (GMDSS) and not covered by Council Directive 96/98/EC on marine equipment (OJ L 269, 21.10.2000, p. 52)

Commission Decision of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons (OJ L 55, 24.2.2001, p. 65)

- Switzerland
- Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187)
- Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086)
- Ordinance of 14 June of the Federal Office for Communications (OFCOM) on Telecommunications Equipment (RO 2002 2111)
- Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115)
- List of technical standards published in the *Feuille Fédérale* with titles and references, as last amended on 24 April 2001
- Ordinance of 31 October 2001 on Telecommunication Services (RO 2001 2795), as last amended on 19 December 2001 (RO 2002 271)

Section III

Designating authorities*European Community:*

- Belgium: Institut belge des services postaux et des télécommunications
Belgisch Instituut voor Postdiensten en Telecommunicatie
- Denmark: Ministeriet for Videnskab, Teknologi og Udvikling, IT- og Telestyrelsen
- Germany: Bundesministerium für Wirtschaft und Technologie
- Greece: Ministry of Transport
- Spain: Ministerio de Ciencia y Tecnología
- France: Ministère de l'Economie, des Finances et de l'Industrie
Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DIGITIP), STSI
- Ireland: Department of Transport, Energy and Communications
- Italy: Ministero delle Comunicazione (aspects CEM) Ministero dell'Industria, del Commercio e dell'Artigianato
- Luxembourg: Ministère des Transports (aspects CEM) Administration des Postes et Télécommunications
- Netherlands: Ministerie van Economische Zaken
- Austria: Bundesministerium für Verkehr, Innovation und Technologie
- Portugal: Instituto das Comunicações de Portugal
- Finland: Liikenne- ja viestintäministeriö/Kommunikationsministeriet
- Sweden: Under the authority of the Government of Sweden:
Styrelsen för ackreditering och teknisk kontrol (SWEDAC)
- United Kingdom: Department of Trade and Industry
- 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 Annex 2 to this Agreement and those in Annex VI to Directive 1999/5/EC.

Section V

Additional provisions1. *TCAM*

Switzerland shall participate as observer in TCAM work and that of its subgroups.

2. *Market surveillance*

The Parties shall notify each other of the authorities established on their territory responsible for carrying out the surveillance tasks involved in the implementation of their legislation as set out in Section I.

The Parties shall notify each other of their market surveillance activities within the bodies designated for this purpose.

3. *Regulated interfaces*

The Parties shall inform each other of the interfaces they have regulated on their territory. When establishing the equivalence of notified interfaces and determining equipment class identifiers, the European Community shall take account of the interfaces regulated in Switzerland.

4. *Interfaces offered by public telecommunications network operators*

The Parties shall inform each other of interfaces offered on their territory by public telecommunications network operators.

5. *Application of essential requirements*

When the Commission intends to adopt a decision to apply a requirement set in Article 3(3) of Directive 1999/5/EC, it shall consult Switzerland on the issue before submitting it formally to the Committee.

When Switzerland intends to adopt a technical and administrative regulation to apply a requirement set in Article 7.4 of the Ordinance on Telecommunications Equipment, it shall consult the Commission on the issue before submitting it formally to the Committee.

6. *Authorisation to disconnect*

Where one of the Parties considers that apparatus declared to comply with its legislation causes serious damage to a network or radioelectric interference, or degradation of a network or its operation, and that Party has authorised the operator to refuse connection of the apparatus, disconnect it or withdraw it from service, it shall inform the other Party of this authorisation.

7. *Harmonised standards*

Where Switzerland considers that compliance with a harmonised standard does not guarantee that the essential requirements of its legislation as listed in Section I will be fulfilled, it shall inform the Committee and give its reasons.

The Committee shall consider the case and may ask the European Community to act in accordance with the procedure provided for in Article 5 of Directive 1999/5/EC. The Committee shall be informed of the result of the procedure.

8. *Mutual notification concerning radiocommunication equipment which conforms to requirements but is not intended for use in the spectrum of one of the parties*

When either of the Parties adopts any appropriate measure to prohibit or restrict the placing on its market and/or require the withdrawal from its market of radiocommunications equipment, including types of radio equipment which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands, it shall notify the other party thereof giving its reasons and naming the countries concerned.

9. *Safeguard clause relating to industrial products*

- 9.1. Where either of the Parties takes a measure to prohibit the placing of its market of a telecommunications installation declared to be in compliance with Directive 1999/5/EC, it shall immediately inform the other party, giving the reasons for its decision and stating how non compliance was established.
- 9.2. The Parties shall consider the measure and the evidence presented to them and shall notify each other of the results of their investigations.
- 9.3. If the parties agree regarding the results of their investigations they shall take the appropriate measures to ensure that such products are not placed on the market.
- 9.4. If the Parties disagree regarding the results of their investigations, the case shall be forwarded to the Committee, which may decide to have an expert study carried out.
- 9.5. Where the Committee considers that the measure is
 - (a) unjustified, the national authority of the Party which took the measure shall withdraw it;
 - (b) justified, they shall take the appropriate measures to ensure that products are not placed on the market

CHAPTER 8

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Section I

Legislation, regulations and administrative provisions

Provisions covered by Article 1(2)

European Community

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, 19.4.1994, p. 1)

Council Directive 76/117/EEC of 18 December 1975 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres (OJ L 24, 30.1.1976, p. 45)

Council Directive 79/196/EEC 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, as last amended by Commission Directive 97/53/EC of 11 September 1997 (OJ L 257, 20.9.1997, p. 27)

Council Directive 82/130/EEC 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, as last amended by Commission Directive 98/65/EC of 3 September 1998 (OJ L 257, 19.9.1998, p. 29)

Switzerland

Federal Law of 24 June 1902 concerning the electrical weak an heavy current installations (RO 19 252 and RS 4 798), as last amended on 18 June 1999 (RO 1999 3086)

Ordinance on of 2 March 1998 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 1998 963), as last amended on 2 February 2000 (RO 2002 763)

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 27 March 2002 (RO 2002 853)

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

Section III

Designating authorities*European Community:*

- Belgium: Ministère des Affaires Economiques/Ministerie van Economische Zaken
- Denmark: For electrical aspects:
Økonomi- og Erhvervsministeriet, Elektricetsrådet

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

CHAPTER 9

ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(2)*

European Community

Council Directive 73/23/EEC of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 77, 26.3.1973, p. 29), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)

Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)

- Switzerland
- Federal Law of 24 June 1902 concerning the electrical weak an heavy current installations (RO 19 252 and RS 4 798), as last amended on 18 June 1999 (RO 1999 3086)
- Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 2 February 2000 (RO 2000 739)
- Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 8 December 1997 (RO 1998 54)
- Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016), as last amended on 2 February 2000 (RO 2000 763)
- Ordinance of 9 April 1997 on electromagnetic compatibility (RO 1997 1008), as last amended on 4 December 2000 (RO 2000 3014)
- Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086)

Section III

Designating authorities*European Community:*

- Belgium: Ministère des Affaires Economiques/Ministerie van Economische Zaken
- Denmark: For electrical aspects:
Økonomi- og Erhvervsministeriet, Elektricitetsrådet
For EMC aspects:
Ministeriet for Videnskab, Teknologi og Udvikling, IT- og Telestyrelsen
- Germany: For electrical aspects:
Bundesministerium für Arbeit und Sozialordnung
For EMC aspects:
Bundesministerium für Wirtschaft und Technologie
- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry)
- Spain: Ministerio de Ciencia y Tecnología
- France: Ministère de l'Economie, des Finances et de l'Industrie. Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DIGITIP) — SQUALPI
- Ireland: Department of Enterprise and Employment
- Italy: Ministero delle Attività Produttive
- Luxembourg: Ministère de l'Economie — Service de l'Energie de l'Etat
Ministère du Travail (Inspection du Travail et des Mines)
- Netherlands: For electrical aspects:
Minister van Volksgezondheid, Welzijn en Sport (consumer goods). Minister van Sociale Zaken en Werkgelegenheid (others)
For EMC aspects:
Ministerie van Verkeer en Waterstaat
- Austria: Bundesministerium für Wirtschaft und Arbeit
- Portugal: Under the authority of the Government of Portugal:
Instituto Português da Qualidade

— Finland:	Kauppa- ja teollisuusministeriö/Handels- och industriministeriet For EMC aspects of telecommunications and radio equipment: Liikenne-javiestintäministeriö/Kommunikationsministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontrol (SWEDAC)
— United Kingdom:	Department of Trade and Industry
Switzerland:	Federal Office of Energy Federal Office for Communications (for EMC aspects of radio- and telecommunications terminal equipment)

CHAPTER 10

CONSTRUCTION PLANT AND EQUIPMENT

Section I

Legislation, regulations and administrative provisions*Provisions covered by Article 1(1)*

European Community	Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (O) L No 162, 3.7.2000, p. 1)
Switzerland	No legislation

Section III

Designating authorities*European Community:*

— Belgium:	Ministère de l'Emploi et du Travail/Ministerie voor Arbeid en Tewerkstelling
— Denmark:	National Agency for Enterprise and Housing
— Germany:	
— Greece:	Ministry of Environment and Public Works
— Spain:	Ministerio de Ciencia y Tecnología Ministerio de Fomento
— France:	
— Ireland:	
— Italy:	
— Luxembourg:	
— Netherlands:	Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieu
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	
— Finland:	Ympäristöministeriö/Miljöministeriet

- Sweden: For Directive 2000/14/EC, under the Government of Sweden:
Styrelsen för ackreditering och teknisk kontroll
- United Kingdom: Department of Trade and Industry
- Switzerland: Swiss Agency for the 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 Annex 2 and those in Annex IX to Directive 2000/14/EC of the European Parliament and the Council.

CHAPTER 11

MEASURING INSTRUMENTS AND PREPACKAGES

Section I

Legislation, regulations and administrative provisions

Provisions covered by Article 1(1)

European Community

Council Directive 71/347/EEC 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 (OJ L No 239, 28.10.1971), as subsequently amended

Council Directive 71/349/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to the calibration of the tanks of vessels (OJ L 239, 28.10.1971, p. 15), as subsequently amended

Council Directive 75/33/EEC of 17 December 1974 on the approximation of the laws of the Member States relating to cold-water meters (OJ L 14, 20.1.1975, p. 1), as subsequently amended

Council Directive 76/765/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholometers and alcohol hydrometers (OJ L 262, 27.9.1976, p. 143), as subsequently amended

Council Directive 77/95/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters (OJ L 26, 31.1.1977, p. 59), as subsequently amended

Council Directive 78/1031/EEC of 5 December 1978 on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines (OJ L 364, 27.12.1978), as subsequently amended

Council Directive 79/830/EEC of 11 September 1979 on the approximation of the laws of the Member States relating to hot-water meters (OJ L 259, 15.10.1979, p. 1), as subsequently amended

Council Directive 86/217/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (OJ L 152, 6.6.1986, p. 48), as subsequently amended

Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments (OJ L 189, 20.7.1990, p. 1), as subsequently amended

Council Directive 75/106/EEC 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 (OJ L 42, 15.2.1975, p. 1), as subsequently amended

Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14), as subsequently amended

Council Directive 76/211/EEC 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 (OJ L 46, 21.2.1976, p. 1), as subsequently amended

Council Directive 80/232/EEC 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 (OJ L 51, 25.2.1980, p. 1), as subsequently amended

Switzerland	<p>Ordinance of 21 May 1986 on measuring instruments for thermal energy (RS 941.231), as subsequently amended</p> <p>Ordinance of 8 June 1998 concerning the measurement and declaration of quantities of goods in trade (RS 941.281), as subsequently amended</p> <p>Ordinance of 12 June 1998 on technical provisions concerning the declaration of quantities on industrial pre-packages (RS 941.281.1), as subsequently amended</p> <p>Ordinance of 2 November 1999 of the Federal Ministry of Justice and Police on volume measures (RS 941.211), as subsequently amended</p> <p>Ordinance of 17 December 1984 on the qualification of measuring instruments (RS 941.210), as subsequently amended</p> <p>Ordinance of 15 August 1986 on weighing instruments (RS 941.221.1), as subsequently amended</p>
<i>Provisions covered by Article 1(2)</i>	
European Community	<p>Directive 1999/103/EC of the European Parliament and of the Council of 24 January 2000 amending Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement (OJ L 34, 9.2.2000, p. 17)</p> <p>Council Directive 71/316/EEC 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, as last amended by Council Directive 88/665/EEC of 21 December 1988 (OJ No L 382, 31.12.1988, p. 42)</p> <p>Council Directive 71/317/EEC 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 (OJ No L 202, 6.9.1971, p. 14)</p> <p>Council Directive 71/318/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to gas volume meters, as last amended by Commission Directive 82/623/EEC of 1 July 1982 (OJ No L 252, 27.8.1982, p. 5)</p> <p>Council Directive 71/319/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to meters for liquids other than water (OJ No L 202, 6.9.1971, p. 32)</p> <p>Council Directive 71/348/EEC 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 (OJ No L 239, 25.10.1971, p. 9)</p> <p>Council Directive 73/362/EEC of 19 November 1973 on the approximation of the laws of the Member States relating to material measures of length, as last amended by Commission Directive 85/146/EEC of 31 January 1985 (OJ No L 54, 23.2.1985, p. 29)</p> <p>Council Directive 74/148/EEC 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 (OJ No L 84, 28.3.1974, p. 3)</p> <p>Council Directive 75/410/EEC of 24 June 1975 on the approximation of the laws of the Member States relating to continuous totalizing weighing machines (OJ No L 183, 14.7.1975, p. 25)</p> <p>Council Directive 76/766/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (OJ No L 262, 27.9.1976, p. 149)</p> <p>Council Directive 76/891/EEC of 4 November 1976 on the approximation of the laws of the Member States relating to electrical energy meters, as last amended by Commission Directive 82/621/EEC of 1 July 1982 (OJ No L 252, 27.8.1982, p. 1)</p> <p>Council Directive 77/313/EEC of 5 April 1977 on the approximation of the laws of the Member States relating to measuring systems for liquids other than water, as last amended by Commission Directive 82/625/EEC of 1 July 1982 (OJ No L 252, 27.8.1982, p. 10)</p>

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 the electrical energy and power (RO 1986 1496)

Section III

Designating authorities*Provisions covered by Article 1(1)**European Community:*

— Belgium:	Ministère des Affaires Economiques/Ministerie van Economische Zaken
— Denmark:	National Agency for Enterprise and Housing
— Germany:	
— Greece:	Ministry of Development, General Secretariat of Consumer
— Spain:	Ministerio de Fomento
— France:	Measuring Instruments: Ministère de l'Economie, des Finances et de l'Industrie, Direction de l'action régionale et de la petite et moyenne industrie, Sous-direction de la métrologie Prepackages: Ministère de l'Economie, des Finances et de l'Industrie, Direction générale de la consommation, de la concurrence et de la répression des fraudes
— Ireland:	
— Italy:	
— Luxembourg:	
— Netherlands:	Minister van Economische Zaken
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	
— Finland:	Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll For Directive 75/33/EEC and Directive 79/830/ECC, Boverket For Directive 77/95/EEC, Vägverket
— United Kingdom:	Department of Trade and Industry

Switzerland:	Federal Office of Metrology and Accreditation
<i>Provisions covered by Article 1(2)</i>	
<i>European Community:</i>	
— Belgium:	Ministère des Affaires Economiques/ Ministerie van Economische Zaken
— Denmark:	National Agency for Enterprise and Housing
— Germany:	
— Greece:	Ministry of Development, General Secretariat of Consumer
— Spain:	Ministerio de Fomento
— France:	
— Ireland:	
— Italy:	
— Luxembourg:	
— Netherlands:	Minister van Economische Zaken
— Austria:	Bundesministerium für Wirtschaft und Arbeit
— Portugal:	
— Finland:	Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll For Directive 75/33/EEC and Directive 79/830/ECC, Boverket For Directive 77/95/EEC, Vägverket
— United Kingdom:	Department of Trade and Industry
Switzerland:	Federal Office of Metrology and Accreditation

Section V

Additional provisions

1. Information exchange

The conformity assessment bodies listed in Section II shall periodically provide the Member States and the competent Swiss authorities with the information provided for in point 1.5 of Annex II to Directive 90/384/EEC.

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.

2. Prepackages

Switzerland shall recognise checks carried out in accordance with the provisions of Community legislation listed in Section I by a Community body listed in Section II in the case of Community prepackages placed on the market in Switzerland.

As regards statistical checking of the quantities declared on prepackages, the European Community shall recognise the Swiss method laid down in Articles 3 to 17 of the Ordinance on technical provisions concerning the declaration of quantities on industrial pre-packages (RS 941.281.1) as equivalent to the Community method laid down in Annex II of Directives 75/106/EEC and 76/211/EEC, as amended by Directive 78/891/EEC. Swiss producers whose prepackages conform to Community legislation and have been checked according to the Swiss method shall affix the 'e' mark on their products exported to the EC.

3. Marking

3.1. For the purposes of this Agreement, the provisions of Council Directive 71/316/EEC of 26 July 1971 shall be read with the following adaptations:

(a) To the first indent of point 3.1 of Annex I and to the first indent of point 3.1.1.1 (a) of Annex II, the following shall be added to the text in brackets: 'CH for Switzerland';

(b) The drawings to which Annex II point 3.2.1 refers, shall be supplemented by the letters necessary for the sign 'CH'.

3.2. For the purposes of this Agreement, the Ordinance on the qualification of measuring instruments (RS 941.210) shall be read with the following amendments:

In the Annex, the text under point 3, signs identifying the service issuing the stamp; the following shall be added:

'3.5. Offices of the Member States of the Community'.

The Member States of the European Community shall be identified using the acronyms defined in Annex II to Directive 71/316/EEC.

3.3. By way of derogation from the last sentence of Article 1(2) of this Agreement, the rules on marking for measuring instruments placed on the Swiss market are as follows:

Where Swiss and Community legislation are deemed equivalent within the meaning of Article 1(2) of this Agreement, the marking that must be affixed is the CE marking or the national sign of the EC Member State concerned as provided in the first indent of point 3.1 of Annex I and the first indent of point 3.1.1.1 of Annex II to Council Directive 71/316/EEC of 26 July 1971.

Where the measuring instruments are subject to the legislation referred to in Article 1(1) of this Agreement, the marking to be affixed shall be the Swiss sign provided for under points 1 (approval mark) or 21 (verification mark) of the Annex to the Ordinance on the qualification of measuring instruments (RS 941.210) combined with the CE marking and the national sign(s) of the EC Member State concerned as provided in Annex I, point 3.1, first indent and Annex II, point 3.1.1.1, first indent, to Directive 71/316/EEC.

4. Weighing instruments

By way of derogation from Article 1(2) of this Agreement, Switzerland shall recognise certificates confirming the compliance of weighing instruments with Directive 90/384/EEC.

CHAPTER 12

MOTOR VEHICLES

Section I

Legislation, regulations and administrative provisions

Provisions covered by Article 1(2)

European Community

Council Directive 70/156/EEC 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, as last amended by Commission Directive 2001/116/EC of 20 December 2001 (OJ L 18, 21.1.2002, p. 1)

Council Directive 70/157/EEC 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, as last amended by Commission Directive 99/101/EC of 15 December 1999 (OJ L 334, 28.12.1999, p. 41)

Council Directive 70/220/EEC 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, as last amended by Directive 2001/100/EC of the European Parliament and of the Council of 7 December 2001 (OJ L 16, 18.1.2002, p. 32)

Council Directive 70/221/EEC 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, as last amended by Commission Directive 2000/8/EC of 20 March 2000 (OJ L 106, 3.5.2000, p. 7)

Council Directive 70/222/EEC 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 (OJ L 76, 6.4.1970, p. 25) as last adjusted by Council Decision of 1 January 1973 (OJ L 2, 1.1.1973, p. 1)

Council Directive 70/311/EEC 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, as last amended by Commission Directive 99/7/EC of 26 January 1999 (OJ L 40, 13.2.1999, p. 36)

Council Directive 70/387/EEC of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers as last amended by Commission Directive 2001/31/EC of 8 May 2001 (OJ L 130, 12.5.2001, p. 33)

Council Directive 70/388/EEC of 27 July 1970 on the approximation of the laws of the Member States relating to audible warning devices for motor vehicles as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11.7.1987, p. 43)

Council Directive 71/127/EEC of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles, as last amended by Commission Directive 88/321/EEC of 16 May 1988 (OJ L 147, 14.6.1988, p. 77)

Council Directive 71/320/EEC 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, as last amended by Commission Directive 98/12/EC of 27 January 1998 (OJ L 81, 18.3.1998, p. 1)

Council Directive 72/245/EEC 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, as last amended by Commission Directive 95/54/EC of 31 October 1995 (OJ L 266, 8.11.1995, p. 1)

Council Directive 72/306/EEC 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, as last amended by Commission Directive 97/20/EC of 18 April 1997 (OJ L 125, 16.5.1997, p. 21)

Council Directive 74/60/EEC 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), as last amended by Commission Directive 2000/4/EC of 28 February 2000 (OJ L 87, 8.4.2000, p. 22)

Council Directive 74/61/EEC 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, as last amended by Commission Directive 95/56/EC of 8 November 1995 (OJ L 286, 29.11.1995, p. 1) and corrigenda (OJ L 40, 13.2.1998, p. 18 and OJ L 103, 3.4.1998, p. 38)

Council Directive 74/297/EEC 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), as last amended by Commission Directive 91/662/EEC of 6 December 1991 (OJ L 366, 31.12.1991, p. 1) and corrigendum (OJ L 172, 27.6.1992, p. 86)

Council Directive 74/408/EEC 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), as last amended by Commission Directive 96/37/EC of 17 June 1996 (OJ L 186, 25.7.1996, p. 28) and corrigenda (OJ L 214, 23.8.1996, p. 27 and OJ L 221, 31.8.1996, p. 71)

Council Directive 74/483/EEC of 17 September 1974 on the approximation of the laws of the Member States relating to the external projections of motor vehicles, as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11.7.1987, p. 43)

Council Directive 75/443/EEC of 26 June 1975 on the approximation of the laws of the Member States relating to the reverse and speedometer equipment of motor vehicles, as last amended by Commission Directive 97/39/EC of 24 June 1997 (OJ L 177, 5.7.1997, p. 15)

Council Directive 76/114/EEC 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, as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11.7.1987, p. 43.)

Council Directive 76/115/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts, as last amended by Commission Directive 96/38/EC of 17 June 1996 (OJ L 187, 26.7.1996, p. 95) and corrigendum (OJ L 76, 18.3.1997, p. 35)

Council Directive 76/756/EEC 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, as last amended by Commission Directive 97/28/EC of 11 June 1997 (OJ L 171, 30.6.1997, p. 1) completed by the technical requirements of Regulation No 48 (OJ L 203, 30.7.1997, p. 1)

Council Directive 76/757/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers, as last amended by Commission Directive 97/29/EC of 11 June 1997 (OJ L 171, 30.6.1997, p. 11) completed by the technical requirements of Regulation No 3 (OJ L 203, 30.7.1997, p. 39)

Council Directive 76/758/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to rear position (side) lamps and stop lamps for motor vehicles and their trailers, as last amended by Commission Directive 97/30/EC of 11 June 1997 (OJ L 171, 30.6.1997, p. 25) completed by the technical requirements of Regulations No 7, 87 and 91 (OJ L 203, 30.7.1997, p. 55, 63 and 67)

Council Directive 76/759/EEC 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, as last amended by Commission Directive 99/15/EC of 16 March 1999 (OJ L 97 12.4.1999, p. 14)

Council Directive 76/760/EEC 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, as last amended by Council Directive 97/31/EC of 11 June 1997 (OJ L 171, 30.6.1997, p. 49) completed by the technical requirements of Regulation No 4 (OJ L 203, 30.7.1997, p. 74)

Council Directive 76/761/EEC 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, as last amended by Commission Directive 99/17/EC of 18 March 1999 (OJ L 97, 12.4.1999, p. 45)

Council Directive 76/762/EEC 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, as last amended by Council Directive 99/18/EC of 18 March 1999 (OJ L 97, 12.4.1999, p. 82)

Council Directive 77/389/EEC of 17 May 1977 on the approximation of the laws of the Member States relating to motor-vehicle towing-devices, as last amended by Commission Directive 96/64/EC of 2 October 1996 (OJ L 258, 11.10.1996, p. 26)

Council Directive 77/538/EEC 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, as last amended by Commission Directive 99/14/EC of 16 March 1999 (OJ L 97, 12.4.1999, p. 1)

Council Directive 77/539/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers, as last amended by Commission Directive 97/32/EC (OJ L 171, 30.6.1997, p. 63) completed by the technical requirements of Regulation No 23 (OJ L 203, 30.7.1997, p. 79)

Council Directive 77/540/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to parking lamps for motor vehicles, as last amended by Commission Directive 99/16/EC of 16 March 1999 (OJ L 97, 12.4.1999, p. 33)

Council Directive 77/541/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles, as last amended by Commission Directive 2000/3/EC of 22 February 2000 (OJ L 53, 25.2.2000, p. 1)

Council Directive 77/649/EEC of 27 September 1977 on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers, as last amended by Commission Directive 90/630/EEC of 30 October 1990 (OJ L 341, 6.12.1990, p. 20)

Council Directive 78/316/EEC 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), as last amended by Commission Directive 94/53/EC of 15 November 1994 (OJ L 299, 22.11.1994, p. 26)

Council Directive 78/317/EEC 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 (OJ L 81, 28.3.1978, p. 27) and corrigendum (OJ L 194, 19.7.1978, p. 30)

Council Directive 78/318/EEC of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles, as last amended by Commission Directive 94/68/EC of 16 December 1994 (OJ L 354, 31.12.1994, p. 1)

Council Directive 78/548/EEC 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, as last repealed by the Directive 2001/56/EC of the European Parliament and of the Council of 27 September 2001 (OJ L 292, 9.11.2001, p. 21)

Council Directive 78/549/EEC of 12 June 1978 on the approximation of the laws of the Member States relating to the wheel guards of motor vehicles, as last amended by Commission Directive 94/78/EC of 21 December 1994 (OJ L 354, 31.12.1994, p. 10) and corrigendum (OJ L 153, 4.7.1995, p. 35)

Council Directive 78/932/EEC of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles, as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11.7.1987, p. 43)

Council Directive 80/1268/EEC of 16 December 1980 on the approximation of the laws of the Member States relating to the fuel consumption of motor vehicles, as last amended by Commission Directive 99/100/EC of 15 December 1999 (OJ L 334, 28.12.1999, p. 36)

Council Directive 80/1269/EEC of 16 December 1980 on the approximation of the laws of the Member States relating to the engine power of motor vehicles, as last amended by Commission Directive 99/99/EC of 15 December 1999 (OJ L 334, 28.12.1999, p. 32)

Council Directive 88/77/EEC 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, as last amended by Commission Directive 2001/27/EC of 10 April 2001 (OJ L 107, 18.4.2001, p. 10) and corrigendum (OJ L 266, 6.10.2001, p. 15)

Council Directive 89/297/EEC 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 (OJ L 124, 5.5.1989, p. 1)

Council Directive 89/459/EEC 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 (OJ L 226, 3.8.1989, p. 4)

Council Directive 91/226/EEC 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 (OJ L 103, 23.4.1991, p. 5)

Council Directive 92/6/EEC of 10 February 1992 on the installation and use of speed limitation devices for certain categories of motor vehicles in the Community (OJ L 57, 2.3.1992, p. 27) and corrigendum (OJ L 244, 30.9.1993, p. 34)

Council Directive 92/21/EEC of 31 March 1992 on the masses and dimensions of motor vehicles of category M1, as last amended by Commission Directive 95/48/EC of 20 September 1995 (OJ L 233, 30.9.1995, p. 73) and corrigenda (OJ L 252, 20.10.1995, p. 27 and OJ L 304, 16.12.1995, p. 60)

Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers, as last amended by Commission Directive 2001/92/EC of 30 October 2001 (OJ L 291, 8.11.2001, p. 24)

Council Directive 92/23/EEC of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting, as last amended by Directive 2001/43/EC of the European Parliament and of the Council of 27 June 2001 (OJ L 211, 4.8.2001, p. 25)

Council Directive 92/24/EEC of 31 March 1992 relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles Directive (OJ L 129, 14.5.1992, p. 154) and corrigendum (OJ L 244, 30.9.1993, p. 34)

Council Directive 92/114/EEC of 17 December 1992 relating to the external projections forward of the cab's rear panel of motor vehicles of category N (OJ L 409, 31.12.1992, p. 17)

Directive 94/20/EC 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 (OJ L 195, 29.7.1994, p. 1)

Directive 95/28/EC 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 (OJ L 281, 23.11.1995, p. 1)

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) and corrigendum (OJ L 102, 19.4.1997, p. 46)

Council Directive 96/53/EC 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 (OJ L 235, 17.9.1996, p. 59)

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, as last amended by Commission Directive 1999/98/EC of 15 December 1999, (OJ L 9, 13.1.2000, p. 14)

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, as last amended by Directive 2001/85/EC of the European Parliament and of the Council of 20 November 2001 (OJ L 42, 13.2.2002, p. 1)

Directive 98/91/EC of the European Parliament and of the Council of 14 December 1998 relating to motor vehicles and their trailers intended for the transport of dangerous goods by road and amending Directive 70/156/EEC relating to the type approval of motor vehicles and their trailers (OJ L 11, 16.1.1999, p. 25)

Directive 2000/40/EC of the European Parliament and of the Council of 26 June 2000 on the approximation of the laws of the Member States relating to the front underrun protection of motor vehicles and amending Council Directive 70/156/EEC. (OJ L 203 10.8.2000, p. 9)

Directive 2001/56/EC of the European Parliament and of the Council of 27 September 2001 relating to heating systems for motor vehicles and their trailers, amending Council Directive 70/156/EEC and repealing Council Directive 78/548/EEC, (OJ L 292, 9.11.2001, p. 21)

Directive 2001/85/EC of the European Parliament and of the Council of 20 November 2001 relating to special provisions for vehicles used for the carriage of passengers comprising more than eight seats in addition to the driver's seat, and amending Directives 70/156/EEC and 97/27/EC (OJ L 42, 13.2.2002, p. 1)

Switzerland

Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as last amended on 21 August 2002 (RO 2002 3178)

Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 6 September 2000 (RO 2000 2291)

Section III

Designating authorities*European Community:*

— Belgium:	Ministère des Communications et de l'Infrastructure Ministerie van Verkeer en Infrastructuur
— Denmark:	Road safety and Transport Agency
— Germany:	Bundesministerium für Verkehr, Bau- und Wohnungswesen
— Greece:	Ministry of Transport
— Spain:	Ministerio de Ciencia y Tecnología
— France:	Ministère des Transports
— Ireland:	Department of Enterprise and Employment
— Italy:	Ministero dei Trasporti
— Luxembourg:	Ministère des Transports
— Netherlands:	Rijksdienst voor het Wegverkeer
— Austria:	Bundesministerium für Verkehr, Innovation und Technologie
— Portugal:	Direcção-Geral de Viação
— Finland:	Liikenneministeriö/Trafikministeriet
— Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) Vägverket Statens Naturvårdsverk (for emissions aspects: Directives 70/220/EEC, 72/306/EEC, 88/77/EEC, 77/537/EEC and 2000/25/EC)
— United Kingdom:	Department for Transport, Vehicle Certification Agency
<i>Switzerland:</i>	Federal Roads Authority Worbentalstrasse 68, Ittigen CH-3003 Berne, Switzerland

Section V

Supplementary provisions

The provisions of this section shall apply exclusively to relations between Switzerland and the Community.

1. Information exchange

The competent type-approval authorities in Switzerland and the Member States shall in particular exchange the information referred to in Article 4(5) and (6) of Directive 70/156/EEC, as last amended by Commission Directive 2001/116/EC of 20 December 2001.

In the event of refusal by Switzerland or the Member States to grant type-approval in accordance with Article 4(2) of Directive 70/156/EEC, as last amended by Directive 2001/116/EC, their competent authorities shall notify each other of their decision and give the reasons for it. The competent Swiss authority shall likewise inform the Commission thereof.

2. Recognition of vehicle type-approval

Switzerland shall also recognise vehicle type-approval granted before the entry into force of this Agreement in accordance with Directive 70/156/EEC, as last amended by Directive 2001/116/EC, by the authorities responsible for type-approval listed in section II of this Chapter where that approval is still valid in the EC.

The European Community shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of Directive 70/156/EEC, as last amended by Directive 2001/116/EC.

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

3. *Vehicle type-approval safeguard clauses*

Registration and entry into service

1. Each Member 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 Member 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.

2. Each Member 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.

3. If a Member 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 other Member States, Switzerland and the Commission thereof, stating the reasons on which its decision is based. If the Member State or Switzerland which granted type-approval disputes the risk to road safety notified to it, the Member States or Switzerland concerned shall endeavour to settle the dispute. The Commission and 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

1. When a Member State or Switzerland grants type-approval, it shall take the necessary measures in accordance with Annex X to Framework Directive 70/156/EEC, as last amended by Directive 2001/116/EC, in relation to that approval to verify, if need be in cooperation with the approval authorities of the other Member 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.

2. When a Member 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, as last amended by Directive 2001/116/EC, in relation to that approval to verify, if need be in cooperation with the approval authorities of the other Member 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, as last amended by Directive 2001/116/EC, and in those separate Directives that contain specific requirements.

Nonconformity with the approved type

1. 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 Member 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.

2. Where a Member 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 Member State or Switzerland shall notify those of the other Member States and/or Switzerland of the measures taken which may extend to withdrawal of type-approval.

3. If a Member 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 Member 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.

4. 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 Member 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 Member State or Switzerland making the request.

Where a failure to conform is established, the approval authorities of the Member 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 Article 11 (2) of Directive 70/156/EEC, as last amended by Directive 2001/116/EC.

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

6. If the Member State or Switzerland which granted type-approval disputes the failure to conform notified to it, the Member States concerned and Switzerland shall endeavour to settle the dispute. The Commission and 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

Legislation, regulations and administrative provisions

Provisions covered by Article 1(2)

European Community

Council Directive 74/150/EEC 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, as last amended by Commission Directive 2001/3/EC of 8 January 2001 (OJ L 28, 30.1.2001, p. 1)

Council Directive 74/151/EEC 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, as last amended by Commission Directive 98/38/EC of 3 June 1998, (OJ L 170, 16.6.1998, p. 13)

Council Directive 74/152/EEC 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, as last amended by Directive 98/89/EC of the European Parliament and the Council of 20 November 1998 (OJ L 322, 1.12.1998, p. 40)

Council Directive 74/346/EEC 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, as last amended by Commission Directive 98/40/EC of 8 June 1998, (OJ L 171, 17.6.1998, p. 28) and corrigendum (OJ L 351, 29.12.1998, p. 42)

Council Directive 74/347/EEC 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, 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)

Council Directive 75/321/EEC 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, as last amended by Commission Directive 98/39/EC of 5 June 1998 (OJ L 170, 16.6.1998, p. 15)

Council Directive 75/322/EEC 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, as last amended by Commission Directive 2001/3/EC of 8 January 2001 (OJ L 28, 30.1.2001, p. 1)

Council Directive 76/432/EEC 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, 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)

Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, as last amended by Directive 99/86/EC of the European Parliament and the Council of 11 November 1999 (OJ L 297, 18.11.1999, p. 22) and corrigendum (OJ L 87, 8.4.2000, p. 34)

Council Directive 77/311/EEC 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, as last amended by Decision 2000/63/EC of the Commission of 18 January 2000 (OJ L 22, 27.1.2000, p. 66)

Council Directive 77/536/EEC 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, as last amended by Commission Directive 99/55/EC of 1 June 1999 (OJ L 146, 11.6.1999, p. 28)

Council Directive 77/537/EEC 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, 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)

Council Directive 78/764/EEC 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, as last amended by Directive 99/57/EC of the Commission of 7 June 1999 (OJ L 148, 15.6.1999, p. 35)

Council Directive 78/933/EEC 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, as last amended by Directive 99/56/EC of the Commission 3 June 1999 (OJ L 146, 11.6.1999, p. 31)

Council Directive 79/532/EEC 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, 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)

Council Directive 79/533/EEC 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, as last amended by Directive 99/58/EC of the Commission of 7 June 1999 (OJ L 148, 15.6.1999, p. 37)

Council Directive 79/622/EEC 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), as last amended by Commission Directive 99/40/EC of 6 May 1999 (OJ L 124, 18.5.1999, p. 11)

Council Directive 80/720/EEC 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, 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)

Council Directive 86/297/EEC 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, 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)

Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Commission Directive 2000/19/EC of 13 April 2000 (OJ L 94, 14.4.2000, p. 31)

Council Directive 86/415/EEC of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors, 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)

Council Directive 87/402/EEC 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, as last amended by Commission Directive 2000/22/EC of 28 April 2000 (OJ L 107, 4.5.2000, p. 26)

Council Directive 89/173/EEC 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, as last amended by Commission Directive 2000/1/EC of 14 January 2000 (OJ L 21, 26.1.2000, p. 16)

Directive 2000/25/EC of the European Parliament and of the Council of 22 May 2000 on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors and amending Council Directive 74/150/EEC (OJ L 173, 12.7.2000, p. 1)

Switzerland

Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 21 August 2002 (RO 2002 3182)

Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 6 September 2000 (RO 2000 2291)

Section III

Designating authorities

European Community:

- Belgium: Ministère des Communications et de l'Infrastructure
Ministerie van Verkeer en Infrastructuur
- Denmark: Road safety and Transport Agency
- Germany: Kraftfahrt-Bundesamt
- Greece: Ministry of Transport
- Spain: Ministerio de Ciencia y Tecnología
- France: Ministère des Transports
- Ireland: Department of Enterprise and Employment
- Italy: Ministero dei Trasporti
- Luxembourg: Ministère des Transports
- Netherlands: Rijksdienst voor het Wegverkeer
- Austria: Bundesministerium für Verkehr, Innovation und Technologie
- Portugal: Direcção-Geral de Viação
- Finland: Liikenneministeriö/Trafikministeriet
- Sweden: Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) Vägverket Statens Naturvårdsverk (for emissions aspects: Directives 70/220/EEC, 72/306/EEC, 88/77/EEC, 77/537/EEC and 2000/25/EC)
- United Kingdom: Vehicle Certification Agency

Switzerland:

Federal Roads Authority Worblentalstrasse 68, Ittigen CH-3003 Berne, Switzerland

Section V

Supplementary provisions

The provisions of this section shall apply exclusively to relations between Switzerland and the Community.

1. Information exchange

The competent Member State's and Swiss authorities shall notify each other of conforming (Article 5 and 6, Directive 74/150/EEC, as last amended) or non-conforming (Article 8, Directive 74/150/EEC, as last amended by Commission Directive 2001/3/EC) vehicles, devices and systems placed on the market.

In the event of refusal by Switzerland or the Member States to grant type-approval in accordance with Article 4 of Directive 74/150/EEC, as last amended by Directive 2001/3/EC, 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 tractor or separate technical unit type-approvals granted before the entry into force of this Agreement in accordance with Directive 74/150/EEC, as last amended by Commission Directive 2001/3/EC, by the authorities responsible for type-approval in the EU Member States where that approval is still valid in the EC.

The European Community shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of Directive 74/150/EEC, as last amended by Commission Directive 2001/3/EC.

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

*3. Vehicle type-approval safeguard clauses*Registration and entry into service

1. Each Member State and Switzerland shall permit the registration, the sale or entry into service of new tractors on grounds relating to their construction and operation if, and only if, they are accompanied by a valid certificate of conformity.

2. Each Member State and Switzerland shall permit the sale or entry into service of 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.

3. If a Member State or Switzerland finds that tractors of a particular type maybe a hazard to safety on the road or at work, although they are accompanied by a valid certificate of conformity, it may, for a maximum period of six months, refuse to register new tractors of that type or may prohibit their sale, entry into service or use in its territory. It shall forthwith notify the other Member States, Switzerland and the Commission thereof, stating the reasons on which its decision is based. The Commission shall within six weeks consult the States concerned by the dispute (Member States or Switzerland). The Commission shall deliver an opinion without delay and take appropriate steps.

Measures related to the conformity of production

1. When a Member State or Switzerland grants type-approval, it shall take the necessary measures to verify, if need be in cooperation with the approval authorities of the other Member States or Switzerland, that production models conform to the approved prototype. Such verification shall be limited to spot checks.

2. When a Member State or Switzerland has granted a type approval, it shall take the necessary measures to ensure that it is informed of any cessation of production and of any change in particulars appearing in the information document. If the State in question finds that an amendment to an information document warrants fresh checks or fresh tests and that it is accordingly necessary to amend the existing type-approval certificate or complete a new type-approval certificate, the competent authorities of that state shall inform the manufacturer thereof and shall, within one month of such new documents being completed, send them to the competent authorities of the other Member States or Switzerland.

Nonconformity with the approved type

1. There shall be failure to conform to the approved type where deviations from the particulars in the information document are found to exist and where these deviations have not been authorised under Article 6(2) or (3) of the Directive 74/150/EEC, as last amended by Directive 2001/3/EC, by the Member State or Switzerland which granted the type-approval. A tractor shall not be considered to deviate from the approved type where tolerances are permitted by separate Directives and these tolerances are respected.

2. Where a Member State or Switzerland has granted type-approval and finds that a number of tractors accompanied by a certificate of conformity do not conform to the type it has approved, it shall take the necessary measures to ensure that production models conform to the approved type. The approval authorities of that Member State or Switzerland shall notify those of the other Member States and/or Switzerland of the measures taken which may extend to withdrawal of the type-approval. The said authorities shall take like measures if they are informed by the type-approval authorities of another Member State or Switzerland of such failure to conform.

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

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

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 this Agreement concerning origin do not apply.

Unless specific definitions are given, the definition of terms in the 'OECD Principles of Good Laboratory Practice' as revised in 1997 [ENV/MC/CHEM(98)17] based on OECD Council Decision of 12 May 1981 C(81)30(Final)] amended on 26 November 1997 [C(97) 186 FINAL], as well as 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 Parties 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 Parties mutually accept studies and data generated therefrom, produced by the test facilities of the other Party listed in Section II provided they participate in the Good Laboratory Practice compliance monitoring programme of that Party in accordance with the principles and provisions stated above.

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

Section I

Legislation, regulations 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(1)

European Community

Feed additives

Council Directive 83/228/EEC of 18.4.1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition (OJ L 126, 13.5.1983, p. 23), as subsequently amended

Council Directive 87/153/EEC of 16.2.1987 fixing guidelines for the assessment of additives in animal nutrition (OJ L 64, 7.2.1987, p. 19), as subsequently amended

Foodstuffs:

Council Directive 89/397/EEC of 14.6.1989 on the official control of foodstuffs (OJ L 186 of 30.6.1989, p. 23), as subsequently amended

Council Directive 93/99/EEC of 29.10.1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290 of 24.11.1993, p. 14) as subsequently amended

Cosmetics:

Council Directive 93/35/EEC of 14.6.1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ L 151, 23.6.1993, p. 32) as subsequently amended

Switzerland

No GLP-relevant legislation

Provisions covered by Article 1(2)

European Community

New and existing chemicals:

Council Directive 87/18/EEC of 18.12.1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 15, 17.1.1987, p. 29) as last amended by Commission Directive 99/11/EC of 8 March 1999 (OJ L 77, 23.3.1999, p. 8)

Council Directive 92/32/EEC of 30.4.1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 154, 5.6.1992, p. 1)

Council Regulation 793/93/EEC of 23.3.93 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1)

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999 p. 1)

Medicinal products:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

Veterinary Drugs:

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

Plant Protection Products:

Council Directive 91/414/EEC of 15.7.1991 concerning the placing of plant protection products on the market (OJ L 230 of 19.8.1991, p. 1)

Commission Directive 93/71/EEC of 27.7.1993 amending Council Directive 91/414 concerning the placing of plant protection products on the market (OJ L 221 of 31.8.1993, p. 27)

Commission Directive 95/35/EC of 14.7.95 amending Council Directive 91/414/EEC concerning the placing on the market of plant protection products (OJ L 172 of 22.7.1995, p. 6)

Biocides:

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1)

Switzerland

Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 15 December 2000 (RO 2001 2827)

Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 17 October 2001 (RO 2001 3296)

Federal law of 21 March 1969 on trade in toxic substances (RO 1972 435) as last amended on 29 April 1998 (RO 1998 3087)

Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 1 May 2002 (RO 2002 1406)

Ordinance of 23 June 1999 on the authorisation of plant protection products (RO 1999 2045) as last amended on 25 August 1999 (RO 1999 2779)

Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790)

Ordinance of 17 October 2001 on medicinal products (RO 2001 3420)

Section III

Designating authorities

For the purpose of this sectoral Annex, the term 'Designating authorities' means the GLP monitoring authorities of the parties.

European Community:

- Belgium: Ministère de la Santé Publique. Institut Scientifique pour la Santé Publique — Louis Pasteur. Ministerie van Volksgezondheid. Wetenschappelijk Instituut voor Volksgezondheid — Louis Pasteur
- Denmark: For Pharmaceuticals:
Lægemiddelstyrelsen (Danish Medicines Agency)
For Industrial chemicals and pesticides:
National Agency for Enterprise and Housing
- Germany: Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit
- Greece: General Chemical State Laboratory
- Spain: Agencia Española del Medicamento
Ministerio de Ciencia y Tecnología
Ministerio Sanidad y Consumo
Ministerio de Agricultura, Pesca y Alimentación
- France: Pour les produits chimiques autres que les médicaments et les cosmétiques: GIPC
Pour les médicaments à usage humain et les cosmétiques: Agence française de sécurité sanitaire des produits de santé (AFSSAPS)
Pour les médicaments à usage vétérinaire: Agence national du médicament vétérinaire
- Ireland: Irish Laboratory Accreditation Board (ILAB)
- Italy: Ministry of Health Department of Prevention GLP Compliance Monitoring Unit
- Netherlands: Ministerie van Volksgezondheid, Welzijn en Sport
Inspectie Volksgezondheid
- Austria: Bundesministerium für soziale Sicherheit und Generationen
(Pharmaceuticals, cosmetic products)
Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft (all others)
- Portugal: For Pharmaceuticals and veterinary drugs:
Instituto Nacional de Farmacia e do Medicamento (INFARMED)
For Industrial chemicals and pesticides:
Instituto Português da Qualidade
- Finland: Sosiaali- ja terveystieteiden ministeriö/Social- och hälsovårdsministeriet
- Sweden: For Pharmaceuticals and hygiene and cosmetic products:
Läkemedelsverket (Medical Products Agency)
For all other products:
Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
- United Kingdom: Department of Health GLP Monitoring Authority

Switzerland:

For environmental studies on all products:

Swiss Agency for the Environment, Forests and Landscape

CH-3003 Berne

For health studies on pharmaceutical products:

Swissmedic, Swiss Agency for Therapeutic Products

CH-3003 Bern 9

For health studies on all products except pharmaceuticals:

Federal Office of Public Health

Chemicals Division

CH-3003 Berne

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):

European Community

Council Directive 87/18/EEC of 18.12.1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 15, 17.1.1987, p. 29) as last amended by Commission Directive 99/11/EC of 8 March 1999 (OJ L 77, 23.3.1999, p. 8)

Council Directive 88/320/EEC of 9.6.1988 on the inspection and verification of Good Laboratory Practice (GLP) (OJ L 145, 11.6.1988, p. 35) as last amended by Commission Directive 99/12/EC of 8 March 1999 (OJ L 77, 23.3.1999, p. 22)

Commission Directive 90/18/EEC of 18.12.1989 adapting to technical progress the Appendix of Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP) (OJ L 11, 13.1.1990, p. 37)

Switzerland

Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 15 December 2000 (RO 2001 2827)

Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 17 October 2001 (RO 2001 3296)

Federal law of 21 March 1969 on trade in toxic substances (RO 1972 435) as last amended on 29 April 1998 (RO 1998 3087)

Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 1 May 2002 (RO 2002 1406)

Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790)

Ordinance of 17 October 2001 on medicinal products (RO 2001 3420)

Ordinance of 2 February 2000 on Good Laboratory Practice (RO 2000 548) as last amended on 16 November 2001 (RO 2001 3165)

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 European Community, and to which Good Manufacturing Practice (GMP) requirements apply.

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

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

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

'Medicinal products' means all products regulated by pharmaceutical legislation in the European Community 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.

With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection be made by the locally competent inspection service. This provision shall apply, *inter alia*, 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 the other Party, 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 two parties, 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, *inter alia*, 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 European Community the 'qualified person' referred to in Article 48 of Directive 2001/83/EC and Article 52 of Directive 2001/82/EC, and in Switzerland the 'responsible person' referred to in Articles 5 and 10 of the Ordinance on establishment licences.

Official batch release

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

For the Community, the official batch release procedure is specified in document 'Control Authority Batch Release of Vaccination and Blood Products, 2001' or subsequent versions and in different specific batch release procedures. For Switzerland, the official batch release procedure is specified in Article 17 of the Federal Law on medicinal products and medical devices and in Articles 18 to 21 of the Ordinance of the Swiss Agency for Therapeutic Products on the requirements for the marketing authorisation of medicinal products.

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 Party.

Provisions covered by Article 1(2)

European Community

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

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

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

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

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

Guidelines on Good Distribution Practice of medicinal products for human use (94/C 63/03)

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

Switzerland

Federal law of December 15, 2000 on medicinal products and medical devices (RO 2001 2790)

Ordinance of October 17, 2001 on establishment licences (RO 2001 3399)

Ordinance of the Swiss Agency for Therapeutic Products of November 9, 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437)

Section II

Conformity assessment bodies

For the purpose of this Chapter 'Conformity Assessment Bodies' means the official GMP inspection services of each Party.

European Community ⁽¹⁾

— Germany:

Bundesministerium für Gesundheit
Am Propsthof 78a
D-53108 Bonn;
Tel. (49-228) 941 23 40
Fax. (49-228) 941 49 23

for immunologicals:

Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
Paul-Ehrlichstr. 51-59
D-63225 Langen;
Tel. (49-6103) 77 10 10
Fax. (49-6103) 77 12 34

— Austria:

Bundesministerium für soziale Sicherheit und Generationen
Radetzkystraße 2
A-1030 Wien
Tel. (43-1) 711 72 46 42
Fax. (43-1) 714 92 22

— Belgium:

Inspection générale de la Pharmacie/Algemene Farmaceutische Inspectie Vesaliusgebouw V309
Pachecolaan 19 bus 5
B-1010 Bruxelles
Tel. (32-2) 210 49 24
Fax. (32-2) 210 48 80

— Denmark:

Lægemiddelstyrelsen:
Frederikssundsvej 378
DK-2700 Bronshøj
Tel. (45-44) 88 91 11
Fax. (45-44) 88 91 95

— Spain:

Agencia Española del Medicamento
c/Paseo del Prado, 18-20
E-28014 Madrid
Tel. (34-91) 596 14 64 65 66
Fax. (34-91) 596 14 55

— Finland:

Lääkelaitos
Feld 55
FIN-00301 Helsinki
Tel. (358-9) 47 33 41
Fax. (358-9) 71 44 69

⁽¹⁾ Up-to-date contact points should be confirmed with the EMEA

— France:

for medicinal products for human use:

Agence Française de Sécurité Sanitaire des Produits de Santé
143-147 Boulevard Anatole France
F-93285 Saint-Denis Cedex
Tel. (33-1) 55 87 30 00
Fax. (33-1) 55 87 37 20

for veterinary medicinal products:

Agence Française de Sécurité Sanitaire des Aliments/Agence Nationale du Médicament Vétérinaire (AFSSA — ANMV)
BP 90203
F-35302 Fougeres
Tel. (33-2) 99 94 78 78
Fax. (33-2) 99 94 78 99

— Greece:

National Organisation for Medicines (EOF)
284 Mesogion Avenue Hologos
GR-15562 Athinai
Tel. (30-210) 650 72 00
Fax. (30-210) 654 95 91

— Ireland:

Irish Medicines Board (Bord Leigheasra na hÉireann)
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Ireland
Tel. (353-1) 676 49 71
Fax. (353-1) 676 78 36

— Italy:

For medicinal products for human use:

Ministero della Salute
Viale della Civiltà Romana 7
I-00144 Roma
Tel. (39-06) 59 94 36 76
Fax. (39-06) 59 94 33 65

For medicinal products for veterinary use:

Ministero della Salute Direzione Generale Sanità Pubblica Veterinaria, Alimenti e Nutrizione Ufficio XI
Piazzale G Marconi 25
I-00144 Roma
Tel. (39-06) 59 94 39 46
Fax. (39-06) 59 94 33 17

— Luxembourg:

Direction de la Santé
Villa Louvigny
Allée Marconi
L-2120 Luxembourg
Tel. (352) 478-55 90-93
Fax.: (352) 22 44 58

— Netherlands:

Staatstoezicht op de volksgezondheid — Inspectie voor de Gezondheidszorg
Postbus 16119
2500 BC Den Haag
Netherlands
Tel. (31 70) 340 79 11
Fax. (31 70) 340 51 77

— Portugal:

Instituto Nacional da Farmácia e do Medicamento — Infarmed
Parque de Saúde de Lisboa Av. do Brasil, 53
P-1749-004 Lisboa
Tel. (351-21) 217 98 52 74
Fax. (351-21) 217 98 72 57

— United Kingdom:

for human and veterinary (non immunologicals):

Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
United Kingdom
Tel. (44-20) 72 73 05 00
Fax. (44-20) 72 73 06 76/06 38

for veterinary immunologicals:

Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS
United Kingdom
Tel. (44-193)-233 69 11
Fax. (44-193)-233 66 18

— Sweden:

Läkemedelsverket (Medical Products Agency)
Husargatan 8
PO Box 26
S-751 03 Uppsala
Tel. (46-18) 17 46 00
Fax. (46-18) 54 85 66

Switzerland

Swiss Agency for Therapeutic Products, Swissmedic
Erlachstraße 8
CH-3000 Bern

(for all products for human and veterinary use — except immunological products for veterinary use)

Tel. (41-31) 3 22 02 11
Fax. (41-31) 3 22 02 12

Institute for Virology and Immunoprophylaxis Research Station of the Swiss Federal Veterinary Office
Sensemattstr. 293

CH-3147 Mittelhäusern
(for immunobiological products for veterinary use)
Tel. (41-31) 848 92 11
Fax. (41-31) 848 92 22
