

## II

*(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)*

## ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

**DECISION No 2/2008****of 16 May 2008**

**of the Committee updating the legal references in the Agreement between the European Community and the Swiss Confederation on Mutual Recognition in relation to conformity assessment**

(2009/455/EC)

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment (the Agreement) signed on 21 June 1999, and in particular Article 10(4)(e), 10(5) and 18(2) thereof,

Whereas:

the Agreement entered into force on 1 June 2002.

the Committee is to take a decision to revise the legal references listed in Annex 1 to the Agreement,

HAS DECIDED AS FOLLOWS:

1. The legal references listed in the Annex are updated in Annex 1 of the Agreement.
2. This Decision, done in duplicate, shall be 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 at Bern, 16 May 2008

*On behalf of the Swiss Confederation*

Heinz HERTIG

Signed at Brussels, 8 May 2008

*On behalf of the European Community*

Fernando PERREAU DE PINNINCK

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## ANNEX

## ‘ANNEX 1

**PRODUCT SECTORS**

This Annex is divided up into the following chapters by sector:

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

## CHAPTER 1

**MACHINERY**

## Section I

**Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

- |                    |      |   |
|--------------------|------|---|
| European Community | 1.   | Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1), 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        | 100. | 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).   |
|                    | 101. | 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).  |
|                    | 102. | Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783).   |

## Section II

**Conformity assessment bodies**

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

**Designating authorities**

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 to this Agreement and the assessment criteria set out in Annex VII to Directive 98/37/EC.

## Section V

**Supplementary provisions****1. Second-hand machinery**

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

The principle contained in Article 1 paragraph 2 of this Agreement shall apply, however, to machinery legally placed on the market and/or put into service in one of the Parties and exported as second-hand machinery to the market of the other Party.

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

## CHAPTER 2

**PERSONAL PROTECTIVE EQUIPMENT**

## Section I

**Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

- |                    |      |  |
|--------------------|------|--|
| European Community | 1.   | 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 Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1). |
| Switzerland        | 100. | 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).  |
|                    | 101. | 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).   |
|                    | 102. | Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783).  |

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## 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 to this Agreement and the assessment criteria set out in Annex V to Directive 89/686/EEC.

## CHAPTER 3

**TOYS**

## Section I

**Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

- |                    |      |  |
|--------------------|------|--|
| European Community | 1.   | Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ L 187, 16.7.1988, p. 1) and corrected by corrigenda (OJ L 281, 14.10.1988, p. 55 and OJ L 37, 9.2.1991, p. 42), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| Switzerland        | 100. | Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 21 March 2003 (RO 2003 4803).  |
|                    | 101. | Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 15 November 2006 (RO 2006 4909).   |
|                    | 102. | Ordinance of EDI of 27 March 2002 on the safety of toys (RO 2002 1082) as last amended on 15 November 2006 (RO 2006 5157).   |

## Section II

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## 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 to this Agreement and the assessment criteria set out in Annex III to Directive 88/378/EEC.

## Section V

**Supplementary provisions***1. Information concerning the certificate and the technical file*

In accordance with Article 10(4) of Directive 88/378/EEC, the designating authorities may obtain on request a copy of the certificate and, on reasoned request, a copy of the technical file and the reports on the examinations and tests carried out.

*2. Notification of grounds for refusal by approved bodies*

In accordance with Article 10(5) of Directive 88/378/EEC, the Swiss bodies shall inform the Swiss Federal Office of Public Health when refusing to issue an EC type-examination certificate. The Federal Office shall likewise notify the Commission of the European Communities thereof.

## CHAPTER 4

**MEDICAL DEVICES**

## Section I

**Legislative, regulatory and administrative provisions***Provisions covered by Article 1(2)*

European Community	1.	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 Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1).
	2.	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1).
	3.	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), as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and corrected by corrigenda (OJ L 22, 29.1.1999, p. 75 and OJ L 6, 10.1.2002, p. 70).
	4.	Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).
	5.	Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

6. Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (OJ L 105, 26.4.2003, p. 18) and corrected by corrigendum (OJ L 6, 8.1.2005, p. 10).
  7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).
  8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98).
  9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21).
- Switzerland
100. Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 20 December 2006 (RO 2006 5599).
  101. 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 17 June 2005 (RO 2006 2197).
  102. Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2005 (RO 2006 2197).
  103. Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 21 March 2003 (RO 2004 4719).
  104. Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 18 May 2005 (RO 2005 2695).
  105. Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847).

## Section II

### Conformity assessment bodies

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## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 to this Agreement and the assessment criteria set out in Annex XI to Directive 93/42/EEC, in Annex 8 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

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

Any manufacturer or his authorised representative 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.

For devices imported from third countries, in view of their distribution in the Community and Switzerland, the label, or the outer packaging, or instructions for use, shall contain the name and address of the single authorised representative of the manufacturer established within the Community or Switzerland, as appropriate.

**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

**Legislative, regulatory and administrative provisions***Provisions covered by Article 1(1)*

European Community	1.	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	100.	Ordinance of 16 December 1985 on Air Pollution Control (OAPC) (Annex 3 and 4) (RS 814.318.142.1), as subsequently amended.

*Provisions covered by Article 1(2)*

European Community	2.	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, 30.8.1993, p. 1).
Switzerland	101.	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).
	102.	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).
	103.	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783).

## Section II

**Conformity assessment bodies**

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**Designating authorities**

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## 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 to this Agreement and the assessment criteria set out in Annex V to Directive 90/396/EEC.

## CHAPTER 6

**PRESSURE VESSELS**

## Section I

**Legislative, regulatory and administrative provisions***Provisions covered by Article 1(1)*

- |                    |      |  |
|--------------------|------|--|
| European Community | 1.   | 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.   |
|                    | 2.   | 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.                                      |
|                    | 3.   | 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.   |
|                    | 4.   | Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment (OJ L 138, 1.6.1999, p. 20), as last amended by Commission Directive 2001/2/EC of 4 January 2001 (OJ L 005, 10.1.2001, p. 4), as subsequently amended.   |
| Switzerland        | 100. | No legislation relating to Directives 84/525/EEC, 84/526/EEC and 84/527/EEC.   |
|                    | 101. | Relating to Directive 1999/36/EC:<br><br>Ordinance of 29 November 2002 on the transport of dangerous goods by road (RS 741.621) as subsequently amended.<br><br>Ordinance of 3 December 1996 on the transport of dangerous goods by rail (RS 742.401.6) as subsequently amended. |

*Provisions covered by Article 1(2)*

- |                    |    |   |
|--------------------|----|---|
| European Community | 5. | 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 last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1).   |
|                    | 6. | Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1), as last amended by Regulation No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1). |



- |             |  |
|-------------|--|
| Switzerland | 102. 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).<br><br>103. Ordinance of 20 November 2002 on the safety of simple pressure vessels (RO 2003 107).<br><br>104. Ordinance of 20 November 2002 on the safety of pressure equipment (RO 2003 38). |
|-------------|--|

## Section II

### Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 to this Agreement and the assessment criteria set out in Annex III to Directive 87/404/EEC, Annexes IV or V to Directive 97/23/EC or Annexes I, II or III to Directive 99/36/EC.

## Section V

### Supplementary provisions

#### 1. *Recognition of certificates and conformity marks*

By way of derogation of Article 1(2) of this Agreement, both Parties shall recognise certificates and conformity marks on the compliance of transportable pressure vessels with Directive 99/36/EC which have been issued by conformity assessment bodies recognised in accordance with the procedure provided for in Article 11 of this Agreement.

#### 2. *Technical documentation*

It shall be sufficient for manufacturers, their authorised representatives or, where neither of these is present, 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 10 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

##### Legislative, regulatory and administrative provisions

*Provisions covered by Article 1(2)*

- |                    |  |
|--------------------|--|
| European Community | 1. 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, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1). |
|--------------------|--|

2. Commission Decision 2000/299/EC 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).
  3. Commission Decision 2000/637/EC 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).
  4. Commission Decision 2000/638/EC 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).
  5. Commission Decision 2001/148/EC 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).
  6. Commission Decision 2004/71/EC of 4 September 2003 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS) (OJ L 16, 23.1.2004, p. 54).
  7. Commission Decision 2005/53/EC of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS) (OJ L 22, 26.1.2005, p. 14).
  8. Commission Decision 2005/631/EC of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services (OJ L 225, 31.8.2005, p. 28).
- Switzerland
100. Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187), as last amended on 24 March 2006 (RO 2007 737 and 921).
  101. Ordinance of 14 June 2002 on Telecommunications Equipment; (RO 2002 2086) as last amended on 16 April 2008 (RO 2008 1903).
  102. Ordinance of 14 June 2002 of the Federal Office of Communications on Telecommunications Equipment (RO 2002 2111), as last amended on 17 September 2007 (RO 2007 4427).
  103. Annex 1 to the Federal Office of Communications Ordinance on Telecommunications Equipment (RO 2002 2111), as last amended on 21 November 2005 (RO 2005 5139).
  104. List of technical standards published in the *Feuille Fédérale* with titles and references, as last amended on 9 October 2007 (FF 2007 6431).
  105. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945).

## Section II

### Conformity assessment bodies

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## Section III

### Designating authorities

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## 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 the assessment criteria set out in Annex VI to Directive 1999/5/EC.

## Section V

**Supplementary provisions**

## 1. 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 radio communication 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 radio communications 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 on 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

#### Legislative, regulatory and administrative provisions

*Provisions covered by Article 1(2)*

European Community	1.	Directive 94/9/EC of the European Parliament and of 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, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and corrected by corrigenda (OJ L 21, 26.1.2000, p. 42 and OJ L 304, 5.12.2000, p. 19).
Switzerland	100.	Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 17 June 2005 (RO 2006 2197).
	101.	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).
	102.	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).
	103.	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).
	104.	Ordinance of 12 June 1995 on the procedures of conformity assessment of technical installations and equipment (RO 1995 2783).

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## 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 assessment criteria set out in Annex XI to Directive 94/9/EC.

## Section V

**Supplementary provisions***1. Information exchange*

The conformity assessment bodies recognised under this Agreement shall provide the other conformity assessment bodies with the information concerning EC type-examination certificates and additions issued and withdrawn as well as quality system approvals issued and withdrawn as provided for, respectively, in Annex III, point 7, Annex IV, point 6 and Annex VII, point 6 of Directive 94/9/EC. In addition they shall keep at the disposal of the other conformity assessment bodies the annexes to the EC type-examination certificates issued as provided for in Annex III, point 8 of Directive 94/9/EC.

*2. Technical documentation*

It shall be sufficient for manufacturers, their authorised representatives or, where neither of these is present, 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 10 years after the last date of manufacture of the product.

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

## CHAPTER 9

**ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY**

## Section I

**Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

European Community	1.	Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (codified version) (OJ L 374, 27.12.2006, p. 10).
	2.	Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p. 24).
Switzerland	100.	Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 17 June 2005 (RO 2006 2197).

101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 2 February 2000 (RO 2000 734).
102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 8 December 1997 (RO 1998 54).
103. Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016), as last amended on 2 February 2000 (RO 2000 734 and 764).
104. Ordinance of 9 April 1997 on electromagnetic compatibility (RO 1997 1008), as last amended on 4 December 2000 (RO 2000 3012).
105. Ordinance of 14 June 2002 on Telecommunications Equipment; (RO 2002 2086) as last amended on 9 March 2007 (RO 2007 995).

## Section II

### Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 the assessment criteria set out in Annex VI to Directive 2004/108/EC.

## Section V

### Supplementary provisions

#### 1. 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 10 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.

#### 2. Indication of the name and address of the manufacturer

It shall be sufficient for manufacturers, their authorised representatives or, where neither of these is present the person responsible for placing products on the market established in the territory of one of the Parties to indicate their name or trade name and address as specified in Article 9(2) of Directive 2004/108/EC. They shall not be obliged to be established or appoint a representative in the territory of the Party in which the products are placed on the market in order to fulfil that provision.

#### 3. Standardisation bodies

In accordance with Article 11 of Directive 2006/95/EC, the Parties shall notify each other of the bodies responsible for drawing up the standards referred to in Article 5 of this Directive.

#### 4. Notified bodies

The Parties shall inform each other of and mutually recognise the bodies made responsible for drawing up technical reports and/or certificates pursuant to Articles 8(2) and 9(3) of Directive 2006/95/EC as well as those made responsible for the tasks as described in Annex III to Directive 2004/108/EC.

### 5. *Safeguard clause*

Where either of the Parties takes a measure to prohibit the placing on its market of a product declared to be in compliance with Directive 2004/108/CE, it shall immediately inform the other Party, giving the reasons for its decision and stating how non-compliance was established.

The Parties shall consider the measure and the evidence presented to them and shall notify each other of the results of their investigations.

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.

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.

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 10

### CONSTRUCTION PLANT AND EQUIPMENT

#### Section I

#### **Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

European Community	1.	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 (OJ L 162, 3.7.2000, p. 1), as amended by Directive 2005/88/EC of the European Parliament and of the Council of 14 December 2005 (OJ L 344, 27.12.2005, p. 44) and corrected by corrigendum (OJ L 165, 17.6.2006, p. 35).
Switzerland	100.	Ordinance of 22 May 2007 on the noise emission in the environment by equipment for use outdoors (RO 2007 2827).

#### Section II

#### **Conformity assessment bodies**

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

#### Section III

#### **Designating authorities**

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

#### 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 assessment criteria set out in Annex IX to Directive 2000/14/EC of the European Parliament and of the Council.

## Section V

**Supplementary provisions***1. Location of the manufacturer*

By way of derogation from Article 4 of Directive 2000/14/EC, it shall be sufficient that the manufacturer or his authorised representative or, where neither of these is present, the person responsible for placing the equipment on the market or putting it into service is established in the territory of one of the Parties.

*2. Information exchange*

In accordance with Article 9 of the Agreement, the Parties shall in particular exchange the information referred to in Articles 9 and 14(3) of Directive 2000/14/EC.

In addition, the conformity assessment bodies recognised under this Agreement shall provide the other conformity assessment bodies with the information concerning quality system approvals issued and withdrawn as provided for in Annex VIII, point 6 of Directive 2000/14/EC.

*3. Collection of noise data*

The competent Swiss authorities shall have access to the database established under Article 16 of Directive 2000/14/EC. They shall transmit to the Commission and/or body responsible for managing the database the data provided for in this Article as collected in Switzerland for entry into the database.

## CHAPTER 11

**MEASURING INSTRUMENTS AND PRE-PACKAGES**

## Section I

**Legislative, regulatory and administrative provisions***Provisions covered by Article 1(1)*

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|--------------------|--|
| European Community | <ol style="list-style-type: none"><li>1. 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 239, 25.10.1971, p. 1), as subsequently amended.</li><li>2. 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, 25.10.1971, p. 15), as subsequently amended.</li><li>3. Council Directive 76/765/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholmeters and alcohol hydrometers (OJ L 262, 27.9.1976, p. 143), as subsequently amended.</li><li>4. 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.</li><li>5. 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 pre-packaged liquids (OJ L 42, 15.2.1975, p. 1), as subsequently amended.</li><li>6. 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.</li><li>7. 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 pre-packaged products (OJ L 46, 21.2.1976, p. 1), as subsequently amended.</li></ol> |
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8. 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 pre-packaged products (OJ L 51, 25.2.1980, p. 1), as subsequently amended.
  9. Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17) applicable as from 11 April 2009.
- Switzerland
100. Ordinance of 8 June 1998 concerning the measurement and declaration of quantities of goods in trade (RS 941.281), as subsequently amended.
  101. Ordinance of 12 June 1998 on technical provisions concerning the declaration of quantities on industrial pre-packages (RS 941.281.1), as subsequently amended.

*Provisions covered by Article 1(2)*

10. 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 Commission Directive 2007/13/EC of 7 March 2007 (OJ L 73, 13.3.2007, p. 10).
  11. 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 L 202, 6.9.1971, p. 14).
  12. 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 L 84, 28.3.1974, p. 3).
  13. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40) as last amended by Directive 1999/103/EC of the European Parliament and of the Council of 24 January 2000 (OJ L 34, 9.2.2000, p. 17).
  14. Council Directive 76/766/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (OJ L 262, 27.9.1976, p. 149).
  15. Council Directive 90/384/EEC of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments (OJ L 189, 20.7.1990, p. 1), as amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1).
  16. European Parliament and Council Directive 2004/22/EC of 31 March 2004 on measuring instruments (2004/22/EC) (OJ L 135, 30.4.2004, p. 1).
- Switzerland
102. Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2005 (RO 2006 2197).
  103. Ordinance of 23 November 1994 on units of measurement (RO 1994 3109).
  104. Ordinance of 15 February 2006 concerning measuring instruments (RO 2006 1453).
  105. Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO 2004 2093).
  106. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO 2006 1433).
  107. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO 2006 1525).
  108. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring systems for liquids other than water (RO 2006 1533).

109. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO 2006 1545).
110. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO 2006 1569).
111. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO 2006 1591).
112. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO 2006 1599).
113. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for the electrical energy and power (RO 2006 1613).
114. Ordinance of 15 August 1986 on weights (RO 1986 2022), as last amended on 21 November 1995 (RO 1995 5646).

## Section II

### Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 the assessment criteria set out in Annex V to Directive 90/384/EEC and in Article 12 to Directive 2004/22/EC, as regards the products covered by those Directives.

## Section V

### Supplementary provisions

#### 1. *Information exchange*

The conformity assessment bodies recognised under this Agreement 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 recognised under this Agreement may request the information provided for in point 1.6 of Annex II to Directive 90/384/EEC.

#### 2. *Pre-packages*

Switzerland shall recognise checks carried out in accordance with the provisions of Community legislation listed in section I by a Community body recognised under this Agreement in the case of Community pre-packages placed on the market in Switzerland.

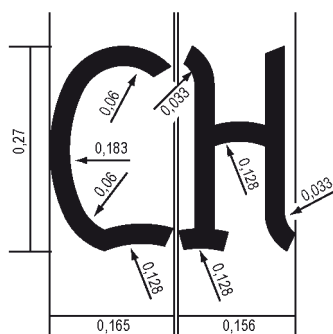
As regards statistical checking of the quantities declared on pre-packages, the European Community shall recognise the Swiss method laid down in Articles 14 to 17 of the Ordinance on technical provisions concerning the declaration of quantities on industrial pre-packages (RS 941.281.1) as equivalent 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 pre-packages 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 point 3.2.1 of Annex II refers, are supplemented by the following drawing:



3.2. By the way of derogation from Article 1 of this Agreement, the rules on marking for measuring instruments placed on the Swiss market are as follows:

The marking that must be affixed is the EC marking and supplementary metrology 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.

### 4. Measuring instruments covered by Directive 2004/22/EC

#### 4.1. Information exchange, market surveillance and administrative cooperation

In accordance with Article 18 of Directive 2004/22/EC, the competent authorities of the Member States and Switzerland shall assist each other in the fulfilment of their obligations to carry out market surveillance.

In particular, the competent authorities shall exchange:

- Information concerning the extent to which instruments they examine comply with the provisions of Directive 2004/22/EC, and the results of such examinations,
- EC-type examination and design examination certificates and their annexes issued by notified bodies as well as additions, amendments and withdrawals relating to certificates already issued,
- quality system approvals issued by notified bodies, as well as information on quality systems refused or withdrawn,
- evaluation reports established by notified bodies, when demanded by other authorities,

The Member States and Switzerland shall ensure that all necessary information relating to the certificates and quality system approvals is made available to bodies they have notified.

Each Party shall inform the other Party which competent authorities it has designated for such an exchange of information.

#### 4.2. Technical documentation and declaration of conformity

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing the products on the market to hold the technical documentation and declarations of conformity 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 10 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 12

#### MOTOR VEHICLES

##### Section I

##### Legislative, regulatory and administrative provisions

###### *Provisions covered by Article 1(2)*

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| European Community | <ol style="list-style-type: none"><li>1. Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (70/156/EEC), as last amended by Commission Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>2. Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (70/157/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>3. Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles (70/220/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>4. Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to liquid fuel tanks and rear protective devices for motor vehicles and their trailers (70/221/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>5. Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to the space for mounting and the fixing of rear registration plates on motor vehicles and their trailers (70/222/EEC) (OJ L 76, 6.4.1970, p. 25) as last adjusted by Council Decision of 25 April 2005 (OJ L 157, 21.6.2005, p. 9).</li><li>6. Council Directive of 8 June 1970 on the approximation of the laws of the Member States relating to the steering equipment for motor vehicles and their trailers (70/311/EEC), as last amended by Commission Directive 1999/7/EC of 26 January 1999 (OJ L 40, 13.2.1999, p. 36).</li><li>7. Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers (70/387/EEC) as last amended by Commission Directive 2001/31/EC of 8 May 2001 (OJ L 130, 12.5.2001, p. 33).</li><li>8. Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to audible warning devices for motor vehicles (70/388/EEC) as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>9. Council Directive of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles (71/127/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li><li>10. Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and of their trailers (71/320/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li></ol> |
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11. Council Directive of 20 June 1972 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles (72/245/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
12. Council Directive of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles (72/306/EEC), as last amended by Commission Directive 2005/21/EC of 7 March 2005 (OJ L 61, 8.3.2005, p. 25).
13. Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of the seats) (74/60/EEC), as last amended by Directive 2000/4/EC of the European Parliament and of the Council of 28 February 2000 (OJ L 87, 8.4.2000, p. 22).
14. Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to devices to prevent the unauthorised use of motor vehicles (74/61/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
15. Council Directive of 4 June 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact) (74/297/EEC), 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).
16. Council Directive of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seats and of their anchorages) (74/408/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
17. Council Directive of 17 September 1974 on the approximation of the laws of the Member States relating to the external projections of motor vehicles (74/483/EEC), as last amended by Commission Directive 2007/15/EC of 14 March 2007 (OJ L 75, 15.3.2007, p. 21).
18. Council Directive of 26 June 1975 on the approximation of the laws of the Member States relating to the reverse and speedometer equipment of motor vehicles (75/443/EEC), as last amended by Commission Directive 97/39/EC of 24 June 1997 (OJ L 177, 5.7.1997, p. 15).
19. Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment (76/114/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
20. Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor vehicle safety belts (76/115/EEC), as last amended by Directive 2005/41/EC of the European Parliament and of the Council of 7 September 2005 (OJ L 255, 30.9.2005, p. 149).
21. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the installation of lighting and light signalling devices on motor vehicles and their trailers (76/756/EEC), as last amended by Commission Directive 2007/35/EC of 18 June 2007 (OJ L 157, 19.6.2007, p. 14).
22. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers (76/757/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
23. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to end-outline marker lamps, front position (side) lamps, rear position (side) lamps and stop lamps for motor vehicles and their trailers (76/758/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).

24. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers (76/759/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
25. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers (76/760/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
26. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to motor vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such headlamps (76/761/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
27. Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps (76/762/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
28. Council Directive of 17 May 1977 on the approximation of the laws of the Member States relating to motor vehicle towing devices (77/389/EEC), as last amended by Commission Directive 96/64/EC of 2 October 1996 (OJ L 258, 11.10.1996, p. 26).
29. Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers (77/538/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
30. Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers (77/539/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
31. Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to parking lamps for motor vehicles (77/540/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
32. Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles (77/541/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
33. Council Directive of 27 September 1977 on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers (77/649/EEC), as last amended by Commission Directive 90/630/EEC of 30 October 1990 (OJ L 341, 6.12.1990, p. 20).
34. Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (identification of controls, tell-tales and indicators) (78/316/EEC), as last amended by Commission Directive 94/53/EC of 15 November 1994 (OJ L 299, 22.11.1994, p. 26).
35. Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles (78/317/EEC) (OJ L 81, 28.3.1978, p. 27), and corrigendum (OJ L 194, 19.7.1978, p. 30).
36. Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles (78/318/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
37. Council Directive of 12 June 1978 on the approximation of the laws of the Member States relating to the wheel guards of motor vehicles (78/549/EEC), 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).

38. Council Directive of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles (78/932/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
39. Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the fuel consumption of motor vehicles (80/1268/EEC), as last amended by Directive 2004/3/EC of the Council and of the European Parliament of 11 February 2004 (OJ L 49, 19.2.2004, p. 36).
40. Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the engine power of motor vehicles (80/1269/EEC), as last amended by Commission Directive 99/99/EC of 15 December 1999 (OJ L 334, 28.12.1999, p. 32).
41. Council Directive of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles (88/77/EEC), as last amended by Directive 2005/55/EC of the European Parliament and of the Council (OJ L 275, 20.10.2005, p. 1).
42. Council Directive of 13 April 1989 on the approximation of the laws of the Member States relating to the lateral protection (side guards) of certain motor vehicles and their trailers (89/297/EEC) (OJ L 124, 5.5.1989, p. 1).
43. Council Directive of 27 March 1991 on the approximation of the laws of the Member States relating to the spray-suppression systems of certain categories of motor vehicles and their trailers (91/226/EEC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
44. Council Directive of 31 March 1992 on the masses and dimensions of motor vehicles of category M1 (92/21/EEC), 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).
45. Council Directive of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers (92/22/EEC), as last amended by Commission Directive 2001/92/EC of 30 October 2001 (OJ L 291, 8.11.2001, p. 24).
46. Council Directive of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting (92/23/EEC), as last amended by Directive 2005/11/EC of 16 February 2005 (OJ L 46, 17.2.2005, p. 42).
47. Council Directive of 31 March 1992 relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles Directive (92/24/EEC) (OJ L 129, 14.5.1992, p. 154), as last amended by Directive 2004/11/EC of the European Parliament and of the Council of 11 February 2004 (OJ L 44, 14.2.2004, p. 19).
48. Council Directive of 17 December 1992 relating to the external projections forward of the cab's rear panel of motor vehicles of category N (92/114/EEC) (OJ L 409, 31.12.1992, p. 17).
49. Directive of the European Parliament and of the Council of 30 May 1994 relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles (94/20/EC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
50. Directive of the European Parliament and of the Council of 24 October 1995 relating to the burning behaviour of materials used in the interior construction of certain categories of motor vehicle (95/28/EC), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
51. 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).
52. 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).



53. 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 2003/19/EC of 21 March 2003 (OJ L 79, 26.3.2003, p. 6).
54. 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).
55. 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, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
56. 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, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
57. 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, and as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
58. Directive 2003/97/EC of the European Parliament and of the Council of 10 November 2003 on the approximation of the laws of the Member States relating to the type-approval of devices for indirect vision and of vehicles equipped with these devices, amending Directive 70/156/EEC and repealing Directive 71/127/EEC, and as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
59. Directive 2003/102/EC of the European Parliament and of the Council of 17 November 2003 relating to the protection of pedestrians and other vulnerable road users before and in the event of a collision with a motor vehicle and amending Council Directive 70/156/EEC, completed by Commission Decision 2004/90/EC of 23 December 2003 (OJ L 31, 4.2.2004, p. 21) and corrigendum (OJ L 25, 1.2.2007, p. 12).
60. Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p. 24).
61. Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles, as last amended by Commission Directive 2006/81/EC of 23 October 2006 (OJ L 362, 20.12.2006, p. 92).
62. Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC (OJ L 310, 25.11.2005, p. 10).
63. Directive 2005/66/EC of the European Parliament and of the Council of 26 October 2005 relating to the use of frontal protection systems on motor vehicles and amending Council Directive 70/156/EEC (OJ L 309, 25.11.2005, p. 37).
64. Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC (OJ L 161, 14.6.2006, p. 12).



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| Switzerland | 100. 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 28 March 2007 (RO 2007 2177). |
|             | 101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 29 November 2006 (RO 2007 95).  |

## Section II

### Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## Section IV

### Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in section I.

## Section V

### Supplementary provisions

The provisions of this section shall apply exclusively to relations between Switzerland and the 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).

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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81), 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81), by the authorities responsible for type-approval 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).

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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81), 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81), 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81), 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 multistage 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).

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

#### Legislative, regulatory and administrative provisions

*Provisions covered by Article 1(2)*

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| European Community | <ol style="list-style-type: none"> <li>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 2006/26/EC of 2 March 2006 (OJ L 65, 7.3.2006, p. 22).</li> <li>2. 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 Commission Directive 98/89/EC of 20 November 1998 (OJ L 322, 1.12.1998, p. 40).</li> <li>3. 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).</li> <li>4. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).</li> <li>5. 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).</li> <li>6. 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).</li> <li>7. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).</li> </ol> |
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8. 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 Council of 11 November 1999 (OJ L 297, 18.11.1999, p. 22) and corrigendum (OJ L 87, 8.4.2000, p. 34).
9. 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 Commission Directive 2006/26/EC of 2 March 2006 (OJ L 65, 7.3.2006, p. 22).
10. Council Directive 77/536/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the rollover protection structures of wheeled agricultural or forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
11. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).
12. 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
13. 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 Commission Directive 2006/26/EC of 2 March 2006 (OJ L 65, 7.3.2006, p. 22).
14. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).
15. 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 Commission Directive 1999/58/EC of 7 June 1999 (OJ L 148, 15.6.1999, p. 37).
16. Council Directive 79/622/EEC of 25 June 1979 on the approximation of the laws of the Member States relating to the rollover protection structures of wheeled agricultural or forestry tractors (static testing), as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
17. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).
18. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).
19. Council Directive 86/298/EEC of 26 May 1986 on rear-mounted rollover protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).
20. 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 of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24).

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|             | 21.  | Council Directive 87/402/EEC of 25 June 1987 on rollover protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).  |
|             | 22.  | 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 Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).   |
|             | 23.  | 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 as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81).                           |
|             | 24.  | Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81). |
| Switzerland | 100. | Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 28 March 2007 (RO 2007 2181).  |
|             | 101. | Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 29 November 2006 (RO 2007 95).   |

## Section II

### Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## Section IV

### Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in section I.

## Section V

### Supplementary provisions

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

#### 1. Information exchange

The competent Member State's and Swiss authorities shall notify each other of conforming Articles 4, 6, 8 and 9 of Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, as last amended) or non-conforming Articles 14 and 16 of Directive 2003/37/EC, as last amended) vehicles, systems, components and separate technical units 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 2003/37/EC, as last amended, 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 or 2003/37/EC, both as last amended, 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 2003/37/EC, as last amended.

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 conclude whether the measure is justified or not, and the procedure established in Article 16 of Directive 2003/37/EC shall apply.

### Measures related to the conformity of production

1. When a Member State or Switzerland grants type-approval, it shall take the measures referred to in Annex IV of Directive 2003/37/EC 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 the vehicles, systems, components or separate technical units produced conform to the approved type. This verification shall be limited to the procedures set out in Section 2 of Annex IV of Directive 2003/37/EC.
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 EC type-approval certificate and/or the information package are found to exist and where these deviations have not been authorised under Article 5(3) of Directive 2003/37/EC as last amended, by the Member State 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 a number of vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an EC type-approval mark 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)] amended on 9 March 1995 [C(95)8(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 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 GLP monitoring authorities.

#### Section I

### Legislative, regulatory and administrative provisions

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

#### *Provisions covered by Article 1(1)*

#### European Community

##### Feed additives

1. Council Directive 83/228/EEC of 18 April 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.
2. Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (OJ L 64, 7.3.1987, p. 19), as subsequently amended.

##### Foodstuffs

3. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official control performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1 and corrected by corrigenda OJ L 191, 28.5.2004, p. 1 and OJ L 204, 4.8.2007, p. 29), as last amended by Commission Regulation (EC) No 776/2006 of 23 May 2006 (OJ L 136, 24.5.2006, p. 3).

#### Switzerland

No GLP-relevant legislation.

*Provisions covered by Article 1(2)*

## European Community

New and existing chemicals

4. Council Directive 92/32/EEC of 30 April 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).
5. Council Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1) as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ L 284, 31.10.2003, p. 1).
6. 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), as last amended by Directive 2006/08/EC of 23 January 2006 (OJ L 19, 24.1.2006, p. 12).

Medicinal products

7. 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), as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34). NB: Directive 2001/83/EC has been amended and the GLP requirement is now contained in the Introduction and General Principles chapter of Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).

Veterinary Drugs

8. 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), as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).

Plant Protection Products

9. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1), as last amended by Commission Directive 2006/64/EC of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances (OJ L 206, 27.7.2006, p. 107).

Biocides

10. 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) as last amended by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biological products on the market (OJ L 142, 30.5.2006, p. 6).

## Switzerland

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 20 December 2006 (RO 2007 2701).



101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763) as last amended on 17 June 2005 (RO 2006 2197).
102. Ordinance of 18 May 2005 on protection against dangerous substances and preparations (RO 2005 2721) as last amended on 28 February 2007 (RO 2007 821).
103. Ordinance of 18 May 2005 on biocidal products (RO 2005 2821) as last amended on 28 February 2007 (RO 2007 851).
104. Ordinance of 18 May 2005 on the authorisation of plant protection products (RO 2005 3035) as last amended on 28 February 2007 (RO 2007 821).
105. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790) as last amended on 20 December 2006 (RO 2006 5599).
106. Ordinance of 17 October 2001 on medicinal products (RO 2001 3420) as last amended on 16 March 2007 (RO 2007 1961).

## Section II

### Conformity assessment bodies

For the purpose of this Sectoral Chapter, "Conformity Assessment Bodies" means the test facilities recognised under each Party's GLP monitoring programme.

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

## Section III

### Designating authorities

For the purpose of this Sectoral Annex, the term "Designating Authorities" means the GLP Monitoring Authorities of the Parties. The Contact Details of the GLP Monitoring Authorities of the Member States of the European Union and of Switzerland can be found in the websites indicated below.

*For the European Community:*

[http://ec.europa.eu/enterprise/chemicals/legislation/glp/national\\_en.htm](http://ec.europa.eu/enterprise/chemicals/legislation/glp/national_en.htm)

*For Switzerland:*

<http://www.bag.admin.ch/themen/chemikalien/00253/00539/02401/index.html?lang=en>

## 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 | <ol style="list-style-type: none"><li>1. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 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 50, 20.2.2004, p. 44).</li><li>2. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28).</li></ol> |
|--------------------|---|

- |             |      |  |
|-------------|------|--|
| Switzerland | 100. | Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 16 December 2005 (RO 2006 2677).                      |
|             | 101. | Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763) as last amended on 17 June 2005 (RO 2006 2197). |
|             | 102. | Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790) as last amended on 20 December 2006 (RO 2006 5599).               |
|             | 103. | Ordinance of 18 May 2005 on Good Laboratory Practice (RO 2005 2795).   |

## Section V

### Supplementary provisions

#### 1. *Information exchange*

In accordance with Article 12 of this Agreement, the Parties in particular provide each other at least annually with a list of the test facilities which, in the light of the results of the inspections and study audits, conform to Good Laboratory Practice, as well as of the dates of inspection or audit and their compliance status.

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

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

#### 2. *Test facility inspections*

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

If, in exceptional cases, doubts persist and the requesting Party can justify special concern, it may, in accordance with Article 8 of the Agreement, designate one or more experts of its GLP monitoring authorities to participate in a laboratory inspection or the audit of a study conducted by the authorities of the other Party.

#### 3. *Confidentiality*

In conformity with Article 13 of the Agreement, the Parties shall keep confidential any information brought to their knowledge pursuant to this Sectoral Chapter or that came to their knowledge in the framework of participation in an inspection or study audit and which falls within the definition of a trade secret or confidential commercial or financial information. They shall treat such information with at least the same confidentiality as that accorded to it by the providing Party and ensure that any authority to whom the information is transmitted treats it in the same way.

#### 4. *Cooperation*

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

## 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, premixes 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 i.a. to the manufacture of active pharmaceutical ingredients, intermediate products and investigational medicinal products, as well as to pre-marketing inspections. Operational arrangements are detailed under section III, paragraph 3.

#### *Certification of manufacturers*

At the request of an exporter, importer or the competent authority of 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 30 calendar days. In exceptional cases, i.a. when a new inspection has to be carried out, this period may be extended to 60 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 18–21 of the Ordinance of the Swiss Agency for Therapeutic Products on the requirements for the marketing authorisation of medicinal products.

## Section I

**Legislative, regulatory and administrative provisions**

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	<ol style="list-style-type: none"><li>1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).</li><li>2. 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, as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34).</li><li>3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).</li><li>4. 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) as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).</li><li>5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).</li><li>6. 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).</li><li>7. Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 63, 1.3.1994, p. 4) (published on website of the European Commission).</li><li>8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission).</li><li>9. Directive 2001/20/EC of 04 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).</li></ol>
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- |             |      |   |
|-------------|------|---|
|             | 10.  | Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13). |
| Switzerland | 100. | Federal law of December 15, 2000 on medicinal products and medical devices (RO 2001 2790) as last amended on 20 December 2006 (RO 2007 14 11).  |
|             | 101. | Ordinance of October 17, 2001 on authorisations in the field of medicines (RO 2001 3399) as last amended on 16 March 2006 (RO 2007 1961).   |
|             | 102. | 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) as last amended on 22 June 2006 (RO 2006 3587).   |
|             | 103. | Ordinance of October 17, 2001 on clinical trials of pharmaceutical products (RO 2001 3511) as last amended on 16 March 2007 (RO 2007 1961).   |

## Section II

### Conformity assessment bodies

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

The Contact Details of the official GMP Inspection Services of the Member States of the European Union and of Switzerland can be found in the websites indicated below.

<http://www.hma.eu/index.php?id=148>

*For Swiss conformity assessment bodies*

For all products for human and veterinary use (except immunological products for veterinary use):

<http://www.swissmedic.ch/?lang=2>

*For immunobiological products for veterinary use*

<http://www.bvet.admin.ch/ivi/index.html?lang=en>

*For conformity assessment bodies of the European Community*

[http://ec.europa.eu/enterprise/pharmaceuticals/mra/index\\_a.htm](http://ec.europa.eu/enterprise/pharmaceuticals/mra/index_a.htm)

## Section III

### Supplementary provisions

#### 1. Transmission of inspection reports

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

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

#### 2. Inspection reports

A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific queries about a firm by the other Party.

### 3. *GMP Reference*

- (a) Manufacturers shall be inspected against the applicable GMP of the exporting party (see section I).
- (b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations shall inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Party.

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

### 4. *Nature of inspections*

- (a) Inspections shall routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).
- (b) "Product- or process-oriented" inspections (which may be "pre-marketing" inspections as relevant) focus on the manufacture of one or a series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) shall be provided in confidence to the inspectorate.

### 5. *Fees*

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

### 6. *Safeguard clause for inspections*

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

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

In accordance with the general provisions of this Agreement, the parties shall exchange any information necessary for the mutual recognition of inspections.

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

### 8. *Inspectors training*

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

### 9. *Joint Inspections*

In accordance with Article 12 of this Agreement, and by mutual agreement between the Parties, joint inspections may be organised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Committee established under Article 10 of this Agreement.

### 10. *Alert system*

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

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

#### 11. *Contact points*

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

For the EC

The Director of the European Medicines Agency.

For Switzerland

The official GMP inspection services listed in Section II above.

#### 12. *Divergence of views*

Both Parties shall use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Committee as established under Article 10 of this Agreement.

### CHAPTER 16

#### CONSTRUCTION PRODUCTS

##### Section I

##### **Legislative, regulatory and administrative provisions**

*Provisions covered by Article 1(2)*

- |                    |   |
|--------------------|---|
| European Community | 1. Council Directive 89/106/EEC of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products (OJ L 40, 11.2.1989, p. 12). |
|--------------------|---|

##### *Implementing measures*

- |     |  |
|-----|--|
| 2.  | Commission Decision 94/23/EC of 17 January 1994 on common procedural rules for European technical approval (OJ L 17, 20.1.1994, p. 34).  |
| 2a. | Commission Decision 94/611/EC of 9 September 1994 implementing Article 20 of Directive 89/106/EEC on construction products (OJ L 241, 16.9.1994, p. 25).   |
| 2b. | Commission Decision 95/204/EC of 31 May 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 129, 14.6.1995, p. 23).   |
| 3.  | Commission Decision 95/467/EC of 24 October 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 268, 10.11.1995, p. 29).  |
| 4.  | Commission Decision 96/577/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fixed firefighting systems (OJ L 254, 8.10.1996, p. 44). |
| 5.  | Commission Decision 96/578/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sanitary appliances (OJ L 254, 8.10.1996, p. 49).        |
| 6.  | Commission Decision 96/579/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures (OJ L 254, 8.10.1996, p. 52).       |



7. Commission Decision 96/580/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards curtain walling (OJ L 254, 8.10.1996, p. 56).
8. Commission Decision 96/581/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards geotextiles (OJ L 254, 8.10.1996, p. 59).
9. Commission Decision 96/582/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural sealant glazing systems and metal anchors for concrete (OJ L 254, 8.10.1996, p. 62).
10. Commission Decision 96/603/EC of 4 October 1996 establishing the list of products belonging to classes A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 267, 19.10.1996, p. 23).
11. Commission Decision 97/161/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal anchors for use in concrete for fixing light-weight systems (OJ L 62, 4.3.1997, p. 41).
12. Commission Decision 97/176/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural timber products and ancillaries (OJ L 73, 14.3.1997, p. 19).
13. Commission Decision 97/177/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal injection anchors for use in masonry (OJ L 73, 14.3.1997, p. 24).
14. Commission Decision 97/462/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards wood-based panels (OJ L 198, 25.7.1997, p. 27).
15. Commission Decision 97/463/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards plastic anchors for use in concrete and masonry (OJ L 198, 25.7.1997, p. 31).
16. Commission Decision 97/464/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 198, 25.7.1997, p. 33).
17. Commission Decision 97/555/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders (OJ L 229, 20.8.1997, p. 9).
18. Commission Decision 97/556/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) (OJ L 229, 20.8.1997, p. 14).
19. Commission Decision 97/571/EC of 22 July 1997 on the general format of European Technical Approval for construction products (OJ L 236, 27.8.1997, p. 7).
20. Commission Decision 97/597/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards reinforcing and prestressing steel for concrete (OJ L 240, 2.9.1997, p. 4).
21. Commission Decision 97/638/EC of 19 September 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fasteners for structural timber (OJ L 268, 1.10.1997, p. 36).



22. Commission Decision 97/740/EC of 14 October 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards masonry and related products (OJ L 299, 4.11.1997, p. 42).
23. Commission Decision 97/808/EC of 20 November 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards floorings (OJ L 331, 3.12.1997, p. 18).
24. Commission Decision 98/143/EC of 3 February 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards systems of mechanically fastened flexible roof waterproofing membranes (OJ L 42, 14.2.1998, p. 58).
25. Commission Decision 98/213/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits (OJ L 80, 18.3.1998, p. 41).
26. Commission Decision 98/214/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural metallic products and ancillaries (OJ L 80, 18.3.1998, p. 46).
27. Commission Decision 98/279/EC of 5 December 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards non-load-bearing permanent shuttering kits/systems based on hollow blocks or panels of insulating materials and, sometimes, concrete (OJ L 127, 29.4.1998, p. 26).
28. Commission Decision 98/436/EC of 22 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards roof coverings, roof lights, roof windows and ancillary products (OJ L 194, 10.7.1998, p. 30).
29. Commission Decision 98/437/EC of 30 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal and external wall and ceiling finishes (OJ L 194, 10.7.1998, p. 39).
30. Commission Decision 98/456/EC of 3 July 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards post-tensioning kits for the prestressing of structures (OJ L 201, 17.7.1998, p. 112).
31. Commission Decision 98/457/EC of 3 July 1998 concerning the test of the Single Burning Item (SBI) referred to in Council Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 201, 17.7.1998, p. 114).
32. Commission Decision 98/598/EC of 9 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards aggregates (OJ L 287, 24.10.1998, p. 25).
33. Commission Decision 98/599/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid applied roof waterproofing kits (OJ L 287, 24.10.1998, p. 30).
34. Commission Decision 98/600/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards self-supporting translucent roof kits (except glass-based kits) (OJ L 287, 24.10.1998, p. 35).
35. Commission Decision 98/601/EC of 13 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards road construction products (OJ L 287, 24.10.1998, p. 41).
36. Commission Decision 1999/89/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated stair kits (OJ L 29, 3.2.1999, p. 34).

37. Commission Decision 1999/90/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards membranes (OJ L 29, 3.2.1999, p. 38).
38. Commission Decision 1999/91/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards thermal insulating products (OJ L 29, 3.2.1999, p. 44).
39. Commission Decision 1999/92/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards light composite wood-based beams and columns (OJ L 29, 3.2.1999, p. 49).
40. Commission Decision 1999/93/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware (OJ L 29, 3.2.1999, p. 51).
41. Commission Decision 1999/94/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/lightweight autoclaved aerated concrete products (OJ L 29, 3.2.1999, p. 55).
- 41a. Commission Decision 1999/453/EC of 18 June 1999 amending decision 96/579/EC and 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures and floorings respectively (OJ L 178, 14.7.1999, p. 50).
42. Commission Decision 1999/454/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fire stopping, fire sealing and fire protective products (OJ L 178, 14.7.1999, p. 52).
43. Commission Decision 1999/455/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards timber frame and log prefabricated building kits (OJ L 178, 14.7.1999, p. 56).
44. Commission Decision 1999/469/EC of 25 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards products related to concrete, mortar and grout (OJ L 184, 17.7.1999, p. 27).
45. Commission Decision 1999/470/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards construction adhesives (OJ L 184, 17.7.1999, p. 32).
46. Commission Decision 1999/471/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards space heating appliances (OJ L 184, 17.7.1999, p. 37).
47. Commission Decision 1999/472/EC of 1 July 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pipes, tanks and ancillaries not in contact with water intended for human consumption (OJ L 184, 17.7.1999, p. 42).
48. Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products (OJ L 50, 23.2.2000, p. 14).
49. Commission Decision 2000/245/EC of 2 February 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(4) of Council Directive 89/106/EEC as regards flat glass, profiled glass and glass block products (OJ L 77, 28.3.2000, p. 13).
50. Commission Decision 2000/273/EC of 27 March 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European Technical Approvals without Guideline (OJ L 86, 7.4.2000, p. 15).

51. Commission Decision 2000/367/EC of 3 May 2000 implementing Council Directive 89/106/EEC as regards the classification of the resistance to fire performance of construction products, construction works and parts thereof (OJ L 133, 6.6.2000, p. 26).
52. Commission Decision 2000/447/EC of 13 June 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated wood-based load-bearing stressed skin panels and self-supporting composite lightweight panels (OJ L 180, 19.7.2000, p. 40).
53. Commission Decision 2000/553/EC of 6 September 2000 implementing Council Directive 89/106/EEC as regards the external fire performance of roof coverings (OJ L 235, 19.9.2000, p. 19).
- 53a. Commission Decision 2000/605/EC of 26 September 2000 amending Decision 96/603/EC establishing the list of products belonging to class A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 258, 12.10.2000, p. 36).
54. Commission Decision 2000/606/EC of 26 September 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards six products for European Technical Approvals without Guideline (OJ L 258, 12.10.2000, p. 38).
55. Commission Decision 2001/19/EC of 20 December 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards expansion joints for road bridges (OJ L 5, 10.1.2001, p. 6).
56. Commission Decision 2001/308/EC of 31 January 2001 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards ventures (OJ L 107, 18.4.2001, p. 25).
- 56a. Commission Decision 2001/596/EC of 8 January 2001 amending Decisions 95/467/EC, 96/578/EC, 96/580/EC, 97/176/EC, 97/462/EC, 97/556/EC, 97/740/EC, 97/808/EC, 98/213/EC, 98/214/EC, 98/279/EC, 98/436/EC, 98/437/EC, 98/599/EC, 98/600/EC, 98/601/EC, 1999/89/EC, 1999/90/EC, 1999/91/EC, 1999/454/EC, 1999/469/EC, 1999/470/EC, 1999/471/EC, 1999/472/EC, 2000/245/EC, 2000/273/EC, 2000/447/EC on the procedure for attesting the conformity of certain construction products pursuant to Article 20 of Council Directive 89/106/EEC (OJ L 209, 2.8.2001, p. 33).
57. Commission Decision 2001/671/EC of 21 August 2001 implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (OJ L 235, 4.9.2001, p. 20).
58. Commission Decision 2002/359/EC of 13 May 2002 on the procedure for attesting the conformity of construction products in contact with water intended for human consumption, pursuant to Article 20(2) of Council Directive 89/106/EEC (OJ L 127, 14.5.2002, p. 16).
59. Commission Decision 2002/592/EC of 15 July 2002 amending Decisions 95/467/EC, 96/577/EC, 96/578/EC and 98/598/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards gypsum products, fixed firefighting systems, sanitary appliances and aggregates respectively (OJ L 192, 20.7.2002, p. 57).
60. Commission Decision 2003/43/EC of 17 January 2003 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 13, 18.1.2003, p. 35).
61. Commission Decision 2003/312/EC of 9 April 2003 on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks in accordance with Council Directive 89/106/EEC (OJ L 114, 8.5.2003, p. 50).
62. Commission Decision 2003/424/EC of 6 June 2003 amending Decision 96/603/EC establishing the list of products belonging to Classes A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 144, 12.6.2003, p. 9).

63. Commission Decision 2003/593/EC of 7 August 2003 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance of certain construction products (OJ L 201, 8.8.2003, p. 25).
64. Commission Decision 2003/629/EC of 27 August 2003 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, as regards the inclusion of smoke and heat control products (OJ L 218, 30.8.2003, p. 51).
65. Commission Decision 2003/632/EC of 26 August 2003 amending Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction-to-fire performance of construction products (OJ L 220, 3.9.2003, p. 5).
66. Commission Decision 2003/639/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pins for structural joints (OJ L 226, 10.9.2003, p. 18).
67. Commission Decision 2003/640/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards kits for exterior wall claddings (OJ L 226, 10.9.2003, p. 21).
68. Commission Decision 2003/655/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards watertight covering kits for wetroom floors and walls (OJ L 231, 17.9.2003, p. 12).
69. Commission Decision 2003/656/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European technical approvals without Guideline (OJ L 231, 17.9.2003, p. 15).
70. Commission Decision 2003/722/EC of 6 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid-applied bridge deck waterproofing kits (OJ L 260, 11.10.2003, p. 32).
71. Commission Decision 2003/728/EC of 3 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rockfall protection kits (OJ L 262, 14.10.2003, p. 34).
72. Commission Decision 2004/663/EC of 20 September 2004 amending Commission Decision 97/464/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 302, 29.9.2004, p. 6).
73. Commission Decision 2005/403/EC of 25 May 2005 establishing the classes of external fire performance of roofs and roof coverings for certain construction products as provided for by Council Directive 89/106/EEC (OJ L 135, 28.5.2005, p. 37).
74. Commission Decision 2005/484/EC of 4 July 2005 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cold storage building kits and cold storage building envelope kits (OJ L 173, 6.7.2005, p. 15).
75. Commission Decision 2005/610/EC of 9 August 2005 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 208, 11.8.2005, p. 21).
76. Commission Decision 2005/823/EC of 22 November 2005 amending Decision 2001/671/EC implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (OJ L 307, 25.11.2005, p. 53).

77. Commission Decision 2006/190/EC of 1 March 2006 amending Decision 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards floorings (OJ L 66, 8.3.2006, p. 47).
  78. Commission Decision 2006/213/EC of 6 March 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards wood flooring and solid wood panelling and cladding (OJ L 79, 16.3.2006, p. 27).
  79. Commission Decision 2006/600/EC of 4 September 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards double skin metal faced sandwich panels for roofs (OJ L 244, 7.9.2006, p. 24).
  80. Commission Decision 2006/673/EC of 5 October 2006 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards gypsum plasterboards (OJ L 276, 7.10.2006, p. 77).
  81. Commission Decision 2006/751/EC of 27 October 2006 amending Decision 2000/147/EC implementing Council Directive 89/106/EC as regards the classification of the reaction-to-fire performance of construction products (OJ L 305, 4.11.2006, p. 8).
  82. Commission Decision 2006/893/EC of 5 December 2006 on the withdrawal of the reference of standard EN 10080:2005 "Steel for the reinforcement of concrete — Weldable reinforcing steel — General" in accordance with Council Directive 89/106/EC (OJ L 343, 8.12.2006, p. 102).
  83. Commission Decision 2007/348/EC of 15 May 2007 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards wood-based panels (OJ L 131, 23.5.2007, p. 21).
- Switzerland
100. Loi fédérale du 8 octobre 1999 sur les produits de construction (RO 2000 3104).
  101. Ordonnance du 27 novembre 2000 sur les produits de construction (RO 2001 100).
  102. Accord intercantonal sur l'élimination des entraves techniques au commerce du 23 octobre 1998 (RO 2003 270).

## Section II

### Conformity assessment bodies

1. The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of this Agreement, a list of the conformity assessment bodies.
2. Conformity assessment bodies can be differentiated in three different bodies involved in the attestation of conformity: Certification body, inspection body and testing laboratory. For the purpose of this Agreement the definitions of Annex III Section 3 to Directive 89/106/EEC shall apply.

## Section III

### Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

## 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 to this Agreement and the assessment criteria set out in Annex IV to Directive 89/106/EEC.

## Section V

**Supplementary provisions****1. European harmonised standards for construction products**

- (a) For the purpose of this Agreement, Switzerland will publish the reference of the European harmonised standards for construction products after their publishing in the *Official Journal of the European Union* according to Article 7 of the Directive 89/106/EEC.
- (b) To state the equivalence of the Swiss systems of conformity attestation, Switzerland will add to every harmonised standard a conversion table. This conversion table shall ensure the comparability of the Swiss and the European systems of conformity attestation describing the relevant procedures to assess conformity.

**2. Interpretative documents and guidance papers**

The six Interpretative Documents referred to in Article 3 of the Directive 89/106/EEC and in the Communication 94/C 62/01 of the Commission (OJ C 62, 28.2.1994, p. 1) established according to Article 20 of the Directive 89/106/EEC shall also apply for the purpose of this Agreement.

**3. European Technical Approvals**

- (a) Switzerland shall be entitled to designate Swiss bodies to issue European technical approvals. It shall make sure that designated bodies become members of the European Organisation for Technical Approvals (EOTA) and participate in its work, in particular for establishing guidelines for European technical approvals according to Article 11 of the Directive 89/106/EEC and issuing European technical approvals (ETAs).

Switzerland shall notify the Committee established under Article 10 of this Agreement of the names and addresses of such bodies.

Decisions of EOTA shall also apply for the purpose of this Agreement.

European Technical Approvals are issued by the EOTA Approval Bodies and are recognised by both Parties for the purpose of this Agreement.

- (b) "Approval Body" shall mean a public or private law body which is authorised to issue European technical approvals.

Approval bodies are designated by the Parties according to their relevant procedures.

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the approval bodies. To this end, the notification procedure described in Section II para. 1 in accordance with Article 11 of this Agreement shall also apply to approval bodies analogously.

The Parties hereby recognise that the bodies thus listed for the purpose of this Agreement fulfil the conditions to issue European technical approvals.

**4. Information exchanges**

In accordance with Article 9 of this Agreement, the Parties shall exchange information needed to ensure a proper implementation of this chapter.

**5. 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 10 years after the last date of manufacture of the product.

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

**6. Person responsible for placing the products on the market and labelling**

The manufacturer shall not be obliged to designate an authorised representative or a person responsible for placing products on the market established in the territory of the other Party, nor to indicate the name and address of an authorised representative, responsible person or importer on the label, outer packaging or instructions for use.'

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