

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2014 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 1 April 2014

**on the amendment of Chapter 6 on pressure vessels, Chapter 16 on construction products and the
update of legal references listed in Annex 1**

(2014/379/EU)

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') and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

- (1) The European Union has adopted a new Directive on the transportable pressure equipment ⁽¹⁾ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation;
- (2) Chapter 6, Pressure vessels, of Annex 1 should be amended to reflect these developments;
- (3) The European Union has adopted a new Regulation on construction products ⁽²⁾ (hereinafter the 'Construction Products Regulation');
- (4) The Swiss legislation on construction products (Federal Law and Ordinance on construction products) is in the process of being amended; however, the Swiss ordinance on Accreditation and Designation ⁽³⁾, establishing the relevant framework requirements for the accreditation and designation of Swiss conformity assessment bodies is already in force;
- (5) Chapter 16, Construction products, of Annex 1 should be amended, in a first step, to reflect the adoption of the Construction Products Regulation by the European Union, and, until the adoption of Swiss equivalent legislation, to enable the Parties during an interim period to grant mutual acceptance of conformity assessment results showing compliance with the Construction Products Regulation; once Swiss legislation equivalent with the Construction Products Regulation is adopted, the Parties shall replace this amendment with a subsequent one reflecting the adoption of both the Construction Products Regulation and the revised equivalent Swiss legislation. It is understood that this decision is meant to ensure continuity in the activities of conformity assessment bodies during this interim period, and is without prejudice to the application of the principles of Article 1 of the Agreement;

⁽¹⁾ Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

⁽²⁾ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

⁽³⁾ Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887).

- (6) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

HAS DECIDED AS FOLLOWS:

1. Chapter 6, Pressure vessels, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.
2. The Swiss Confederation shall accept conformity assessment results of EU recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation. The European Union shall accept conformity assessment results of Swiss recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation until the amendment of Chapter 16 following the adoption of equivalent Swiss legislation.

Chapter 16, Construction products, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision and shall apply during the interim period until such amendment.

3. Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.
4. This Decision, done in duplicate, shall be signed by representatives of the Parties in the Committee who are authorized to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation

Christophe PERRITAZ

Signed at Bern, 1 April 2014

On behalf of the European Union

Fernando PERREAU DE PINNINCK

Signed at Brussels, 1 April 2014

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 6, Pressure Vessels should be deleted and replaced by the following:

‘CHAPTER 6

PRESSURE VESSELS

SECTION I

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

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 1. Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels (OJ L 264, 8.10.2009, p. 12), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12) 2. 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 (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 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1), hereinafter referred to as “Directive 2010/35/EU” 4. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13) |
| Switzerland | <ol style="list-style-type: none"> 100. Federal Law of 12 June 2009 on product safety (RO 2010 2573) 101. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631) 102. Ordinance of 20 November 2002 on the safety of simple pressure vessels (RO 2003 107), as last amended on 19 May 2010 (RO 2010 2583) 103. Ordinance of 20 November 2002 on the safety of pressure equipment (RO 2003 38), as last amended on 19 May 2010 (RO 2010 2583) 104. Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO 2012 6607) 105. Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO 2002 4212), as last amended on 31 October 2012 (RO 2012 6535 and 6537) 106. Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway (RO 2012 6541) |

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 2009/105/EC, Annexes IV or V to Directive 97/23/EC or Chapter 4 of Directive 2010/35/EU.

SECTION V

Additional provisions*1. Simple pressure vessels and pressure equipment*

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 undertake to forward all relevant documents to the authorities of the other Party upon request.

*2. Transportable pressure equipment**1. Market access*

1. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the authorised representative shall indicate its name and address on the certificate of conformity. For the purpose of this obligation; “authorised representative” shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from the manufacturer to act on his behalf in relation to specified tasks.
2. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the importer shall indicate its name and the address at which it can be contacted either on, or attached to the certificate of conformity. For the purpose of this obligation, “importer” shall mean any natural or legal person established within the European Union or Switzerland who places transportable pressure equipment or parts thereof from a third country on the European Union or on the Swiss market.
3. For the purposes of paragraphs 1 and 2, it shall be sufficient to mention either the importer or the authorised representative.

2. Information exchange regarding technical documentation and cooperation regarding corrective action

Economic operators of Switzerland or a Member State shall, further to a reasoned request from the competent national authority of Switzerland or a Member State, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment with Directive 2010/35/EU or the relevant Swiss legislation in a language easily understood by that authority or in English. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by transportable pressure equipment which they have placed on the market.

3. *Identification of economic operators*

Economic operators shall, on request from the market surveillance authority of either an EU Member State or Switzerland, identify the following to it for a period of at least 10 years:

- (a) any economic operator who has supplied them with transportable pressure equipment;
- (b) any economic operator to whom they have supplied transportable pressure equipment.

4. *Mutual assistance of market surveillance authorities*

To ensure efficient cooperation for actions concerning economic operators based in a Member State or in Switzerland, the market surveillance authorities of a Member State and Switzerland shall give each other assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigation or any other appropriate measure, by participating in investigations initiated by the other Party.

5. *Procedure for dealing with transportable pressure equipment presenting a risk at national level*

1. Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a transportable pressure equipment covered by this chapter presents a risk to the health or safety of persons or to other aspects of public interest protection covered by Directive 2010/35/EU respectively the relevant Swiss legislation, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

- the results of the evaluation and of the actions which they have required the economic operator to take.
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the transportable pressure equipment being made available on their national market, to withdraw the equipment from that market or to recall it.

2. This information shall include all available details, in particular the data necessary for the identification of the non-compliant transportable pressure equipment, the origin of the equipment, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. Further, it shall be indicated whether the non-compliance is due to either:

- failure of the transportable pressure equipment to meet requirements relating to the health or safety of persons or to other aspects of public interest protection in the legislation in section I, or
- shortcomings in the standards or technical codes referred to in the legislation in section I.

3. Switzerland, or Member States other than the Member State initiating the procedure shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the transportable pressure equipment concerned.

4. Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the transportable pressure equipment concerned, such as withdrawal of the transportable pressure equipment from their market, without delay.

5. Switzerland shall notify the contact details of its market surveillance authority, as well as any changes thereof, to the European Union via the Committee established under Article 10 of this Agreement.

6. *Safeguard procedure*

Should it disagree with the notified national measure, Switzerland or a Member State shall inform the European Commission of its objections.

1. Objections against national measures

Where, on completion of the procedure set out in paragraph 3 of section 5 above, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be non-compliant with the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland and the relevant economic operator or operators and shall evaluate the national measure, in order to determine whether the national measure is justified or not. If the national measure is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from their markets, and shall inform the Commission accordingly.
- unjustified, the Member State concerned or Switzerland shall withdraw it.

2. Disagreement between the Parties

In case of a disagreement between the Parties the issue will be forwarded to the Joint Committee, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

- justified, the Parties shall take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from their market.
- unjustified, the Member State or Switzerland shall withdraw it;

7. *Free movement of transportable pressure equipment*

Without prejudice to the procedures in paragraph 3 and 4 above, no Member State or Switzerland shall prohibit, restrict or impede on its territory the free movement, the making available on the market and the use of transportable pressure equipment, which complies with the legal provisions in Section I.'

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 16, Construction Products shall be deleted and replaced by the following:

CHAPTER 16

CONSTRUCTION PRODUCTS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraphs 1 and 2:

European Union 1. Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5)

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)
- 2(a). 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)
- 2(b). 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 fire-fighting systems (OJ L 254, 8.10.1996, p. 8)
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 lightweight 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/light-weight 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)
- 53(a). 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)
- 56(a). 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 fire-fighting 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/EEC (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)
84. Commission Decision 2010/81/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards adhesives for ceramic tiles (OJ L 38, 11.2.2010, p. 9)
85. Commission Decision 2010/82/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards decorative wallcoverings in roll and panel form (OJ L 38, 11.2.2010, p. 11)
86. Commission Decision 2010/83/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards air drying jointing compounds (OJ L 38, 11.2.2010, p. 13)

87. Commission Decision 2010/85/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards cementitious screeds, calcium sulphate screeds and synthetic resin floor screeds (OJ L 38, 11.2.2010, p. 17)
88. Commission Decision 2010/679/EU of 8 November 2010 amending Decision 95/467/EC implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 292, 10.11.2010, p. 55)
89. Commission Decision 2010/683/EU of 9 November 2010 amending Decision 97/555/EC 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 293, 11.11.2010, p. 60)
90. Commission Decision 2010/737/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards steel sheets with polyester coating and with plastisol coating (OJ L 317, 3.12.2010, p. 39)
91. Commission Decision 2010/738/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards fibrous gypsum plaster casts (OJ L 317, 3.12.2010, p. 42)
92. Commission Decision 2011/14/EU of 13 January 2011 amending Decision 97/556/EC 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 10, 14.1.2011, p. 5)
93. Commission Decision 2011/19/EU of 14 January 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sealants for non-structural use in joints in buildings and pedestrian walkways (OJ L 11, 15.1.2011, p. 49)
94. Commission Decision 2011/232/EU of 11 April 2011 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, construction works and parts thereof (OJ L 97, 12.4.2011, p. 49)
95. Commission Decision 2011/246/EU of 18 April 2011 amending Decision 1999/93/EC 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 103, 19.4.2011, p. 114)
96. Commission Decision 2011/284/EU of 12 May 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards power, control and communication cables (OJ L 131, 18.5.2011, p. 22)
97. Commission Implementing Decision 2012/201/EU of 26 March 2012 amending Decision 98/213/EC 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 109, 21.4.2012, p. 20)
98. Commission Implementing Decision 2012/202/EU of 29 March 2012 amending Decision 1999/94/EC 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 109, 21.4.2012, p. 22)
99. Commission Implementing Regulation (EU) No 1062/2013 of 30 October 2013 on the format of the European Technical Assessment for construction products (OJ L 289, 31.10.2013, p. 42)

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 assessment and verification of constancy of performance: Product certification body, factory product control certification body and testing laboratory. For the purpose of this Agreement the definitions of Annex V Section 2 to Regulation (EU) No 305/2011 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 and the competent 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 with the assessment criteria set out in Article 43 of Regulation (EU) No 305/2011.

SECTION V

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

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 17(5) of the Regulation (EU) No 305/2011.

To state the equivalence of the Swiss systems of assessment and verification of constancy of performance, 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 assessment and verification of constancy of performance describing the relevant procedures for them.

2. *European Technical Assessments*

- (a) Switzerland shall be entitled to designate Swiss bodies to issue European Technical Assessments. It shall make sure that designated bodies become members of the European Organisation for Technical Assessment (EOTA) and participate in its work, in particular for developing and adopting European Assessment Documents (EADs) according to Article 19 of Regulation (EU) No 305/2011.

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 Assessments are issued by the Technical Assessment Bodies and are recognised by both Parties for the purpose of this Agreement.

- (b) “Technical Assessment Body” shall mean a public or private law body which is authorised to issue European Technical Assessments.

Technical Assessment bodies are designated by the Parties according to their relevant procedures. For the designation of Technical Assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and with the assessment criteria set out in Table 2 of Annex IV to Regulation (EU) No 305/2011.

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 Technical Assessment Bodies. The Parties hereby recognise that the bodies thus listed for the purpose of this Agreement fulfil the conditions to issue European Technical Assessments.

3. *Information exchanges*

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

4. *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 date of placing the product on either Party's market.

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

5. *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.'

ATTACHMENT C

Amendments to Annex 1**Chapter 1 (Machinery)**

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union provisions should be deleted and replaced by the following text:

- | | | |
|-----------------|----|---|
| ‘European Union | 1. | Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006, p. 24), as last amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (OJ L 310, 25.11.2009, p. 29)’ |
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Chapter 2 (Personal Protective Equipment)

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union provision should be deleted and replaced by the following text:

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|-----------------|----|---|
| ‘European Union | 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 (OJ L 399, 30.12.1989, p. 18), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12)’ |
|-----------------|----|---|

Chapter 3 (Toys)

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- | | | |
|-----------------|------|--|
| ‘European Union | 1. | Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1), as last amended by Commission Regulation (EU) No 681/2013 (OJ L 195, 18.7.2013, p. 16) (hereinafter referred to as “Directive 2009/48/EC”) |
| Switzerland | 100. | Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 9 November 2011 (RO 2011 5227) |
| | 101. | Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 23 October 2013 (RO 2013 3669) |
| | 102. | Ordinance of the Federal Department of Home Affairs (FDHA) of 15 August 2012 on the safety of toys (RO 2012 4717) as last amended on 25 November 2013 (RO 2013 5297) |
| | 103. | Ordinance of the FDHA of 23 of November 2005 on the enforcement of foodstuff legislation (RO 2005 6555) as last amended on 15 August 2012 (RO 2012 4855) |
| | 104. | Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887)’ |

Chapter 4 (Medical devices)

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- European Union
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 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 amended by Regulation (EC) No 1882/2003 of the European Parliament and 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 amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)
 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 Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 22, 9.8.2012, p. 3)
 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)
 10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63)
 11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50)
 12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)
 13. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45)

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|-------------|------|--|
| | 14. | Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28) |
| | 15. | Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8) |
| Switzerland | 100. | Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 14 December 2012 (RO 2013 1493) |
| | 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 20 March 2008 (RO 2008 3437) |
| | 102. | Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2011 (RO 2012 6235) |
| | 103. | Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 10 December 2004 (RO 2004 5391) |
| | 104. | Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 11 June 2010 (RO 2010 2749) |
| | 105. | Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847), as last amended on 4 September 2013 (RO 2013 3041) |
| | 106. | Ordinance of 17 June 1996 on Accreditation and Designation of Conformity Assessment Bodies (RO 1996 1904), as last amended on 15 June 2012 (RO 2012 3631) |
| | 107. | Federal Act on Data Protection of 19 June 1992 (RO 1992 1945), as last amended on 30 September 2011 (RO 2013 3215) |

Chapter 5 (Gas Appliances and Boilers)

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union provisions should be deleted and replaced by the following text:

- | | | |
|----------------|----|--|
| European Union | 1. | Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10) |
|----------------|----|--|

Chapter 7 (Radio Equipment and Telecommunications Terminal Equipment)

In Section I, Legislative, regulatory and administrative provisions, provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- | | | |
|----------------|----|--|
| European Union | 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 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)
5. 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)
6. 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)
7. Commission Decision 2013/638/EU of 12 August 2013 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 296, 7.11.2013, p. 22)

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|-------------|---|
| Switzerland | <ol style="list-style-type: none"> 100. Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187), as last amended on 12 June 2009 (RO 2010 2617) 101. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 31 October 2012 (RO 2012 6561) 102. Ordinance of 14 June 2002 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2002 2111), as last amended on 12 August 2013 (RO 2013 2649) 103. Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115), 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 28 December 2012 (FF 2012 9084) 105. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 9 December 2011 (RO 2012 367) |
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Chapter 8 (Equipment and protective systems intended for use in potentially explosive atmospheres)

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 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 (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12) |
| Switzerland | <ol style="list-style-type: none"> 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 20 March 2008 (RO 2008 3437) |

101. Ordinance 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 11 June 2010 (RO 2010 2749)
102. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
103. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631)

Chapter 9 Electrical equipment and Electromagnetic compatibility

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to Swiss provisions should be deleted and replaced by the following text:

- | | |
|--------------|--|
| ‘Switzerland | <ol style="list-style-type: none"> 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 20 March 2008 (RO 2008 3437) 101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 16 November 2011 (RO 2011 6243) 102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 16 November 2011 (RO 2011 6233) 103. Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016), as last amended on 11 June 2010 (RO 2010 2749) 104. Ordinance of 18 November 2009 on electromagnetic compatibility (RO 2009 6243), as last amended on 24 August 2010 (RO 2010 3619) 105. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 31 October 2012 (RO 2012 6561) 106. List of the technical standards published in the Feuille Fédérale with titles and references, as last amended on 6 November 2012 (FF 2012 7968) |
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Chapter 11 Measuring instruments and prepackages

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(1), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- | | |
|-----------------|--|
| ‘European Union | <ol style="list-style-type: none"> 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 2. 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 3. 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 |
|-----------------|--|

4. 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
 5. 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
 6. 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 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended
 101. Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and pre-packaged products (RS 941.204.1), as subsequently amended

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

- European Union
1. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (Recast) (OJ L 106, 28.4.2009, p. 7)
 2. 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)
 3. 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)
 4. 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 2009/3/EC of the European Parliament and of the Council of 11 March 2009 (OJ L 114, 7.5.2009, p. 10)
 5. 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)
 6. Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments (OJ L 122, 16.5.2009, p. 6), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12)
 7. 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 17 June 2011 on metrology (RO 2012 6235)
 103. Ordinance of 23 November 1994 on units measurement (RO 1994 3109), as last amended on 7 December 2012 (RO 2012 7193)

104. Ordinance of 15 February 2006 concerning measuring instruments (RO 2006 1453), as last amended on 7 December 2012 (RO 2012 7207)
105. Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO 2004 2093), as last amended on 7 December 2012 (RO 2012 7183)
106. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO 2006 1433), as last amended on 7 December 2012 (RO 2012 7183)
107. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO 2006 1525), as last amended on 7 December 2012 (RO 2012 7183)
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), as last amended on 7 December 2012 (RO 2012 7183)
109. Ordinance of the federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO 2006 1545), as last amended on 7 December 2012 (RO 2012 7183)
110. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO 2006 1569), as last amended on 7 December 2012 (RO 2012 7183)
111. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO 2006 1591), as last amended on 7 December 2012 (RO 2012 7183)
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), as last amended on 7 December 2012 (RO 2012 7183)
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), as last amended on 7 December 2012 (RO 2012 7183)
114. Ordinance of 15 August 1986 on weights (RO 1986 2022), as last amended on 7 December 2012 (RO 2012 7183)

In Section IV, Special rules relating to the designation of conformity assessment bodies, the provision should be deleted and replaced by the following text:

‘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 2009/23/EC and in Article 12 to Directive 2004/22/EC, as regards the products covered by those Directives.’

In Section V, Supplementary provisions, point 1 (Information exchange), point 2 (Prepackages) and point 3 (Marking) should be deleted and replaced by the following text:

‘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 2009/23/EC.

The conformity assessment bodies recognised under this Agreement may request the information provided for in point 1.6 of Annex II to Directive 2009/23/EC.

2. Prepackages

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

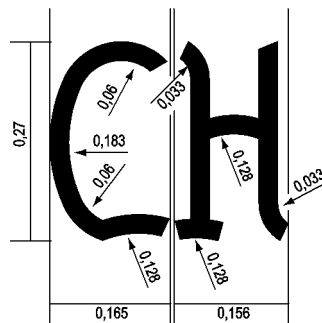
As regards statistical checking of the quantities declared on prepackages, the European Union shall recognise the Swiss method laid down in Annex 3 Point 7 of the Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204) as equivalent to the European Union method laid down in Annex II of Directives 75/106/EEC and 76/211/EEC, as amended by Directive 78/891/EEC. Swiss producers whose prepackages conform to European Union legislation and have been checked according to the Swiss method shall affix the “e” mark on their products exported to the EU.

3. Marking

3.1. For the purposes of this Agreement, the provisions of Directive 2009/34/EC of 23 April 2009 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(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 Directive 2009/34/EC of 23 April 2009.’

Chapter 12 (Motor vehicles)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

‘SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|--|
| European Union | 1. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Regulation (EU) No 195/2013 of the Commission of 7 March 2013 (OJ L 65, 8.3.2013, p. 1), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 1 December 2013 (hereinafter together referred to as “Framework Directive 2007/46/EC”) |
|----------------|--|

- | | |
|-------------|---|
| Switzerland | 100. Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as amended until 30 November 2012 (RO 2012 7137)

101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 7 December 2012 (RO 2012 7065) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1' |
|-------------|---|

Section V, paragraph 1, Amendments to Annex IV respectively to acts listed in Annex IV of Directive 2007/46/EC should be deleted and replaced by the following:

'1. Amendments to Annex IV respectively to acts listed in Annex IV of Directive 2007/46/EC

Without prejudice to article 12(2), the European Union shall notify Switzerland of amendments to Annex IV and to acts listed in Annex IV of Directive 2007/46/EC after 1 December 2013 without delay after their publication in the *Official Journal of the European Union*.

Switzerland shall notify the European Union without delay of the relevant amendments of the Swiss legislation, at the latest by the date of application of these amendments in the European Union.'

Chapter 13 (Agricultural and Forestry Tractors)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|--|
| European Union | 1. Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)

2. 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 2010/52/EU of the Commission of 11 August 2010 (OJ L 213, 13.8.2010, p. 37)

3. Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)

4. 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) |
|----------------|--|

5. 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 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
6. 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 2012/24/EU of the Commission of 8 October 2012 (OJ L 274, 9.10.2012, p. 24)
7. Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
8. 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 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
9. Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
10. 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 Directive 2011/87/EU of the European Parliament and the Council of 16 November 2011 (OJ L 301, 18.11.2011, p. 1)
11. 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 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
12. Directive 2008/2/EC of the European Parliament and the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (OJ L 24, 29.1.2008, p. 30)
13. Directive 2009/57/EC of the European Parliament and the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors (OJ L 261, 3.10.2009, p. 1)
14. Directive 2009/58/EC of the European Parliament and the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors (OJ L 198, 30.7.2009, p. 4)
15. Directive 2009/59/EC of the European Parliament and the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (OJ L 198, 30.7.2009, p. 9)
16. Directive 2009/60/EC of the European Parliament and the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
17. Directive 2009/61/EC of the European Parliament and the Council of 13 July 2009 relating to the installation of lighting and light signalling devices on wheeled agricultural and forestry tractors (OJ L 203, 5.8.2009, p. 19)

18. Directive 2009/63/EC of the European Parliament and the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors (OJ L 214, 19.8.2009, p. 23)
 19. Directive 2009/64/EC of the European Parliament and the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility) (OJ L 216, 20.8.2009, p. 1)
 20. Directive 2009/66/EC of the European Parliament and the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 11)
 21. Directive 2009/68/EC of the European Parliament and the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (OJ L 203, 5.8.2009, p. 52)
 22. Directive 2009/75/EC of the European Parliament and the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (OJ L 261, 3.10.2009, p. 40)
 23. Directive 2009/76/EC of the European Parliament and the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 18)
 24. Directive 2009/144/EC of the European Parliament and the Council of 30 November 2009 on certain components and characteristics of wheeled agricultural or forestry tractors, as last amended by Directive 2013/8/EU of the Commission of 26 February 2013 (OJ L 56, 28.2.2013, p. 8)
 25. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1)
- Switzerland
100. Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 2 March 2012 (RO 2012 1915)
 101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 7 December 2012 (RO 2012 7065)

Chapter 15 (Medicinal products GMP Inspection and batch certification)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

‘SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- European Union
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) as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38)

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 (OJ L 311, 28.11.2001, p. 67) as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1)
 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)
 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)
 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)
 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)
 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)
 8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission)
 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)
 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 Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 July 2013 (RO 2013 1493)
 101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 January 2013 (RO 2012 3631)
 102. Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 1 January 2013 (RO 2012 5651)
 103. Ordinance of 20 September 2013 on clinical trials in human research (RO 2013 3407)
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