ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2017 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 28 July 2017

on the amendment of Chapter 4 on medical devices, Chapter 6 on pressure vessels, Chapter 7 on radio equipment and telecommunication terminal equipment, Chapter 8 on equipment and protective systems intended for use in potentially explosive atmosphere, Chapter 9 on electrical equipment and electromagnetic compatibility, Chapter 11 on measuring instruments, Chapter 15 on medicinal products, GMP inspection and batch certification, Chapter 17 on lifts, and Chapter 20 on explosives for civil use, and the update of legal references listed in Annex 1 [2017/2118]

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 Parties to the Agreement have agreed to adapt Chapter 4, Medical devices, of Annex 1 in order to foster the cooperation among the regulators in the area of medical devices;

(2) The European Union has adopted a new Directive on simple pressure vessels ([1]) and a new Directive on pressure equipment ([2]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(3) Chapter 6, Pressure vessels, of Annex 1 should be amended to reflect these developments;

(4) The European Union has adopted a new Directive on radio equipment ([3]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(5) Chapter 7, Radio equipment and Telecommunications terminal equipment, of Annex 1 should be amended to reflect these developments;

(6) The European Union has adopted a new Directive on equipment and protective systems intended for use in potentially explosive atmosphere ([4]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(7) Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere, of Annex 1 should be amended to reflect these developments;

([1]) Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).
([2]) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).
([3]) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).
([4]) Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309).

(8) The European Union has adopted a new Directive on electrical equipment ([1]) and a new Directive on electromagnetic compatibility ([2]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(9) Chapter 9, Electrical equipment and Electromagnetic compatibility, of Annex 1 should be amended to reflect these developments;

(10) The European Union has adopted a new Directive on non-automatic weighing instruments ([3]) and a new Directive on measuring instruments ([4]) Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(11) Chapter 11, Measuring instruments and prepackages, of Annex 1 should be amended to reflect these developments;

(12) The Parties to the Agreement have agreed to amend Chapter 15, Medicinal products GMP Inspection and Batch Certification, of Annex 1 in order to enable the recognition of results of GMP inspections carried out by the relevant inspection services of the other Party in third countries;

(13) The European Union has adopted a new Directive on lifts ([5]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(14) Chapter 17, Lifts, of Annex 1 should be amended to reflect these developments;

(15) The European Union has adopted a new Directive on explosives for civil use ([6]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(16) Chapter 20, Explosives for civil use, of Annex 1 should be amended to reflect these developments;

(17) It is necessary to update the legal references in Chapters 3, 12, 14, 16, 18 and 19 of Annex 1 to the Agreement;

(18) 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 4, Medical devices, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Chapter 6, Pressure vessels, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.

3. Chapter 7, Radio equipment and Telecommunication terminal equipment, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.

3. Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment D to this Decision.

([1]) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).
([2]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).
([3]) Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).
([4]) Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149).
([5]) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).
([6]) Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1).

4. Chapter 9, Electrical equipment and electromagnetic compatibility, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment E to this Decision.

5. Chapter 11, Measuring instruments and prepackages, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment F to this Decision.

6. Chapter 15, Medicinal products, GMP inspection and batch certification, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment G to this Decision.

8. Chapter 17, Lifts, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment H to this Decision.

9. Chapter 20, Explosives for civil use, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment I to this Decision.

10. Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment J annexed to this Decision.

11. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorised 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	*On behalf of the European Union*
Christophe PERRITAZ	Ignacio IRUARRIZAGA
Signed in Bern on 28 July 2017	Signed in Brussels on 27 July 2017

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 4, Medical devices should be deleted and replaced by the following one:

'CHAPTER 4

MEDICAL DEVICES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

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 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 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 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 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 212, 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)

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 1 January 2014 (RO 2013 4137)

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 15 April 2015 (RO 2015 999)

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)

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 under this Chapter, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and, as laid down in Implementing Regulation (EU) No 920/2013, 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.

Switzerland shall make available assessors for the pool established under Implementing Regulation (EU) No 920/2013.

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 Union 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 Union 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, Article 11 of Directive 98/79/EC and Article 3 of Implementing Regulation (EU) No 920/2013.

4. **European databases**

The competent Swiss authorities shall have access to the European databases established under Article 12 of Directive 98/79/EC, Article 14a of Directive 93/42/EEC and Article 3 of Implementing Regulation (EU) No 920/2013. They shall transmit to the Commission and/or body responsible for managing the databases the data provided for in those Articles collected in Switzerland for entry into the European databases.'

ATTACHMENT B

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

'CHAPTER 6

PRESSURE VESSELS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45)
	2. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164)
	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	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 25 November 2015 on the safety of simple pressure vessels (RO 2016 227)
	103. Ordinance of 25 November 2015 on the safety of pressure equipment (RO 2016 233)
	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)
	107. 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 25 November 2015 (RO 2016 261)

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 Chapter 4 of Directive 2014/29/EU, Chapter 4 of Directive 2014/68/EU or Chapter 4 of Directive 2010/35/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Article 6(3) of Directive 2010/35/EU, respectively Articles 6(6) and 8(3) of Directive 2014/29/EU, or Articles 6(6) and 8(3) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In cases where the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 4(3) and 6(6) of Directive 2010/35/EU, respectively Articles 6(3) and 8(8) of Directive 2014/29/EU or Articles 6(3) and 8(8) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the product has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6) of Directive 2014/29/EU or Articles 6(4), second subparagraph, and 8(6) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 5(2) of Directive 2010/35/EU, respectively Article 7(2) of Directive 2014/29/EU, or Article 7(2) of Directive 2014/68/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 5(1) of Directive 2010/35/EU, respectively Article 7(1) of Directive 2014/29/EU, or Article 7(1) of Directive 2014/68/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 28 of Directive 2010/35/EU, Article 32 of Directive 2014/29/EU and Article 37 of Directive 2014/68/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 29 of Directive 2010/35/EU, Article 33 of Directive 2014/29/EU and Article 38 of Directive 2014/68/EU, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with products presenting a risk not restricted to the national territory**

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 product covered by this chapter presents a risk to the health or safety of persons or to other aspects of public interest protection referred to in the relevant legislation in Section I of this Chapter 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 product being made available on their national market, to withdraw the product from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, 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. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the product 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 harmonised standards referred to in the legislation in Section I.

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 product concerned.

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

6. **Safeguard procedure in case of objections against national measures**

Should it disagree with the notified national measure in paragraph 5, Switzerland or a Member State shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States and Switzerland, and via the Swiss authorities 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 product is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a product that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to other aspects of public interest protection referred to in the relevant legislation in Section I of this Chapter, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the 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:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT C

In Annex 1, Product Sectors, Chapter 7, Radio equipment and telecommunications terminal equipment should be deleted and replaced by the following one:

'CHAPTER 7

RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62)

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) ([1])

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)

8. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) (OJ L 96, 29.3.2014, p. 357) ([2])

9. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79) ([2])

Switzerland

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 25 November 2015 on Telecommunications Equipment (OIT) (RO 2016 179)

102. Ordinance of 26 May 2016 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2016 1673), as last amended on 15 June 2017 (RO 2017 3201)

103. 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 25 November 2015 (RO 2016 261)

104. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 5 November 2014 (RO 2014 4035)

(1) The reference to the class identifier in Article 2 of Commission Decision 2000/299/EC does not apply.
(2) Without prejudice to Chapter 9.

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 Chapter IV of Directive 2014/53/EU.

SECTION V

Supplementary provisions

1. **Amendments to legislative, regulatory and administrative provisions of Section I**

Without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of implementing and delegated acts of the Commission under Directive 2014/53/EU adopted after 13 June 2016 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.

2. **Economic operators**

2.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 10(7) and 12(3) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In cases where the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 10(4) and 12(8) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 10(5), second subparagraph, and 12(6) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

2.2. *Provision of information on radio equipment and software by manufacturer*

(a) Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State or Switzerland without infringing applicable requirements on the use of the radio spectrum. In cases of restrictions on putting into service or of requirements for authorisation of use of radio equipment, information on the packaging shall identify restrictions existing in Switzerland, Member States or geographical areas within their territory.

(b) For radio equipment within the scope of Article 4 of Directive 2014/53/EU and the corresponding Swiss legislation, manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall, where required in the legislation under Section I, provide and continuously update the Member States, Switzerland and the Commission, with information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in Directive 2014/53/EU and the corresponding Swiss legislation, in the form of a statement of compliance which includes the elements of the declaration of conformity.

(c) As from 12 June 2018, where required in the legislation under Section I, manufacturers shall, prior to placing on the Parties' markets radio equipment within categories designated by the European Commission as affected by a low level of compliance, register their types within the central system mentioned in Article 5 of Directive 2014/53/EU. The European Commission shall allocate to each registered radio equipment type a registration number, which manufacturers shall affix on radio equipment placed on the market.

The Parties shall exchange information on registered radio equipment types affected by a low level of compliance.

The Parties shall take into account information on compliance of radio equipment provided by Switzerland and Member States when designating categories of radio equipment affected by a low level of compliance.

2.3. *Authorised representative*

For the purpose of the obligation in Article 11(2) of Directive 2014/53/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 11(1) of Directive 2014/34/EU or the corresponding Swiss provisions.

2.4. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of radio equipment with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the radio equipment.

3. **Assignment of radio equipment classes**

Member States and Switzerland shall notify each other the interfaces they intend to regulate on their territory in cases foreseen under Article 8(1) of Directive 2014/53/EU. When establishing the equivalence of regulated radio interfaces and assigning a radio equipment class, the European Union shall take account of the radio 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, putting into service and use**

(a) When the Commission intends to adopt a requirement related to categories or classes of radio equipment pursuant to Articles 2(6), 3(3), 4(2), 5(2) of Directive 2014/53/EU, it shall consult Switzerland on the issue before submitting it formally to the Committee, unless a consultation took place with the Telecommunication Conformity Assessment and Market Surveillance Committee.

(b) Member States and Switzerland shall allow the putting into service and use of radio equipment if it complies with the legislation in Section I when it is properly installed, maintained and used for its intended purpose. They may only introduce additional requirements for the putting into service and/or use of radio equipment for reasons related to the effective and efficient use of the radio spectrum, to the avoidance of harmful interference, to the avoidance of electromagnetic disturbances or to public health.

6. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 38 of Directive 2014/53/EU, directly or by means of designated representatives.

Conformity assessment bodies shall inform the other bodies recognised under this chapter concerning type examination certificates which they have refused, withdrawn, suspended or restricted, and upon request concerning certificates they have issued.

Conformity assessment bodies shall inform the Member States and Switzerland of type examination certificates issued and/or additions thereto, in those cases where harmonised standards have not been applied or not been fully applied. The Member States, Switzerland, the European Commission and the other bodies may, on request, obtain a copy of the type examination certificates and/or additions thereto, a copy of the technical documentation and the results of the examinations carried out.

7. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 37 of Directive 2014/53/EU.

8. **Telecommunication Conformity Assessment and Market Surveillance Committee**

Switzerland may participate as observer in the Telecommunication Conformity Assessment and Market Surveillance Committee work and that of its sub-groups.

9. **Cooperation between market surveillance authorities**

Pursuant to Article 9 paragraph1 of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

10. **Objections to 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 Commission to act in accordance with the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([1]). The Committee shall be informed of the result of the procedure.

11. **Procedure for dealing with equipment presenting a risk caused by non-compliance not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have found that equipment covered by this chapter does not comply with requirements laid down in the legislation in Section I of this Chapter, 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 operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict equipment being made available on their national market, to withdraw equipment from that market or to recall it.

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

— failure of the radio equipment to meet essential requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States 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 equipment concerned.

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

([1]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

12. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 11, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 11, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It 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 equipment be withdrawn or recalled from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 14.

13. **Compliant radio equipment which nevertheless present a risk**

Where a Member State or Switzerland finds that, although radio equipment that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to health and safety of persons or to other aspects of public interest protection, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 14.

14. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 10 and 11 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, 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

(a) unjustified, the national authority of the Member State or Switzerland shall withdraw it;

(b) justified, they shall take the appropriate measures to ensure that products are withdrawn from their market or recalled.'

ATTACHMENT D

In Annex 1, Product Sectors, Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere should be deleted and replaced by the following one:

'CHAPTER 8

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERE

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmosphere (OJ L 96, 29.3.2014, p. 309)
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 20 March 2008 (RO 2008 3437)
	101. Ordinance of 25 November 2015 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 2016 143)
	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)
	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 25 November 2015 (RO 2016 261)

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 assessment criteria set out in Chapter 4 of Directive 2014/34/EU.

SECTION V

Supplementary provisions

1. Economic operators

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 6(7) and 8(3) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 6(3) and 8(8) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the product has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 6(4), second subparagraph, and 8(6) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 7(2) of Directive 2014/34/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 7(1) of Directive 2014/34/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 32 of Directive 2014/34/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 33 of Directive 2014/34/EU, directly or by means of designated representatives.

Conformity assessment bodies shall provide the other bodies recognised under this chapter carrying out similar conformity assessment activities covering the same product with relevant information on issues relating to negative and, on request, positive conformity assessment results.

The Commission, the Member States, Switzerland and the other bodies recognised under this chapter may request a copy of the type examination certificates and additions thereto. On request, the Commission, Member States, and Switzerland may obtain a copy of the technical documentation and the results of the examinations carried out by a body recognised under this chapter.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with products presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have found that a product covered by this Chapter does not comply with requirements laid down in the legislation in Section I of this Chapter, 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 operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it.

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

— failure of the product to meet requirements relating to the health and safety of persons or to the protection of domestic animals or property requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland, or Member States 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 product concerned.

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

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a product is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant product is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a product that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to domestic animals or property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, 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:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT E

In Annex 1, Product Sectors, Chapter 9, Electrical equipment and electromagnetic compatibility should be deleted and replaced by the following one:

'CHAPTER 9

ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357)
	2. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79)
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 20 March 2008 (RO 2008 3437)
	101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 25 November 2015 (RO 2016 625)
	102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 25 November 2015 (RO 2016 119)
	103. Ordinance of 25 November 2015 on electrical low voltage equipment (RO 2016 105)
	104. Ordinance of 25 November 2015 on electromagnetic compatibility (RO 2016 119)
	105. Ordinance of 25 November 2015 on Telecommunications Equipment (OIT); (RO 2016 179)
	106. 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 25 November 2015 (RO 2016 261)

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 Chapter 4 of Directive 2014/30/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Article 7(6) and 9(3) of Directive 2014/30/EU, respectively Articles 6(6) and 8(3) of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 7(3) and 9(7) of Directive 2014/30/EU, respectively Articles 6(3) and 8(8) of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the equipment has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the equipment has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6), second subparagraph, of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 8(2) of Directive 2014/30/EU, respectively Article 7(2) of Directive 2014/35/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 8(1) of Directive 2014/30/EU, respectively Article 7(1) of Directive 2014/35/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of equipment with the legislation in section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the equipment.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Directive 2014/30/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Directive 2014/30/EU, directly or by means of designated representatives.

4. **Committee on Electromagnetic Compatibility and Committee on Electrical equipment**

Switzerland may participate as an observer in the work of the Committee on Electromagnetic Compatibility and the Committee on Electrical equipment and of their subgroups.

5. **Standards**

For the purpose of this Chapter and according to Article 14 of Directive 2014/35/EU and the corresponding Swiss provisions, competent authorities of Member States and Switzerland shall also regard as complying with their safety objectives for electrical equipment in the scope of Directive 2014/35/EU, equipment manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture or in Switzerland, if it ensures a safety level equivalent to that required in their own territory.

6. **Conformity assessment bodies**

The Parties shall inform each other of and mutually recognise the bodies responsible for the tasks described in Annex III to Directive 2014/30/EU.

Conformity assessment bodies shall provide the other bodies recognised under this chapter carrying out similar conformity assessment activities covering the same equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

The Commission, the Member States, Switzerland and the other bodies recognised under this chapter may request a copy of the type examination certificates and additions thereto. On request, the Commission, Member States, and Switzerland may obtain a copy of the technical documentation and the results of the examinations carried out by a body recognised under this chapter.

7. **Cooperation between market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

8. **Procedure for dealing with equipment presenting a risk not restricted to the national territory**

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 equipment covered by this chapter presents a risk to aspects of public interest protection covered by the legislation in Section I of this Chapter 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 operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict equipment being made available on their national market, to withdraw equipment from that market or to recall it.

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

— failure of equipment to meet requirements referred to in the legislation in Section I, or

— shortcomings in the standards referred to in the legislation in Section I.

Switzerland or Member States 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 equipment concerned.

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

9. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 8, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 8, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It 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 non-compliant equipment be withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 11.

10. **Compliant equipment which nevertheless present a risk**

Where a Member State or Switzerland finds that, although an equipment within the scope of Directive 2014/35/EU that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons, or to domestic animals or to property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of equipment concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 11.

11. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 9 and 10 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, 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

(a) unjustified, the national authority of the Member State or Switzerland shall withdraw it;

(b) justified, they shall take the appropriate measures to ensure that products are withdrawn from their market.'

ATTACHMENT F

In Annex 1, Product Sectors, Chapter 11, Measuring instruments and prepackages should be deleted and replaced by the following one:

'CHAPTER 11

MEASURING INSTRUMENTS AND PREPACKAGES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(1)

European Union

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 prepackaged 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 prepacked 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 prepackaged products (RS 941.204.1), as subsequently amended

Provisions covered by Article 1(2)

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 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107)

7. Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149)

8. Directive 2011/17/EU of the European Parliament and of the Council of 9 March 2011 repealing Council Directives 71/317/EEC, 71/347/EEC, 71/349/EEC, 74/148/EEC, 75/33/EEC, 76/765/EEC, 76/766/EEC and 86/217/EEC regarding metrology (OJ L 71, 18.3.2011, 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 25 November 2015 (RO 2015 5835)

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 25 November 2015 (RO 2015 5849)

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 19 November 2014 (RO 2014 4551)

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 the Federal Ministry of Justice and Police of 15 August 1986 on weights (RO 1986 2022), as last amended on 7 December 2012 (RO 2012 7183)

115. Ordinance of the Federal Ministry of Justice and Police of 5 November 2013 on taximeters (RO 2013 4333), as last amended on 19 November 2014 (RO 2014 4547)

116. 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 25 November 2015 (RO 2016 261)

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 Chapter 4 of Directive 2014/31/EU and Chapter 4 of Directive 2014/32/EU, as regards the products covered by those Directives.

SECTION V

Supplementary provisions

1. **Prepackages**

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

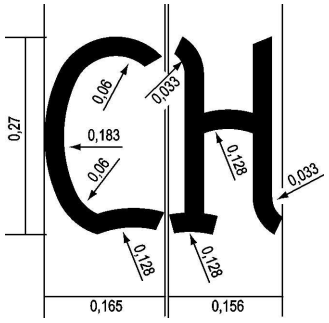
As regards statistical checking of the quantities declared on prepackages, the European Union shall recognise the Swiss method laid down in Annex 3 Point 7 of the Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204) as equivalent to the European 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 Union legislation and have been checked according to the Swiss method shall affix the "e" mark on their products exported to the EU.

2. **Marking**

2.1. For the purposes of this Agreement, the provisions of Council 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 1 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:



2.2. 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.

3. Non-automatic weighing instruments covered by Directive 2014/31/EU and measuring instruments covered by Directive 2014/32/EU

3.1. *Economic operators*

3.1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 6(6) and 8(3) of Directive 2014/31/EU, respectively Articles 8(6) and 10(3) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 6(3) and 8(8) of Directive 2014/31/EU, respectively Articles 8(3) and 10(8) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the instrument has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the instrument has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6) of Directive 2014/31/EU, respectively Articles 8(4), second subparagraph, and 10(6) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

3.1.2. *Authorised representative*

For the purpose of the obligation in Article 7(2) of Directive 2014/31/EU, respectively Article 9(2) of Directive 2014/32/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 7(1) of Directive 2014/31/EU, respectively Article 9(1) of Directive 2014/32/EU or the corresponding Swiss provisions.

3.1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of instrument with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the instrument.

3.2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 34 of Directive 2014/31/EU and Article 39 of Directive 2014/32/EU.

3.3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 35 of Directive 2014/31/EU, respectively Article 40 of Directive 2014/32/EU, directly or by means of designated representatives.

3.4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

3.5. **Procedure for dealing with instruments presenting a risk caused by non-compliance not restricted to the national territory**

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 an instrument covered by this chapter presents a risk to aspects of public interest protection covered by Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, 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 operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

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

— failure of the instrument to meet requirements relating to aspects of public interest protection laid down in Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, or

— shortcomings in the harmonised standards referred to in Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions.

Switzerland, or Member States 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 instrument concerned.

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

3.6. **Safeguard procedure in case of objections against national measures**

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

Where, on completion of the procedure set out in paragraph 3.4, 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 contrary to Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to an instrument is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant instrument is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 3.8.

3.7. **Compliant instruments which nevertheless present a risk to health and safety**

Where a Member State or Switzerland finds that, although an instrument that an economic operator has been made available on the EU and on the Swiss market is in compliance with Directive 2014/31/EU or Directive 2014/32/EU, respectively the relevant Swiss legislation, presents a risk to aspects of public interest protection, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 3.8.

3.8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in subparagraphs 3.6 and 3.7 above, the issue will be forwarded to the 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:

(a) justified, the Parties shall take the measures necessary to ensure that the instrument is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT G

In Annex 1, Product Sectors, Chapter 15, Medicinal products, GMP Inspection and Batch Certification should be deleted and replaced by the following:

'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 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. This includes that each Party recognises conclusions of inspections of manufacturers in third countries carried out by the relevant inspection services of the other Party, inter alia, within the framework of the European Directorate for the Quality of Medicines & HealthCare (EDQM).

The Parties shall cooperate in order to achieve the best use of inspection resources by an appropriate burden sharing.

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. To the products imported from a third country and further exported to the other Party this provision applies only (1) if each batch of the medicinal products has been subject to the re-control in the territory of one of the Parties; and (2) if the manufacturer in the third country has been subject to the inspection by the competent authority of either Party of which the outcome has been that for the products or products category the manufacturer complies with Good Manufacturing Practice. If the above conditions are not met, each Party can require a re-control in its territory.

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 Union and Switzerland as listed in Section I of this Chapter. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs and, where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products.

"GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and products specifications. For the purpose of this Chapter it includes the system whereby the manufacturer receives the specification of the product and the process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification.

With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection be made by the locally competent inspection service. This provision shall apply 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.

For inspections in third countries, at the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for the inspection shall certify that the manufacturer complies or does not comply with the GMP requirements recognised as equivalent by the two Parties, and which are listed in Section I of this Chapter.

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

Certificates shall be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, i.e. when a new inspection has to be carried out, this period may be extended to 90 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 GM P. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union 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 European Union, 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

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 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33)

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) and Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42)

7. Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 343, 23.11.2013, p. 1)

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 4 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) and Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1)

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)

11. Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1)

Switzerland

100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 January 2014 (RO 2013 4137)

101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 May 2016 (RO 2016 1171)

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 May 2016 (RO 2016 1171)

103. Ordinance of 20 September 2013 on clinical trials in human research (RO 2013 3407) as last amended on 1 May 2017 (RO 2017 2439)

SECTION II

Conformity assessment bodies

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

The list of the official GMP Inspection Services of the Member States of the European Union and of Switzerland can be found below.

For conformity assessment bodies of the European Union:

Competent Authorities of the European Union are the following authorities of the Member States of the European Union or authorities succeeding them:

Country	For medicinal products for human use	For medicinal products for veterinary use
Austria	Austrian Agency for Health and Food Safety/ Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See responsible authority for human medicinal products
Belgium	Federal agency for medicines and health products/Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/Agence fédérale des médicaments et produits de santé	See responsible authority for human medicinal products
Bulgaria	Bulgarian Drug Agency/ ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните
Cyprus	Ministry of Health — Pharmaceutical Services/ Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment-Veterinary Services/ Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Czech Republic	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/ Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Croatia	Agency for Medicinal Products and Medical Devices/ Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate/ Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Denmark	Danish Medicines Agency/ Laegemiddelstyrelsen	See responsible authority for human medicinal products
Germany	Federal Institute for Drugs and Medical Devices/ Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines/Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health/Bundesministerium für Gesundheit (BMG)/Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) [1]	Federal Office for Consumer Protection and Food Safety/ Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines/ Ravimiamet	See responsible authority for human medicinal products
Greece	National Organisation for Medicines/ Ethnikos Organismos Farmakon (EOF) — (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See responsible authority for human medicinal products
Spain	Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios [2]	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
Finland	Finnish Medicines Agency/ Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	See responsible authority for human medicinal products
France	French National Agency for Medicines and Health Products Safety/Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety-*National Agency for Veterinary Medicinal Products*/ Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail-Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet/National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products/Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for human medicinal products
Italy	Italian Medicines Agency/Agenzia Italiana del Farmaco	Direction General for Animal Health and Veterinary Medicinal Products/ Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Latvia	State Agency of Medicines/ Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency/ Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service/ Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
Malta	Medicines Regulatory Authority	Veterinary Medicines and Animal Nutrition section VMANS) (Veterinary Regulation Directorate (VRD) within the Veterinary and Phytosanitary Regulation Department (VPRD)
Netherlands	Healthcare Inspectorate/Inspectie voor de Gezondheidszorg (IGZ)	Medicines Evaluation Board/ Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)
Poland	The Main Pharmaceutical Inspectorate/ Główny Inspektorat Farmaceutyczny (GIF)	See responsible authority for human medicinal products
Portugal	National Authority of Medicines and Health Products/ INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary/DGAV — Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices/ Agenția Națională a Medicamentului şi a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority/Autoritatea Națională Sanitară Veterinară şi pentru Siguranța Alimentelor
Sweden	Medical Products Agency/Läkemedelsverket	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia/ Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See responsible authority for human medicinal products
Slovak Republic (Slovakia)	State Institute for Drug Control/ Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/ Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
United Kingdom	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate

(1) For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent *Länder* authorities issuing GMP documents and conducting pharmaceutical inspections.

(2) For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing GMP documents and conducting pharmaceutical inspections.

For Swiss conformity assessment bodies:

For all products for human and veterinary use:

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

For the official batch release of immunobiological products for veterinary use:

http://www.blv.admin.ch/ivi/index.html?lang=en

SECTION III

Additional 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 30 calendar days, this period being extended to 60 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 according to the applicable GMP legislation listed in Section I.

(b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting country, the competent inspection service of the Party willing to carry out an inspection of the relevant manufacturing operations shall inspect according to its own GMP or, in the absence of specific GMP requirements, according to 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 GM P. 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 on manufacturing/import authorisations and GMP compliance**

The Parties shall exchange information on the authorisation status of manufacturers and importers and on the outcome of the inspections, in particular by entering authorisations, GMP certificates and information on GMP non-compliance into the database on GMP managed by the European Medicines Agency (EMA). GMP certificates and information on GMP-compliance shall follow the format in accordance with the procedures published by the EU.

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

The relevant authorities in Switzerland and in the European Union 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 European Union

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.'

ATTACHMENT H

In Annex 1, Product Sectors, Chapter 17, Lifts should be deleted and replaced by the following one:

'CHAPTER 17

LIFTS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251)
Switzerland	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 25 November 2015 on the safety of lifts (RO 2016 219)
	103. 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 25 November 2015 (RO 2016 261)

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 this Agreement and the assessment criteria set out in Chapter 4 of Directive 2014/33/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 8(6) and 10(3) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 8(3) and 10(8) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the safety component for lifts has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the safety component for lifts has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 8(4), second subparagraph, and 10(6) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 9(2) of Directive 2014/33/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 9(1) of Directive 2014/33/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Directive 2014/33/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Directive 2014/33/EU, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with lifts or safety components for lifts presenting a risk not restricted to the national territory**

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 lift or a safety component for lifts covered by this chapter presents a risk to the health or safety of persons or, where appropriate, to the safety of property, covered by the legislation in Section I of this Chapter, 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 operators to take,

— where the installer does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the placing on their national market or the use of the lift concerned, or to recall it,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the safety component for lifts being made available on their national market, to withdraw the safety component for lifts from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant lift or safety component for lifts, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the lift or the safety component for lifts to meet requirements relating to the health and safety requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland, or Member States 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 lift or the safety component for lifts concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the lift or the safety component for lifts concerned, such as withdrawal of the lift or safety component for lifts from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the notified national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a lift is considered justified, all Member States and Switzerland shall take the measures necessary to ensure that the placing on the market or use of the non-compliant lift concerned is restricted or prohibited, or that the lift is recalled, and shall inform the Commission accordingly.

If the national measure relating to a safety component for lift is considered justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant safety component for lifts is withdrawn from their markets, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a lift or a safety component for lifts that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons and, where appropriate, the safety of property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the lift or safety component for lifts concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 6 and 7 above, the issue will be forwarded to the 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:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT I

In Annex 1, Product Sectors, Chapter 20, Explosives for civil use should be deleted and replaced by the following one:

'CHAPTER 20

EXPLOSIVES FOR CIVIL USE

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1) [1]
	2. Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the indication and traceability of explosives for civil uses (OJ L 94, 5.4.2008, p. 8), as amended by Commission Directive 2012/4/EU (OJ L 50, 23.2.2012, p. 18), hereinafter referred to as "Directive 2008/43/EC"
	3. Commission Decision 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document (OJ L 120, 24.4.2004, p. 43), as amended by Commission Decision 2010/347/EU (OJ L 155, 22.6.2010, p. 54), hereinafter referred to as "Decision 2004/388/EC"
Switzerland	100. Federal Act of 25 March 1977 on explosive substances (Explosives Act) as last amended on 12 June 2009 (RO 2010 2617)
	101. Ordinance of 27 November 2000 on explosives (Explosives Ordinance), as last amended on 25 November 2015 (RO 2016 247)
	102. 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 25 November 2015 (RO 2016 261)

[1] This Chapter shall not apply to explosives intended for use, in accordance with national law, by the armed forces or the police, to pyrotechnical articles and to ammunition.

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 designation of 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 Chapter 5 of Directive 2014/28/EU.

SECTION V

Supplementary provisions

1. Economic operators

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 5(5)(b) and 7(3) of Directive 2014/28/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 5(3) and 7(7) of Directive 2014/28/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the explosive has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the explosive has been placed on the market in either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 6(2) of Directive 2014/28/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 6(1) of Directive 2014/28/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 39 of Directive 2014/28/EU.

3. Coordination of conformity assessment bodies

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 40 of Directive 2014/28/EU, directly or by means of designated representatives.

4. Mutual assistance of market surveillance authorities

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with explosives presenting a risk not restricted to the national territory**

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 an explosive covered by this chapter presents a risk to the health or safety of persons or to the property or the environment covered by Directive 2014/28/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 operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the explosives' being made available on their national market, to withdraw the explosive from that market or to recall it.

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

— failure of the explosive to meet requirements relating to the health or safety of persons, or to the protection of property or the environment and safety requirements referred to in the relevant legislation in Section I, or

— shortcomings in the harmonised standards referred to in the relevant legislation in Section I.

Switzerland, or Member States 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 explosive concerned.

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

6. **Safeguard procedure in case of objections against national measures**

Should it disagree with the notified national measure in paragraph 5, Switzerland or a Member State shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, 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 contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It 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 explosive is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although an explosive that an economic operator has been made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to the property or the environment, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the explosive concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the 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:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

9. **Identification of products**

Both Parties shall ensure that undertakings in the explosives sector which manufacture or import explosives or assemble detonators shall mark explosives and each smallest packaging unit with a unique identification. Where an explosive is subject to further manufacturing processes, manufacturers shall not be required to mark the explosive with a new unique identification unless the original unique identification is no longer marked in compliance with Directive 2008/43/EC and/or the Explosives Ordinance.

The unique identification shall comprise the components prescribed in the Annex to Directive 2008/43/EC and Annex 14 to the Explosives Ordinance and shall be mutually recognised by both parties.

Each undertaking in the explosives sector and/or manufacturer shall be attributed a three-digit code by the Member State's or Swiss national authority where it is established. This three-digit code shall be mutually recognised by both Parties if the manufacturing site or the manufacturer is located in the territory of one of the Parties.

10. **Provisions governing the supervision of transfers between the European Union and Switzerland**

1. Explosives covered by this Chapter may be transferred between the European Union and Switzerland only in accordance with the following paragraphs.

2. Approval to transfer explosives shall be obtained by the consignee from the recipient competent authority. The competent authority shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of the necessary licenses or authorisations. The economic operator responsible for the transfer shall notify the competent authorities of the transit Member State or Member States or Switzerland of any movements of explosives through the Member State concerned or Switzerland and shall obtain prior approval of the transit Member State concerned or Switzerland.

3. Where a Member State or Switzerland considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 3, that Member State or Switzerland shall forward the available information on the subject to the European Commission which shall inform the other Member States and Switzerland accordingly through the Committee established under Article 10 of this Agreement.

4. Where the competent authority of the consignee in the Member State or Switzerland approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 10(5). Such a document shall accompany the explosives until they arrive at their stated destination. It shall be produced at the request of the competent authorities. A copy of this document shall be retained by the consignee who shall present it, upon request, for examination by the competent authority of the consignee in the Member State or Switzerland.

5. Where transfers of explosives must be specially supervised in order to comply with special security requirements in the territory or part of the territory of a Member State or Switzerland, prior to the transfer the following information shall be provided by the consignee to the competent authority of the consignee in the Member State or Switzerland:

   (a) the names and addresses of the economic operators concerned;

   (b) the number and quantity of the explosives being transferred;

(c) a full description of the explosive in question and of the means of identification, including the United Nations identification number;

(d) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;

(e) the means of transfer and the itinerary;

(f) the expected dates of departure and arrival;

(g) where necessary, the precise points of entry to and exit from Member States or Switzerland.

The information referred to in point (a) shall be sufficiently detailed in order to enable competent authorities to contact the economic operators and to obtain confirmation that the economic operators concerned are entitled to receive the consignment.

The competent authority of the consignee in the Member State or Switzerland shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the event of transit through the territory of other Member States or Switzerland, those States or Switzerland shall likewise examine and approve, the particulars concerning the transfer.

6. Where the competent authority of a Member State or Switzerland considers that special security requirements referred to in paragraph 10(4) and 10(5) are unnecessary, explosives can be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 10(5). The recipient competent authority shall then grant an approval for a fixed period and liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph 10(4), which must accompany the explosives until they arrive at their destination, shall refer solely to the abovementioned approval.

7. Without prejudice to the normal checks which the country of departure shall carry out in its territory, at the request of the competent authorities concerned, the consignees and the economic operators concerned shall forward to the authorities of the country of departure and to those of country of transit all relevant information they possess concerning the transfer of explosives.

8. No economic operator may transfer explosives unless the consignee has obtained the necessary authorisations for the transfer in accordance with the provisions of paragraphs 10(2), 10(4), 10(5) and 10(6).

9. For the purposes of implementing paragraphs 4 and 5, the provisions of Decision 2004/388/EC shall apply.

11. **Information exchange**

In accordance with the general provisions of this Agreement, the Member States and Switzerland shall keep at each other's disposal any relevant information needed to ensure a proper implementation of Directive 2008/43/EC.'

ATTACHMENT J

Amendments to Annex 1

CHAPTER 3

TOYS

In Section I, Legislative regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the 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 Directive (EU) 2017/898 (OJ L 138, 25.5.2017, p. 128) (hereinafter referred to as "Directive 2009/48/EC")
Switzerland	100. Federal Law of 20 June 2014 on foodstuffs and commodities (RO 2017 249)
	101. Ordinance of 16 December 2016 on foodstuffs and commodities (RO 2017 283) as last amended on 2 May 2017 (RO 2017 2695)
	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 1 May 2017 (RO 2017 1525)
	103. Ordinance of the FDHA of 16 December 2016 on the enforcement of foodstuff legislation (RO 2017 359
	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 20 April 2016 (RO 2016 261)'

CHAPTER 12

MOTOR VEHICLES

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 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) 2015/758 of the European Parliament and of the Council of 29 April 2015 (OJ L 123, 19.5.2015, p. 77), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 29 April 2015 (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 16 November 2016 (RO 2016 5195)
	101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 16 November 2016 (RO 2016 5213) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1'

In 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 text:

'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 29 April 2015 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 14

GLP

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

'European Union

Food and feed:

1. Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1)
2. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 64, 11.3.2011, p. 15)
3. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1)

New and existing chemicals:

4. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), as last amended by Commission Regulation (EU) No 348/2013 of 17 April 2013 (OJ L 108, 18.4.2013, p. 1)
5. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), as last amended by Commission Regulation (EU) No 944/2013 of 2 October 2013 (OJ L 261, 3.10.2013, p. 5)

Medicinal products:

6. 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 (OJ L 299, 27.10.2012, p. 1). 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)
7. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1)

Veterinary medicinal products:

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 Commission Directive 2009/9/EC of 10 February 2009 (OJ L 44, 14.2.2009, p. 10)

Plant protection products:

9. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)

10. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1)

11. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85)

Biocidal products:

12. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)

Cosmetic products:

13. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)

Detergents:

14. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)

Medical devices:

15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)

Switzerland

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 20 June 2014 (RO 2016 689)

101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 20 June 2014 (RO 2016 689)

102. Ordinance of 5 June 2015 on protection against dangerous substances and preparations (RO 2015 1903), as last amended on 22 March 2017 (RO 2017 2593)

103. Ordinance of 18 May 2005 on biocidal products (RO 2005 2821) as last amended on 28 March 2017 (RO 2017 2441)

104. Ordinance of 12 May 2010 on the authorisation of plant protection products (RO 2010 2331), as last amended on 22 March 2017 (RO 2017 2593)

105. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137)

106. Ordinance of 17 October 2001 on medicinal products (RO 2001 3420), as last amended on 23 March 2016 (RO 2016 1171)'

In Section III, Designating authorities, the Contact Details of the GLP 'Monitoring Authorities' of the European Union should be deleted and replaced by the following:

'For the European Union:

http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en'

CHAPTER 16

CONSTRUCTION PRODUCTS

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

1. 'Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5), as last amended by Commission Delegated Regulation (EU) No 574/2014 from 21 February 2014 (OJ L 159, 28.5.2014, p. 41), as well as implementing and delegated acts of the Commission adopted under this regulation until 1 December 2016 (hereinafter together referred to as Regulation (EU) No 305/2011)'

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

'European Union

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)
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)
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)'

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

'Switzerland

100. Federal law of 21 March 2014 on construction products (RO 2014 2867)
101. Ordinance of 27 August 2014 on construction products (RO 2014 2887)
102. Ordinance of the Federal office for Building and Logistics on the designation of European implementing and delegated acts regarding construction products of 10 September 2014 as last amended on 24 May 2016 (RO 2016 1413)
103. 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 25 November 2015 (RO 2016 261)
104. Accord intercantonal sur l'élimination des entraves techniques au commerce du 23 octobre 1998 (RO 2003 270)'

In Section V, paragraph 1, Amendments to legislative, regulatory and administrative provisions of Section I should be deleted and replaced by the following text:

'1. **Amendments to legislative, regulatory and administrative provisions of Section I**

Without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of implementing and delegated acts of the Commission under Regulation (EU) No 305/2011 adopted after 1 December 2016 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.'

CHAPTER 18

BIOCIDAL PRODUCTS

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

'European Union

1. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), (OJ L 167, 27.6.2012, p. 1), as last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 (OJ L 103, 5.4.2014, p. 22), as well as implementing and delegated acts of the Commission adopted under this regulation until 3 December 2015

Switzerland	100. Federal Law of 15 December 2000 for the protection against dangerous substances and preparations (RO 2004 4763), as last amended on 13 June 2006 (RO 2006 2197)
	101. Federal Law of 7 October 1983 relating to the protection of the Environment (RO 1984 1122), as last amended on 1 August 2010 (RO 2010 3233)
	102. Ordinance of 18 May 2005 concerning the making available on the market and the use of biocidal products (Ordinance on Biocidal Products, RO 2005 2821), as last amended on 1 September 2015 (RO 2015 2803) (hereinafter "OPBio")
	103. Ordinance of 15 August 2014 of the Department of Home Affairs on implementing rules related to the Ordinance on Biocidal Products (RO 2014 2755), as last amended on 15 September 2015 (RO 2015 3073)'