

This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

► **B****AGREEMENT**

between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment

(OJ L 114, 30.4.2002, p. 369)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Decision No 2/2002 of 8 January 2003	L 68	1	12.3.2003
► <u>M2</u>	Decision No 1/2004 of 16 January 2004	L 34	72	6.2.2004
► <u>M3</u>	Decision No 1/2005 of the Committee of 7 March 2005	L 93	40	12.4.2005
► <u>M4</u>	Decision No 2/2005 of 30 March 2005	L 110	78	30.4.2005
► <u>M5</u>	Decision No 3/2005 of 25 October 2005	L 322	29	9.12.2005
► <u>M6</u>	Decision No 4/2005 of 25 October 2005	L 322	31	9.12.2005
► <u>M7</u>	Decision No 1/2006 of 29 September 2006	L 325	22	24.11.2006
► <u>M8</u>	Agreement revising the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment	L 386	51	29.12.2006
► <u>M9</u>	Decision No 2/2006 of 13 December 2006	L 32	135	6.2.2007
► <u>M10</u>	Decision No 1/2008 of 12 March 2008	L 282	22	25.10.2008
► <u>M11</u>	Decision No 2/2008 of 16 May 2008	L 158	1	19.6.2009
► <u>M12</u>	Decision No 1/2009 of 21 December 2009	L 147	11	12.6.2010
► <u>M13</u>	Decision No 1/2010 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 18 October 2010	L 46	51	19.2.2011
► <u>M14</u>	Decision No 1/2011 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 20 December 2011	L 80	31	20.3.2012
► <u>M15</u>	Decision No 1/2012 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 17 December 2012	L 136	17	23.5.2013
► <u>M16</u>	Decision No 1/2014 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 1 April 2014	L 182	61	21.6.2014
► <u>M17</u>	Decision No 1/2015 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 14 April 2015	L 171	25	2.7.2015
► <u>M18</u>	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	L 323	51	7.12.2017

- **M19** Decision No 2/2017 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 22 December 2017 L 72 24 15.3.2018

▼B**AGREEMENT****between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment**

THE EUROPEAN COMMUNITY, hereinafter referred to as ‘the Community’,
and

THE SWISS CONFEDERATION, hereinafter referred to as ‘Switzerland’,

together hereinafter referred to as ‘the Parties’,

Considering the close ties that exist between the Community and Switzerland;

Considering the Free Trade Agreement of 22 July 1972 between Switzerland and the European Economic Community;

Desiring to conclude an Agreement providing for the mutual recognition of the results of conformity assessment procedures required for access to the respective markets of the Parties;

Considering that mutual recognition in relation to conformity assessment will facilitate trade between the Parties and ensure protection for health, safety, the environment and consumers;

Considering the alignment of legislation will facilitate mutual recognition;

Considering their obligations as Contracting Parties to the Agreement establishing the World Trade Organisation and, in particular, to the Agreement on Technical Barriers to Trade, which encourages the negotiation of mutual recognition agreements;

Considering that mutual recognition agreements contribute to harmonisation at international level of the technical regulations, standards and principles governing implementation of conformity assessment procedures;

Considering that the close ties between the Community and Switzerland, of the one part, and Iceland, Liechtenstein and Norway, of the other, makes the conclusion of parallel agreements between those countries and Switzerland appropriate,

Have agreed to conclude the following Agreement:

*Article 1***Purpose**

1. The Community and Switzerland hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the ►**M8** bodies recognised in accordance with the procedures of this Agreement (hereinafter recognised conformity assessment bodies) ◀ and of the manufacturer's declarations of conformity certifying conformity to the requirements of the other Party in the areas covered by Article 3.

2. In order to avoid duplication of procedures when Swiss and Community requirements are deemed equivalent, the Community and Switzerland shall mutually accept reports, certificates and authorisations issued by ►**M8** recognised conformity assessment bodies ◀ and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3. Reports, certificates, authorisations and manufacturer's declarations of conformity shall in particular indicate conformity with the Community legislation. Conformity marks required by the legislation of one of the Parties must be affixed to products placed on the market of that Party.

▼B

3. The Committee provided for in Article 10 shall specify the cases in which paragraph 2 shall apply.

*Article 2***Definitions**

1. For the purposes of this Agreement:

‘Conformity assessment’ shall mean systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

‘Conformity assessment body’ shall mean a public or private law body whose activities include performance of all or any stage of the conformity assessment process;

‘Designating authority’ shall mean an authority with the legal power to designate, suspend, withdraw designation or remove suspension of conformity assessment bodies under its jurisdiction.

2. ►**M8** The definitions laid down by ISO and IEC may be used to establish the meaning of the general terms relating to conformity assessment contained in this Agreement. ◀

*Article 3***Scope**

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

2. Annex 1 defines the product sectors covered by this Agreement. The Annex is divided up into sectoral chapters and these are subdivided in principle as follows:

section I: legislative, regulatory and administrative provisions;

section II: conformity assessment bodies;

section III: designating authorities;

section IV: special rules relating to the designation of conformity assessment bodies;

section V: any additional provisions.

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

▼M8*Article 4***Origin**

The provisions of this Agreement shall apply to products covered by this Agreement irrespective of their origin.

▼M8*Article 5***Recognised conformity assessment bodies**

The Parties hereby agree that conformity assessment bodies recognised in accordance with the procedure provided for in Article 11 fulfil the conditions of eligibility to assess conformity.

*Article 6***Designating authorities**

1. The Parties hereby undertake to ensure that their designating authorities have the necessary power and competence to designate conformity assessment bodies or withdraw designation, suspend or remove suspension of designated conformity assessment bodies under their respective jurisdiction.

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

▼B*Article 7***Verification of designation procedures**

1. The Parties shall exchange information concerning the procedures used to ensure ►**M8** recognised conformity assessment bodies under their jurisdiction ◀ comply with the general principles of designation outlined in Annex 2 subject to the provisions of the respective section IV in Annex 1.

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

3. Verification shall be carried out in accordance with the procedure implemented by the Committee under Article 10 below.

*Article 8***Verification of compliance of conformity assessment bodies**

1. Each Party shall, in exceptional circumstances, have the right to contest the technical competence of the conformity assessment bodies proposed by the other Party or ►**M8** of recognised conformity assessment bodies ◀ under the jurisdiction of the other Party.

For this purpose, it shall submit in writing an objective and reasoned argument to the other Party ►**M8** ————— ◀.

▼B

2. In the event of a disagreement between the Parties, confirmed in the Committee, a verification of the technical competence of the conformity assessment body in question shall be undertaken in accordance with requirements jointly by the Parties, with the participation of the competent authorities concerned.

The result of that verification shall be discussed in the Committee with a view to resolving the issue as soon as possible.

3. Each Party shall ensure that the conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.

4. Unless otherwise decided by the Committee, the disputed body shall be suspended by the competent designating authority from the time disagreement has been established until agreement has been reached in the Committee. ►**M8** Such suspension shall be indicated in the common list of recognised conformity assessment bodies referred to in Annex 1. ◀

*Article 9***Implementation of the Agreement**

1. The Parties shall cooperate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Annex 1.

2. The designating authorities shall ascertain by appropriate means whether the ►**M8** recognised conformity assessment bodies under their jurisdiction ◀ are observing the general principles of designation listed in Annex 2, subject to the provisions listed in the respective section IV in Annex 1.

3. ►**M8** The recognised conformity assessment bodies ◀ shall cooperate in an appropriate way in the framework of the coordination and comparison work conducted by each of the Parties in respect of the sectors covered by Annex 1 in order to ensure that the conformity assessment procedures provided for in the laws and regulations of the Parties covered by this Agreement are applied in a consistent manner. ►**M8** The designating authorities shall use their best endeavours to ensure that recognised conformity assessment bodies cooperate in an appropriate way. ◀

*Article 10***Committee**

1. A Committee on mutual recognition in relation to conformity assessment (hereinafter referred to as the 'Committee'), is hereby established. It shall be composed of representatives of the Parties, and shall be responsible for the management and monitoring of the smooth functioning of this Agreement. To that end, it shall issue recommendations and take decisions in the circumstances provided for in this Agreement. It shall act by mutual agreement.

2. The Committee shall establish its own rules of procedure, which shall contain, *inter alia*, provisions on the convening of meetings, the appointment of the chairman and the chairman's term of office.

3. The Committee shall meet as and when necessary and at least once a year. Either Party may request the convening of a meeting.

▼M8

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

- (a) drawing up the procedure for carrying out the verifications provided for in Article 7;
- (b) drawing up the procedure for carrying out the verifications provided for in Article 8;
- (c) deciding on the recognition of conformity assessment bodies contested under Article 8;
- (d) deciding on the withdrawal of recognition of recognised conformity assessment bodies contested under Article 8;
- (e) examining any legislative, regulatory and administrative provisions notified by one Party to another pursuant to Article 12 in order to assess their repercussions on the Agreement and to amend the appropriate sections in Annex 1.

▼B

5. The Committee may, on a proposal from one of the Parties, modify the Annexes to this Agreement.

▼M8*Article 11***Recognition, withdrawal of recognition, modification of the scope, and suspension of conformity assessment bodies**

1. The following procedure shall apply for the recognition of conformity assessment bodies in relation to the requirements set out in the relevant Chapters of Annex 1:

- (a) a Party wishing to have recognised any conformity assessment body shall notify the other Party in writing of its proposal, to that effect, adding the appropriate information to its request;
- (b) if the other Party agrees to the proposal or raises no objection within 60 days of the notification of the proposal, the conformity assessment body shall be considered to be a recognised conformity assessment body under the terms of Article 5;
- (c) if the other Party raises objections in writing within that 60-day period, Article 8 shall apply.

2. A Party can withdraw or suspend the recognition or remove the suspension of recognition of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party of its decision in writing, together with the date of such decision. The withdrawal, suspension, or removal of suspension shall take effect at that date. Such withdrawal or suspension shall be indicated in the common list of recognised conformity assessment bodies referred to in Annex 1.

3. A Party can propose that the scope of activity of a recognised conformity assessment body under its jurisdiction be amended. For scope extensions and scope reductions the procedures provided for in Article 11(1) and (2) respectively shall apply.

▼ M8

4. A Party can, in exceptional circumstances, contest the technical competence of a recognised conformity assessment body under the jurisdiction of the other Party. In this case Article 8 shall apply.

5. Reports, certificates, authorisation and conformity marks issued by a conformity assessment body after the date at which its recognition has been withdrawn or suspended need not be recognised by the Parties. Reports, certificates, authorisations and conformity marks issued by a conformity assessment body before the date its recognition has been withdrawn shall continue to be recognised by the Parties unless the responsible designating authority has limited or cancelled their validity. The Party under whose jurisdiction the responsible designating authority is operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.

▼ B*Article 12***Information exchange**

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

2. Each Party shall inform the other Party of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Agreement and shall notify ► **M8** in writing ◀ the other Party of the new provisions at least 60 days before their entry into force.

▼ M8

2a. Each Party shall notify changes to its designating authorities and competent authorities to the other Party in writing.

▼ B

3. Where the legislation of one of the Parties stipulates that a specific item of information must be made available to the competent authority by a person established in its territory, that authority may also approach the competent authority of the other Party or enter into direct contact with the manufacturer or, if appropriate, the latter's agent in the territory of the other Party, in order to obtain that information.

4. Each Party shall immediately notify the other Party of safeguard measures taken in its territory.

*Article 13***Confidentiality**

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Agreement.

▼B*Article 14***Dispute settlement**

Each Party may refer any dispute relating to the interpretation or application of this Agreement to the Committee. The Committee shall endeavour to settle the dispute, and must be supplied with any information which may facilitate a thorough examination of the situation with a view to finding an acceptable solution. For that purpose, the Committee shall consider every possible means of maintaining the smooth functioning of this Agreement.

*Article 15***Agreements with third countries**

The Parties hereby agree that mutual recognition agreements concluded by either Party with a country that is not party to this Agreement shall in no circumstances entail an obligation upon the other Party in terms of the acceptance of manufacturer's declarations of conformity as well as of reports, certificates, authorisations and marks issued by conformity assessment bodies in that third country, unless there is an explicit agreement between the Parties.

*Article 16***Annexes**

The Annexes to this Agreement shall form an integral part thereof.

*Article 17***Territorial application**

This Agreement shall apply, as regards the Community, to the territories in which the Treaty establishing the European Community is applied under the conditions laid down in that Treaty, on the one hand, and to the territory of Switzerland, on the other.

*Article 18***Revision**

1. If a Party wishes to have this Agreement revised, it shall inform the Committee. Modifications to this Agreement shall enter into force after the respective internal procedures have been completed.
2. The Committee may modify Annexes 1 and 2 to this Agreement on a proposal from one of the Parties.

*Article 19***Suspension**

Where a Party establishes that the other Party is failing to comply with the conditions of this Agreement, it may, after consulting the Committee, suspend application of Annex 1 in full or in part.

▼B*Article 20***Acquired rights**

The Parties shall continue to recognise reports, certificates, authorisations and conformity marks and manufacturers' declarations of conformity issued in accordance with, and prior to the expiry of, this Agreement, provided that the request for conformity evaluation to be started was made before the notice of non-renewal or denunciation was given.

*Article 21***Entry into force and duration**

1. This Agreement shall be ratified or approved by the Parties in accordance with their own procedures. It shall enter into force on the first day of the second month following the last notification of deposit of the instruments for ratification or approval of all the following seven agreements:

Agreement on the mutual recognition in relation to conformity assessment

Agreement on the free movement of persons

Agreement on air transport

Agreement on the carriage of goods and passengers by rail and road

Agreement on trade in agricultural products

Agreement on certain aspects of public procurement

Agreement on scientific and technical cooperation.

2. This Agreement shall be concluded for an initial period of seven years. It shall be tacitly extended, unless the Community or Switzerland notifies the other Party to the contrary before the expiry of that period. Where such notification is given, the provisions of paragraph 4 shall apply.

3. The Community or Switzerland may denounce this Agreement by notifying the other Party. Where such notification is given, the provisions of paragraph 4 shall apply.

4. The seven agreements referred to in paragraph 1 shall cease to apply six months after receipt of the non-renewal notice described in paragraph 2 or the denunciation notice described in paragraph 3.

Hecho en Luxemburgo, el veintiuno de junio de mil novecientos noventa y nueve. El presente Acuerdo se establecerá por duplicado en lenguas alemana, danesa, española, finesa, francesa, griega, inglesa, italiana, neerlandesa, portuguesa y sueca y cada uno de estos textos será auténtico.

Udfærdiget i Luxembourg, den enogtyvende juni nitten hundrede og nioghalvfems i to eksemplarer på dansk, engelsk, finsk, fransk, græsk, italiensk, nederlandsk, portugisisk, spansk, svensk og tysk, idet hver af disse tekster har samme gyldighed.

▼B

Geschehen zu Luxemburg am einundzwanzigsten Juni neunzehnhundertneundneunzig in zwei Urschriften in dänischer, deutscher, englischer, finnischer, französischer, griechischer, italienischer, niederländischer, portugiesischer, schwedischer und spanischer Sprache, wobei jeder Wortlaut gleichermaßen verbindlich ist.

Έγινε στο Λουξεμβούργο, στις είκοσι μία Ιουνίου χίλια εννιακόσια ενενήντα εννέα. Η παρούσα συμφωνία καταρτίζεται εις διπλούν στα αγγλικά, τα γαλλικά, τα γερμανικά, τα δανικά, τα ελληνικά, τα ισπανικά, τα ιταλικά, τα ολλανδικά, τα πορτογαλικά, τα σουηδικά και τα φινλανδικά, καθένα από τα κείμενα αυτά είναι αυθεντικό.

Done at Luxembourg on the twenty-first day of June in the year one thousand and ninety-nine. This Agreement is drawn up in duplicate in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic.

Fait à Luxembourg, le vingt-et-un juin mil neuf cent quatre-vingt dix-neuf, en double exemplaire, en langues allemande, anglaise, danoise, espagnole, finnoise, française, grecque, italienne, néerlandaise, portugaise et suédoise, chacun de ces textes faisant également foi.

Fatto a Lussemburgo, addì ventuno giugno millenovecentonovantanove, in due copie nelle lingue danese, finlandese, francese, greco, inglese, italiano, olandese, portoghese, spagnolo, svedese e tedesco; tutte facenti ugualmente fede.

Gedaan te Luxemburg, de eenentwintigste juni negentienhonderd negenenneentig, in tweevoud in de Deense, de Duitse, de Engelse, de Finse, de Franse, de Griekse, de Italiaanse, de Nederlandse, de Portugese, de Spaanse en de Zweedse taal, zijnde alle teksten gelijkelijk authentiek.

Feito em Luxemburgo, em vinte e um de Junho de mil novecentos e noventa e nove, em dois exemplares em língua alemã, inglesa, dinamarquesa, espanhola, finlandesa, francesa, grega, italiana, neerlandesa, portuguesa e sueca, todas as versões fazendo igualmente fé.

Tehty Luxemburgissa kahdentenäkymmenentenäensimmäisenä päivänä kesäkuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäyhdeksän kahtena kappaleena englannin, espanjan, hollannin, italian, kreikan, portugalin, ranskan, ruotsin, saksan, suomen ja tanskan kielellä, ja jokainen teksti on yhtä todistusvoimainen.

Utfärdat i Luxemburg den tjugoförsta juni nittonhundraionio i två exemplar på det danska, engelska, finska, franska, grekiska, italienska, nederländska, portugisiska, spanska, svenska och tyska språket, vilka samtliga texter är lika giltiga.

Por la Comunidad Europea
 For Det Europæiske Fællesskab
 Für die Europäische Gemeinschaft
 Για την Ευρωπαϊκή Κοινότητα
 For the European Community
 Pour la Communauté européenne
 Per la Comunità europea
 Voor de Europese Gemeenschap
 Pela Comunidade Europeia
 Euroopan yhteisön puolesta
 På Europeiska gemenskapens vägnar




▼B

Por la Confederación Suiza
For Det Schweiziske Edsforbund
Für die Schweizerische Eidgenossenschaft
Για την Ελβετική Συνομοσπονδία
For the Swiss Confederation
Pour la Confédération suisse
Per la Confederazione svizzera
Voor de Zwitserse Bondsstaat
Pela Confederação Suíça
Sveitsin valaliiton puolesta
På Schweiziska edsförbundets vägnar

D. Langhin

Hein

▼ M11*ANNEX 1***PRODUCT SECTORS**

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

Chapter 1	Machinery
Chapter 2	Personal protective equipment
Chapter 3	Toys
Chapter 4	Medical devices
Chapter 5	Gas appliances and boilers
Chapter 6	Pressure vessels
Chapter 7	Radio equipment and telecommunications terminal equipment
Chapter 8	Equipment and protective systems intended for use in potentially explosive atmosphere
Chapter 9	Electrical equipment and electromagnetic compatibility
Chapter 10	Construction plant and equipment
Chapter 11	Measuring instruments and prepackages
Chapter 12	Motor vehicles
Chapter 13	Agricultural or forestry tractors
Chapter 14	Good laboratory practice (GLP)
Chapter 15	Medicinal products, GMP Inspection and Batch Certification
Chapter 16	Construction Products
Chapter 17	Lifts
Chapter 18	Biocidal Products
Chapter 19	Cableway installations
Chapter 20	Explosives for civil use

▼ **M12**CHAPTER 1
MACHINERY

Section I

Legislative, regulatory and administrative provisions*Provisions covered by Article 1(2)*▼ **M16**

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

▼ **M15**

- | | |
|-------------|---|
| 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) |
| | 102. Ordinance of 2 April 2008 on the safety of machinery (RO 2008 1785), as last amended on 20 April 2011 (RO 2011 1755) |

▼ **M12**

Section II

Conformity assessment bodies

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

Section III

Designating authorities

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

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Annex XI to Directive 2006/42/EC.

Section V

Supplementary provisions

1. *Second-hand machinery*

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

▼ M12

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

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

2. Information exchange

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

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

3. Person named in the declaration of conformity of machines, authorised to compile the technical file

The declaration of conformity of the machinery must contain the name and address of the person authorised to compile the technical file, who must be established in the respective Parties' territory.

The Parties shall mutually recognise this person. The manufacturer, his authorised representatives or, where neither of these is present, the person responsible for placing products on the market of one Party, shall not be obliged to designate a person, who is responsible for compiling the technical file, in the territory of the other Party.

▼ M19**CHAPTER 2****PERSONAL PROTECTIVE EQUIPMENT****Section I****Legislative, regulatory and administrative provisions***Provisions covered by Article 1(2)*

European Union	1.	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).
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 25 October 2017 (RO 2017 5865)
	102.	Ordinance of 25 October 2017 on the safety of personal protective equipment (RO 2017 5859)
	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.

▼ **M19****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 V of Regulation (EU) 2016/425.

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 Regulation (EU) 2016/425 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 Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the PPE 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 keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the PPE has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 8(4), second subparagraph, and 10(6) of Regulation (EU) 2016/425 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 Regulation (EU) 2016/425 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 Regulation (EU) 2016/425 or the corresponding Swiss provisions.

▼ M19**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 PPE 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 PPE.

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 Regulation (EU) 2016/425.

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 Regulation (EU) 2016/425, 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 PPE 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 PPE covered by this Chapter presents a risk to the health or safety of persons 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 operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE 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 PPE, 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:

▼ M19

- failure of the PPE to meet requirements relating to the health or safety of persons 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 PPE concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the PPE concerned, such as withdrawal of the PPE 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 is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant PPE 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 PPE which nevertheless present a risk

Where a Member State or Switzerland finds that, although a PPE 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, 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 PPE concerned, the origin and the supply chain of the PPE, 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.

▼ M19**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 PPE is withdrawn from their market;
- (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

▼ M15

CHAPTER 3

TOYS

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

▼ M18

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)

▼ M15

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.

▼ **M15****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 with Article 24 of Directive 2009/48/EC.

Section V**Supplementary provisions**

1. *Exchange of information concerning the certificate of conformity and the technical documentation*

The market surveillance authorities of the Member States or Switzerland may, on reasoned request, ask for the technical documentation, or a translation of parts thereof from a manufacturer based in the territory of either Switzerland or a Member State. The market surveillance authorities of the Member states and Switzerland may request from a Swiss or a European Union-based manufacturer the relevant part of the technical documentation into an official language of the requesting authority or in English.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may set a deadline for receipt of 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

If the manufacturer based on the territory of either Switzerland or a Member State does not comply with this provision, the market surveillance authority may require it to have a test performed by a designated body at its own expense within a specified period in order to verify compliance with the harmonised standards and essential requirements.

2. *Information requests to designated bodies*

The market surveillance authorities of the Member States and of Switzerland may request a designated body in Switzerland or in a Member State to provide information relating to any type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.

3. *Information obligations of designated bodies*

In accordance with Article 36(2) of Directive 2009/48/EC, designated bodies shall provide the other bodies designated under this Agreement which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4. *Exchange of experience*

Swiss national authorities may take part in the exchange of experience between the Member States' national authorities responsible for the notification procedure referred to in Article 37 of Directive 2009/48/EC.

▼ **M15**5. *Coordination of designated bodies*

Designated Swiss conformity assessment bodies may take part in the coordination and cooperation mechanisms and sectoral groups or groups of notified bodies provided for in Article 38 of Directive 2009/48/EC, directly or by means of designated representatives.

6. *Market access*

Importers based in the European Union or Switzerland shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, when that is not possible, on its packaging or in a document accompanying the toy.

The Parties mutually recognise this indication of the coordinates of the manufacturer and importer, registered trade name or registered trade mark and the address at which they can be contacted, which must be mentioned as above. For the purpose of this specific obligation, 'importer' shall mean any natural or legal person established within the territory of either the European Union or Switzerland who places a toy from a third country on the European Union or on the Swiss market.

7. *Harmonised standards*

Switzerland recognises harmonised standards conferring a presumption of conformity with the legislation referred to in Section 1 of this Chapter. Where Switzerland considers that compliance with a harmonised standard does not entirely satisfy the requirements which are set out in the legislation listed in Section 1, it shall bring the matter before the Committee and give its reasons.

The Committee shall consider the case and may ask the European Union to act in accordance with the procedure provided for in Article 14 of Directive 2009/48/EC. The Committee shall be informed of the result of the procedure.

8. *Procedure for dealing with toys presenting a non-compliance that is not restricted to their national territory⁽¹⁾*

Pursuant to Article 12(4) of this Agreement, in cases where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reasons to believe that a toy covered by Section I of the present Chapter presents a risk to the health or safety of persons, and if they consider that the non-compliance is not restricted to their national territory, they shall inform each other and the European Commission immediately of:

- the results of the evaluation they have carried out and of the actions which they have required the relevant economic operator to take;
- provisional measures taken to prohibit or restrict the toy being made available on their national market, to withdraw the toy from that market or to recall it when the relevant economic operator does not take adequate corrective action. This includes the details set out in Article 42(5) of Directive 2009/48/EC.

The market surveillance authorities of the Member States or Switzerland other than the one initiating this procedure shall inform without delay 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 toy concerned.

⁽¹⁾ This procedure does not imply an obligation of the European Union to grant Switzerland access to the Community Rapid Information System ('RAPEX') under Article 12(4) of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

▼ M15

The Parties shall ensure that appropriate restrictive measures in respect of the toy concerned, such as withdrawal of the toy from their market, are taken without delay.

9. *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.

Where, on completion of the procedure set out in paragraph 8 above, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State respectively, or where the European Commission considers a national measure to be non-compliant with the legislation referred to in this Chapter, the European Commission shall without delay enter into consultation with the Member States, Switzerland and the relevant economic operator or operators and shall evaluate the national measure in order to determine if it is justified or not.

In case of an agreement between the Parties on the results of their investigations, the Member States and Switzerland shall take the measures necessary to ensure that appropriate restrictive measures are taken in respect of the toy concerned, such as the withdrawal of the toy from their market, without delay.

In case of a disagreement between the Parties on the results of their investigations, the issue will be forwarded to the Committee, which may decide to have an expert study carried out.

Where the Committee considers that the measure is:

- (a) unjustified, the national authority of the Member State or Switzerland which took the measure shall withdraw it;
- (b) justified, the Parties shall take the measures necessary to ensure that the non-compliant toy is withdrawn from their market.

▼ M19

CHAPTER 4

MEDICAL DEVICES

Section I

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

- | | |
|----------------|--|
| European Union | <ol style="list-style-type: none"> 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). |
|----------------|--|

▼ M19

4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).
5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).
6. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 22, 9.8.2012, p. 3).
7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).
8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98).
9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21).
10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63).
11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50).
12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

▼ M19

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).
 16. Chapter IV and Annex VII of 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).
 17. Chapter IV and Annex VII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).
- 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 25 October 2017 (RO 2017 5935)

▼ M19

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 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)
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,
- as laid down in Regulation (EU) No 920/2013, comply with 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, and
- comply with the assessment criteria set out in Chapter IV and Annex VII of Regulation (EU) 2017/745 and of Regulation (EU) 2017/746.

The Parties shall make available assessors for the pool established under Regulation (EC) No 920/2013, Article 40 of Regulation (EU) 2017/745 and Article 36 of Regulation (EU) 2017/746. The designating authorities of the Parties shall cooperate for the assessment of notified bodies in line with Article 39 of Regulation (EU) 2017/745 and Article 35 of Regulation (EU) 2017/746. They shall participate in peer reviews pursuant to Article 48 of Regulation (EU) 2017/745 and Article 44 of Regulation (EU) 2017/746.

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

▼ M19

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 and cooperation

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 Regulation (EU) No 920/2013,
- the Parties shall in particular cooperate according to Articles 102 and 103 of Regulation (EC) No 2017/745 and Articles 97 and 98 of Regulation (EU) 2017/746.
- Switzerland may submit the application of expert laboratories for designation by the Commission in accordance with Article 106 of Regulation (EU) 2017/745 or the application of reference laboratories for designation by the Commission in accordance with Article 100 of Regulation (EU) 2017/746.

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, Article 3 of Regulation (EU) No 920/2013, Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746. 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.

5. Transitional provisions

By way of derogation to the legislation in Section I, devices which comply with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may be placed on the market of both Parties respectively.

By way of derogation to the legislation in Section I, notified bodies which are designated and notified in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may carry out assessment procedures laid down in these regulations and issue certificates in accordance with these Regulations. Such certificates shall be recognized by the Parties.

▼ **M19**

CHAPTER 5

GAS APPLIANCES AND BOILERS

Section I

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

- | | |
|----------------|---|
| European Union | 1. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17), as subsequently amended |
| Switzerland | 100. Ordinance of 16 December 1985 on Air Pollution Control (OAPC) (Annex 3 and 4) (RS 814.318.142.1, as subsequently amended) |

Provisions covered by Article 1(2)

- | | |
|----------------|---|
| European Union | 1. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99). |
| 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 25 October 2017 (RO 2017 5865) |
| | 102. Ordinance of 25 October 2017 on gas appliances (RO 2017 5865) |
| | 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.

▼ **M19****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 IV of Regulation (EU) 2016/426.

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 7(6) and 9(3) of Regulation (EU) 2016/426 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 7(3) and 9(8) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the appliance or the fitting 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 keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the appliance or the fitting has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 7(4), second subparagraph, and 9(6) of Regulation (EU) 2016/426 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 Regulation (EU) 2016/426 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 Regulation (EU) 2016/426 or the corresponding Swiss provisions.

▼ M19**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 an appliance or fitting 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 appliance or the fitting.

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 Regulation (EU) 2016/426.

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 Regulation (EU) 2016/426, 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 appliances or fittings 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 appliance or fitting covered by this Chapter presents a risk to the health or safety of persons or to domestic animals or 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 operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the appliances or fittings being made available on their national market, to withdraw the appliance or fitting 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 appliance or fitting, 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 appliance or fitting to meet requirements relating to the health or safety of persons or to domestic animals or property referred to in the legislation in section I, or

▼ M19

- 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 appliance or fitting concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the appliance or fitting concerned, such as withdrawal of appliance or fitting 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 an appliance or fitting is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant appliance or fitting 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 appliances or fittings which nevertheless present a risk

Where a Member State or Switzerland finds that, although an appliance or fitting 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 appliance or fitting concerned, the origin and the supply chain of the appliance or fitting, 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.

▼ M19**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 appliance or fitting is withdrawn from their market;
- (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

9. Information exchange

In accordance with Article 12 of this Agreement, the Parties shall exchange information on the types of gas and the corresponding supply pressures of gaseous fuels used on their territory referred to in Annex II of Regulation (EU) 2016/426. Further Switzerland shall inform about the changes thereof within six months after the announcement of the envisaged changes. The European Union shall inform about the changes thereof within six months after it received the notification by a Member State.

▼ M18

CHAPTER 6

PRESSURE VESSELS

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	<ol style="list-style-type: none"> 1. Directive 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	<ol style="list-style-type: none"> 100. Federal Law of 12 June 2009 on product safety (RO 2010 2573)

▼M18

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.

▼ **M18**

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.

▼ M18**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

▼M18

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,

▼ M18

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.

CHAPTER 7

RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 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) |
|----------------|---|

⁽¹⁾ The reference to the class identifier in Article 2 of Commission Decision 2000/299/EC does not apply.

▼ **M18**

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) ⁽¹⁾
 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) ⁽¹⁾
- 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)

⁽¹⁾ Without prejudice to Chapter 9.

▼ **M18**

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

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

▼ **M18**

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.

▼ M18**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 2014/53/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.

▼ M18

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 paragraph 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.

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.

⁽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).

▼ M18

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.

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.

▼ M18

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.

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.

▼ **M18****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.

▼ M18**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.

▼ M18

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.

▼M18

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.

CHAPTER 9

ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|--|
| European Union | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 100. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 20 March 2008 (RO 2008 3437) 101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 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) |

▼ **M18**

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 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 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

▼ M18

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.

▼ M18**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

▼M18

— 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

▼ M18

- (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.

▼ M11

CHAPTER 10

CONSTRUCTION PLANT AND EQUIPMENT

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|--------------------|---|
| European Community | 1. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1), as amended by Directive 2005/88/EC of the European Parliament and of the Council of 14 December 2005 (OJ L 344, 27.12.2005, p. 44) and corrected by corrigendum (OJ L 165, 17.6.2006, p. 35). |
| Switzerland | 100. Ordinance of 22 May 2007 on the noise emission in the environment by equipment for use outdoors (RO 2007 2827). |

Section II

Conformity assessment bodies

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

Section III

Designating authorities

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

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and those assessment criteria set out in Annex IX to Directive 2000/14/EC of the European Parliament and of the Council.

Section V

Supplementary provisions1. *Location of the manufacturer*

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

▼ M11**2. Information exchange**

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

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

3. Collection of noise data

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

▼ M18

CHAPTER 11

MEASURING INSTRUMENTS AND PREPACKAGES

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(1)

European Union	<ol style="list-style-type: none"> 1. Council Directive 71/347/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain (OJ L 239, 25.10.1971, p. 1), as subsequently amended 2. Council Directive 76/765/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholmeters and alcohol hydrometers (OJ L 262, 27.9.1976, p. 143), as subsequently amended 3. Council Directive 86/217/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (OJ L 152, 6.6.1986, p. 48), as subsequently amended 4. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14), as subsequently amended 5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain prepackaged products (OJ L 46, 21.2.1976, p. 1), as subsequently amended
----------------	--

▼ **M18**

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)

▼ M18

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)

▼ M18

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.

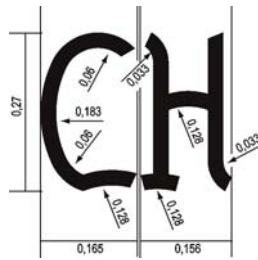
▼ **M18**

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 I and to the first indent of point 3.1.1.1 (a) of Annex II, the following shall be added to the text in brackets: 'CH for Switzerland'.
- (b) The drawings to which point 3.2.1 of Annex II refers, are supplemented by the following drawing:



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

▼M18

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.

▼M18**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.

▼ M18

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.

▼ **M13**CHAPTER 12
MOTOR VEHICLES▼ **M16**

Section I

Legislative, regulatory and administrative provisions*Provisions covered by Article 1(2)*▼ **M18**

- | | |
|----------------|---|
| 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 |

▼ **M13**

Section II

Conformity assessment bodies

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

Section IV

Special rules relating to the designation of conformity assessment bodies

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

▼ **M13**

Section V

Supplementary provisions

The provisions of this Section shall apply exclusively to relations between Switzerland and the European Union.

▼ **M18**

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.

▼ **M13**

2. *Information exchange*

The competent type-approval authorities in Switzerland and the Member States shall in particular exchange the information referred to in Article 8(5) to (8) of the Framework Directive 2007/46/EC.

In the event of refusal by Switzerland or a Member State to grant type-approval in accordance with Article 8(3) of the Framework Directive 2007/46/EC, it shall immediately send the other Member States, Switzerland and the Commission a detailed file explaining the reasons for its decision and setting out the evidence for its findings.

3. *Recognition of vehicle type-approval*

Switzerland shall also recognise vehicle type-approval granted before the entry into force of this Agreement in accordance with Council Directive 70/156/EEC of 6 February 1970 (OJ L 42, 23.2.1970, p. 1), as last amended by Commission Directive 2007/37/EC of 21 June 2007 (OJ L 161, 22.6.2007, p. 60), by the authorities responsible for type-approval where that approval is still valid in the European Union.

The European Union shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of the Framework Directive 2007/46/EC.

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

4. *Safeguard clauses*

1. **Vehicles, systems, components or separate technical units in compliance with the applicable legislation**

1. If a Member State or Switzerland finds that new vehicles, systems, components or separate technical units, albeit in compliance with the applicable requirements or properly marked, present a serious risk to road safety, or seriously harm the environment or public health, that State may, for a maximum period of 6 months, refuse to register such vehicles or to permit the sale or entry into service in its territory of such vehicles, components or separate technical units.

In such cases, the Member State concerned or Switzerland shall immediately notify the manufacturer, the other Member States, Switzerland and the Commission accordingly, stating the reasons on which its decision is based.

▼ **M13**

2. The Commission and Switzerland shall consult the Parties concerned as soon as possible and, in particular, their respective approval authorities that granted the type-approval. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with the view to reaching a settlement.
2. **Vehicles, systems, components or separate technical units not in conformity with the approved type**
 1. If a Member State or Switzerland which has granted a type-approval finds that new vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the type it has approved, it shall take the necessary measures, including, where necessary, the withdrawal of type-approval, to ensure that production vehicles, systems, components or separate technical units, as the case may be, are brought into conformity with the approved type. The approval authority of that Member State or Switzerland shall advise the approval authorities of the other Member States and/or Switzerland of the measures taken.
 2. For the purposes of paragraph 1, deviations from the particulars in the type-approval certificate or the information package shall be deemed to constitute failure to conform to the approved type.

A vehicle shall not be deemed to deviate from the approved type where tolerances are permitted by the relevant regulatory acts and those tolerances are respected.

3. If a Member State or Switzerland demonstrates that new vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, it may ask the Member State or Switzerland which granted the type-approval to verify that vehicles, systems, components or separate technical units in production continue to conform to the approved type. On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action as soon as possible and in any case within 6 months of the date of the request.
4. The approval authority shall request the Member State or Switzerland which granted the system, component, separate technical unit or incomplete vehicle type-approval to take the necessary action to ensure that vehicles in production are brought back into conformity with the approved type in the following cases:
 - (a) in relation to a vehicle type-approval, where the non-conformity of a vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit;
 - (b) in relation to a multi-stage type-approval, where the non-conformity of a completed vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit being part of the incomplete vehicle, or of the incomplete vehicle itself.

On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action, if necessary in conjunction with the Member State making the request or Switzerland, as soon as possible and in any case within 6 months of the date of the request. Where a failure to conform is established, the approval authority of the Member State or Switzerland which granted the system, component or separate technical unit type-approval or the approval of the incomplete vehicle shall take the measures set out in paragraph 1.

5. The approval authorities shall inform each other within 20 working days of any withdrawal of type-approval and of the reasons therefor.

▼ **M13**

6. If the Member State or Switzerland that granted type-approval disputes the failure to conform notified to it, the Member States concerned and Switzerland shall endeavour to settle the dispute. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with a view to reaching a settlement.

▼ **M11**

CHAPTER 13

AGRICULTURAL OR FORESTRY TRACTORS

▼ **M16**

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 1. Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24) 2. Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, as last amended by Directive 2010/52/EU of the Commission of 11 August 2010 (OJ L 213, 13.8.2010, p. 37) 3. Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24) 4. Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81) 5. Council Directive 80/720/EEC of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors, as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7) 6. Council Directive 86/297/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of wheeled agricultural and forestry tractors and their protection, as last amended by Directive 2012/24/EU of the Commission of 8 October 2012 (OJ L 274, 9.10.2012, p. 24) |
|----------------|---|

▼ **M16**

7. Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
8. Council Directive 86/415/EEC of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
9. Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
10. Directive 2000/25/EC of the European Parliament and of the Council of 22 May 2000 on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors and amending Council Directive 74/150/EEC as last amended by Directive 2011/87/EU of the European Parliament and the Council of 16 November 2011 (OJ L 301, 18.11.2011, p. 1)
11. Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, as last amended by 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
12. Directive 2008/2/EC of the European Parliament and the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (OJ L 24, 29.1.2008, p. 30)
13. Directive 2009/57/EC of the European Parliament and the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors (OJ L 261, 3.10.2009, p. 1)
14. Directive 2009/58/EC of the European Parliament and the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors (OJ L 198, 30.7.2009, p. 4)

▼ M16

15. Directive 2009/59/EC of the European Parliament and the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (OJ 198, 30.7.2009, p. 9)
16. Directive 2009/60/EC of the European Parliament and the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
17. Directive 2009/61/EC of the European Parliament and the Council of 13 July 2009 relating to the installation of lighting and light signalling devices on wheeled agricultural and forestry tractors (OJ L 203, 5.8.2009, p. 19)
18. Directive 2009/63/EC of the European Parliament and the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors (OJ L 214, 19.8.2009, p. 23)
19. Directive 2009/64/EC of the European Parliament and the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility) (OJ L 216, 20.8.2009, p. 1)
20. Directive 2009/66/EC of the European Parliament and the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 11)
21. Directive 2009/68/EC of the European Parliament and the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (OJ L 203, 5.8.2009, p. 52)
22. Directive 2009/75/EC of the European Parliament and the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (OJ L 261, 3.10.2009, p. 40)
23. Directive 2009/76/EC of the European Parliament and the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 18)
24. Directive 2009/144/EC of the European Parliament and the Council of 30 November 2009 on certain components and characteristics of wheeled agricultural or forestry tractors, as last amended by Directive 2013/8/EU of the Commission of 26 February 2013 (OJ L 56, 28.2.2013, p. 8)

▼ M16

25. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1)
- Switzerland
100. Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 2 March 2012 (RO 2012 1915)
101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 7 December 2012 (RO 2012 7065)

▼ M11

Section II

Conformity assessment bodies

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

Section III

Designating authorities

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

Section IV

Special rules relating to the designation of conformity assessment bodies

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

Section V

Supplementary provisions

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

1. *Information exchange*

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

In the event of refusal by Switzerland or the Member States to grant type-approval in accordance with Article 4 of Directive 2003/37/EC, as last amended, their competent authorities shall notify each other of their Decision and give the reasons for it.

▼ M11*2. Recognition of vehicle type-approval*

Switzerland shall also recognise tractor or separate technical unit type-approvals granted before the entry into force of this Agreement in accordance with Directive 74/150/EEC or 2003/37/EC, both as last amended, by the authorities responsible for type-approval in the EU Member States where that approval is still valid in the EC.

The European Community shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of Directive 2003/37/EC, as last amended.

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

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

1. Each Member State and Switzerland shall permit the registration, the sale or entry into service of new tractors on grounds relating to their construction and operation if, and only if, they are accompanied by a valid certificate of conformity.
2. Each Member State and Switzerland shall permit the sale or entry into service of separate technical units if, and only if, they comply with the requirements of the relevant separate Directive or the requirements of the Swiss legislation equivalent to the relevant separate Directive.
3. If a Member State or Switzerland finds that tractors of a particular type maybe a hazard to safety on the road or at work, although they are accompanied by a valid certificate of conformity, it may, for a maximum period of six months, refuse to register new tractors of that type or may prohibit their sale, entry into service or use in its territory. It shall forthwith notify the other Member States, Switzerland and the Commission thereof, stating the reasons on which its decision is based. The Commission shall within six weeks consult the States concerned by the dispute (Member States or Switzerland). The Commission shall conclude whether the measure is justified or not, and the procedure established in Article 16 of Directive 2003/37/EC shall apply.

Measures related to the conformity of production

1. When a Member State or Switzerland grants type-approval, it shall take the measures referred to in Annex IV of Directive 2003/37/EC to verify, if need be in cooperation with the approval authorities of the other Member States or Switzerland, that adequate arrangements have been made to ensure that the vehicles, systems, components or separate technical units produced conform to the approved type. This verification shall be limited to the procedures set out in Section 2 of Annex IV of Directive 2003/37/EC.
2. When a Member State or Switzerland has granted a type approval, it shall take the necessary measures to ensure that it is informed of any cessation of production and of any change in particulars appearing in the information document. If the state in question finds that an amendment to an information document warrants fresh checks or fresh tests and that it is accordingly necessary to amend the existing type-approval certificate or complete a new type-approval certificate, the competent authorities of that state shall inform the manufacturer thereof and shall, within one month of such new documents being completed, send them to the competent authorities of the other Member States or Switzerland.

▼ M11**Nonconformity with the approved type**

1. There shall be failure to conform to the approved type where deviations from the particulars in the EC type-approval certificate and/or the information package are found to exist and where these deviations have not been authorised under Article 5(3) of Directive 2003/37/EC as last amended, by the Member State or Switzerland which granted the type-approval. A vehicle shall not be considered to deviate from the approved type where tolerances are permitted by separate Directives and these tolerances are respected.
2. Where a Member State or Switzerland has granted type-approval and finds that a number of vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an EC type-approval mark do not conform to the type it has approved, it shall take the necessary measures to ensure that production models conform to the approved type. The approval authorities of that Member State or Switzerland shall notify those of the other Member States and/or Switzerland of the measures taken which may extend to withdrawal of the type-approval. The said authorities shall take like measures if they are informed by the type-approval authorities of another Member State or Switzerland of such failure to conform.
3. The approval authorities of the Member States or Switzerland shall inform each other within one month of any withdrawal of EC type-approval and of the reasons for such a measure.
4. If the Member State or Switzerland which granted type-approval disputes the failure to conform notified to it, the States (Member States or Switzerland) concerned shall endeavour to settle the dispute. The Commission and the Committee shall be kept informed and shall, where necessary, hold appropriate consultations for the purpose of reaching a settlement.

CHAPTER 14**GOOD LABORATORY PRACTICE (GLP)****Scope and coverage**

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

Unless specific definitions are given, the definition of terms in the OECD Principles of Good Laboratory Practice' as revised in 1997 [ENV/MC/CHEM(98)17] based on OECD Council Decision of 12 May 1981 C(81)30(Final)] amended on 26 November 1997 [C(97) 186 FINAL], as well as Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)] amended on 9 March 1995 [C(95)8(Final)] and GLP Consensus documents, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and all amendments made thereto, shall apply.

The Parties recognise the equivalence of each other's compliance monitoring programmes on Good Laboratory Practice that are in accordance with the OECD decisions and recommendations mentioned above and the legislative, regulatory and administrative procedures and principles listed in section IV.

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

The Parties mutually accept the conclusions of study audits and test facility inspections performed by the GLP monitoring authorities.

▼ M17

Section I

Legislative, regulatory and administrative provisions

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

Provisions covered by Article 1(2)

▼ M18

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)

▼ **M18**

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)

▼ M18

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)

▼ M11

Section II

Conformity assessment bodies

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

▼ M11

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

Section III

Designating authorities

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

▼ M18

For the European Union:

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

▼ M11

Section IV

Special principles for designating conformity assessment bodies

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

▼ M17

- | | |
|-----------------|--|
| European Union: | <ol style="list-style-type: none"> 1. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).
 2. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28). |
| Switzerland: | <ol style="list-style-type: none"> 100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 22 March 2013 (FF 2012 8671)
 101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197)
 102. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137)
 103. Ordinance of 18 May 2005 on Good Laboratory Practice (RO 2005 2795) as last amended on 11 November 2012 (RO 2012 6103) |

▼ M11

Section V

Supplementary provisions**1. Information exchange**

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

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

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

2. Test facility inspections

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

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

3. Confidentiality

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

4. Cooperation

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

▼ M18

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.

▼ M18

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,

▼ M18

- 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 GMP. 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.

▼ **M18**

Section I

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

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 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) |
|----------------|---|

▼ **M18**

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)

▼ **M18**

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

▼ **M18**

Country	For medicinal products for human use	For medicinal products for veterinary use
Germany	Federal Institute for Drugs and Medical Devices/	Federal Office for Consumer Protection and Food Safety/
	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
	Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines/Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel	Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
	Federal Ministry of Health/Bundesministerium für Gesundheit (BMG)/Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) ⁽¹⁾	
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
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- <i>National Agency for Veterinary Medicinal Products</i> / 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

▼ **M18**

Country	For medicinal products for human use	For medicinal products for veterinary use
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	Ministère 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 și a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority/Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor
Sweden	Medical Products Agency/Läkemedelsverket	See responsible authority for human medicinal products

▼ **M18**

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**.

▼ M18**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.

▼ M18

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.

▼ M17CHAPTER 16
CONSTRUCTION PRODUCTS

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2):

- European Union ► **M18** 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) ◀.
2. Commission Decision 94/23/EC of 17 January 1994 on common procedural rules for European technical approval (OJ L 17, 20.1.1994, p. 34).
- 2(a). Commission Decision 94/611/EC of 9 September 1994 implementing Article 20 of Directive 89/106/EEC on construction products (OJ L 241, 16.9.1994, p. 25).
- 2(b). Commission Decision 95/204/EC of 31 May 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 129, 14.6.1995, p. 23).
3. Commission Decision 95/467/EC of 24 October 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 268, 10.11.1995, p. 29).
4. Commission Decision 96/577/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fixed fire-fighting systems (OJ L 254, 8.10.1996, p. 44).
5. Commission Decision 96/578/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sanitary appliances (OJ L 254, 8.10.1996, p. 49).
6. Commission Decision 96/579/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures (OJ L 254, 8.10.1996, p. 52).

▼ M17

7. Commission Decision 96/580/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards curtain walling (OJ L 254, 8.10.1996, p. 56).

► M18 ————— ◀

9. Commission Decision 96/582/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural sealant glazing systems and metal anchors for concrete (OJ L 254, 8.10.1996, p. 62).
10. Commission Decision 96/603/EC of 4 October 1996 establishing the list of products belonging to classes A 'No contribution to fire' provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 267, 19.10.1996, p. 23).
11. Commission Decision 97/161/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal anchors for use in concrete for fixing lightweight systems (OJ L 62, 4.3.1997, p. 41).
12. Commission Decision 97/176/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural timber products and ancillaries (OJ L 73, 14.3.1997, p. 19).
13. Commission Decision 97/177/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal injection anchors for use in masonry (OJ L 73, 14.3.1997, p. 24).
14. Commission Decision 97/462/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards wood-based panels (OJ L 198, 25.7.1997, p. 27).
15. Commission Decision 97/463/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards plastic anchors for use in concrete and masonry (OJ L 198, 25.7.1997, p. 31).

► M18 ————— ◀

▼ M17

17. Commission Decision 97/555/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders (OJ L 229, 20.8.1997, p. 9).
18. Commission Decision 97/556/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) (OJ L 229, 20.8.1997, p. 14).
19. Commission Decision 97/571/EC of 22 July 1997 on the general format of European Technical Approval for construction products (OJ L 236, 27.8.1997, p. 7).
20. Commission Decision 97/597/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards reinforcing and prestressing steel for concrete (OJ L 240, 2.9.1997, p. 4).
21. Commission Decision 97/638/EC of 19 September 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fasteners for structural timber (OJ L 268, 1.10.1997, p. 36).
22. Commission Decision 97/740/EC of 14 October 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards masonry and related products (OJ L 299, 4.11.1997, p. 42).
23. Commission Decision 98/143/EC of 3 February 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards systems of mechanically fastened flexible roof waterproofing membranes (OJ L 42, 14.2.1998, p. 58).
24. Commission Decision 97/808/EC of 20 November 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards floorings (OJ L 331, 3.12.1997, p. 18).
25. Commission Decision 98/213/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits (OJ L 80, 18.3.1998, p. 41).

▼ M17

26. Commission Decision 98/214/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural metallic products and ancillaries (OJ L 80, 18.3.1998, p. 46).
27. Commission Decision 98/279/EC of 5 December 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards non load-bearing permanent shuttering kits/systems based on hollow blocks or panels of insulating materials and, sometimes, concrete (OJ L 127, 29.4.1998, p. 26).
28. Commission Decision 98/436/EC of 22 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards roof coverings, roof lights, roof windows and ancillary products (*notified under document number C(1998) 1598*) (OJ L 194, 10.7.1998, p. 30).
29. Commission Decision 98/437/EC of 30 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal and external wall and ceiling finishes (OJ L 194, 10.7.1998, p. 39).
30. Commission Decision 98/456/EC of 3 July 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards post-tensioning kits for the prestressing of structures (OJ L 201, 17.7.1998, p. 112).
31. Commission Decision 98/457/EC of 3 July 1998 concerning the test of the Single Burning Item (SBI) referred to in Council Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 201, 17.7.1998, p. 114).
32. Commission Decision 98/598/EC of 9 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards aggregates (OJ L 287, 24.10.1998, p. 25)
33. Commission Decision 98/599/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid applied roof waterproofing kits (OJ L 287, 24.10.1998, p. 30).
34. Commission Decision 98/600/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards self-supporting translucent roof kits (except glass-based kits) (OJ L 287, 24.10.1998, p. 35).

▼ M17

35. Commission Decision 98/601/EC of 13 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards road construction products (OJ L 287, 24.10.1998, p. 41).
36. Commission Decision 99/89/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated stair kits (OJ L 29, 3.2.1999, p. 34).
37. Commission Decision 1999/90/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards membranes (OJ L 29, 3.2.1999, p. 38).
38. Commission Decision 1999/91/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards thermal insulating products (OJ L 29, 3.2.1999, p. 44).
39. Commission Decision 1999/92/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards light composite wood-based beams and columns (OJ L 29, 3.2.1999, p. 49).
40. Commission Decision 1999/93/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware (OJ L 29, 3.2.1999, p. 51).
41. Commission Decision 1999/94/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/light-weight auto-claved aerated concrete products (OJ L 29, 3.2.1999, p. 55).
- 41a) Commission Decision 1999/453/EC of 18 June 1999 amending decision 96/579/EC and 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures and floorings respectively (OJ L 178, 14.7.1999, p. 50).
42. Commission Decision 1999/454/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fire stopping, fire sealing and fire protective products (OJ L 178, 14.7.1999, p. 52).

▼ M17

43. Commission Decision 1999/455/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards timber frame and log prefabricated building kits (OJ L 178, 14.7.1999, p. 56).
44. Commission Decision 1999/469/EC of 25 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards products related to concrete, mortar and grout (OJ L 184, 17.7.1999, p. 27).
45. Commission Decision 1999/470/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards construction adhesives (OJ L 184, 17.7.1999, p. 32).
46. Commission Decision 1999/471/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards space heating appliances (OJ L 184, 17.7.1999, p. 37).
47. Commission Decision 1999/472/EC of 1 July 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pipes, tanks and ancillaries not in contact with water intended for human consumption (OJ L 184, 17.7.1999, p. 42).

► M18 ◀

49. Commission Decision 2000/245/EC of 2 February 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(4) of Council Directive 89/106/EEC as regards flat glass, profiled glass and glass block products (OJ L 77, 28.3.2000, p. 13).
50. Commission Decision 2000/273/EC of 27 March 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European Technical Approvals without Guideline (OJ L 86, 7.4.2000, p. 15).
51. Commission Decision 2000/367/EC of 3 May 2000 implementing Council Directive 89/106/EEC as regards the classification of the resistance to fire performance of construction products, construction works and parts thereof (OJ L 133, 6.6.2000, p. 26).

▼ M17

52. Commission Decision 2000/447/EC of 13 June 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated wood-based load-bearing stressed skin panels and self-supporting composite lightweight panels (OJ L 180, 19.7.2000, p. 40).

53. Commission Decision 2000/553/EC of 6 September 2000 implementing Council Directive 89/106/EEC as regards the external fire performance of roof coverings (OJ L 235, 19.9.2000, p. 19).

- 53(a). Commission Decision 2000/605/EC of 26 September 2000 amending Decision 96/603/EC establishing the list of products belonging to class A 'No contribution to fire' provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 258, 12.10.2000, p. 36).

54. Commission Decision 2000/606/EC of 26 September 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards six products for European Technical Approvals without Guideline (OJ L 258, 12.10.2000, p. 38).

55. Commission Decision 2001/19/EC of 20 December 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards expansion joints for road bridges (OJ L 5, 10.1.2001, p. 6).

56. Commission Decision 2001/308/EC of 31 January 2001 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards ventures (OJ L 107, 18.4.2001, p. 25).

- 56(a). Commission Decision 2001/596/EC of 8 January 2001 amending Decisions 95/467/EC, 96/578/EC, 96/580/EC, 97/176/EC, 97/462/EC, 97/556/EC, 97/740/EC, 97/808/EC, 98/213/EC, 98/214/EC, 98/279/EC, 98/436/EC, 98/437/EC, 98/599/EC, 98/600/EC, 98/601/EC, 1999/89/EC, 1999/90/EC, 1999/91/EC, 1999/454/EC, 1999/469/EC, 1999/470/EC, 1999/471/EC, 1999/472/EC, 2000/245/EC, 2000/273/EC, 2000/447/EC on the procedure for attesting the conformity of certain construction products pursuant to Article 20 of Council Directive 89/106/EEC (OJ L 209, 2.8.2001, p. 33).

57. Commission Decision 2001/671/EC of 21 August 2001 implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (OJ L 235, 4.9.2001, p. 20).

▼ M17

58. Commission Decision 2002/359/EC of 13 May 2002 on the procedure for attesting the conformity of construction products in contact with water intended for human consumption, pursuant to Article 20(2) of Council Directive 89/106/EEC (OJ L 127, 14.5.2002, p. 16).
59. Commission Decision 2002/592/EC of 15 July 2002 amending Decisions 95/467/EC, 96/577/EC, 96/578/EC and 98/598/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards gypsum products, fixed fire-fighting systems, sanitary appliances and aggregates respectively (OJ L 192, 20.7.2002, p. 57).
60. Commission Decision 2003/43/EC of 17 January 2003 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 13, 18.1.2003, p. 35).
61. Commission Decision 2003/312/EC of 9 April 2003 on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks in accordance with Council Directive 89/106/EEC (OJ L 114, 8.5.2003, p. 50).
62. Commission Decision 2003/424/EC of 6 June 2003 amending Decision 96/603/EC establishing the list of products belonging to Classes A 'No contribution to fire' provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 144, 12.6.2003, p. 9).
63. Commission Decision 2003/593/EC of 7 August 2003 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance of certain construction products (OJ L 201, 8.8.2003, p. 25).
64. Commission Decision 2003/629/EC of 27 August 2003 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, as regards the inclusion of smoke and heat control products (OJ L 218, 30.8.2003, p. 51).
65. Commission Decision 2003/632/EC of 26 August 2003 amending Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction-to-fire performance of construction products (OJ L 220, 3.9.2003, p. 5).
66. Commission Decision 2003/639/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pins for structural joints (OJ L 226, 10.9.2003, p. 18).

▼ M17

67. Commission Decision 2003/640/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards kits for exterior wall claddings (OJ L 226, 10.9.2003, p. 21).
68. Commission Decision 2003/655/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards watertight covering kits for wetroom floors and walls (OJ L 231, 17.9.2003, p. 12).
69. Commission Decision 2003/656/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European technical approvals without Guideline (OJ L 231, 17.9.2003, p. 15).
70. Commission Decision 2003/722/EC of 6 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid-applied bridge deck waterproofing kits (OJ L 260, 11.10.2003, p. 32).
71. Commission Decision 2003/728/EC of 3 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rockfall protection kits (OJ L 262, 14.10.2003, p. 34).
72. Commission Decision 2004/663/EC of 20 September 2004 amending Commission Decision 97/464/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 302, 29.9.2004, p. 6).
73. Commission Decision 2005/403/EC of 25 May 2005 establishing the classes of external fire performance of roofs and roof coverings for certain construction products as provided for by Council Directive 89/106/EEC (OJ L 135, 28.5.2005, p. 37).
74. Commission Decision 2005/484/EC of 4 July 2005 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cold storage building kits and cold storage building envelope kits (OJ L 173, 6.7.2005, p. 15).

▼ M17

75. Commission Decision 2005/610/EC of 9 August 2005 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 208, 11.8.2005, p. 21).
76. Commission Decision 2005/823/EC of 22 November 2005 amending Decision 2001/671/EC implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (OJ L 307, 25.11.2005, p. 53).
77. Commission Decision 2006/190/EC of 1 March 2006 amending Decision 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards floorings (OJ L 66, 8.3.2006, p. 47).
78. Commission Decision 2006/213/EC of 6 March 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards wood flooring and solid wood panelling and cladding (OJ L 79, 16.3.2006, p. 27).
79. Commission Decision 2006/600/EC of 4 September 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards double skin metal faced sandwich panels for roofs (OJ L 244, 7.9.2006, p. 24).
80. Commission Decision 2006/673/EC of 5 October 2006 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards gypsum plasterboards (OJ L 276, 7.10.2006, p. 77).
81. Commission Decision 2006/751/EC of 27 October 2006 amending Decision 2000/147/EC implementing Council Directive 89/106/EC as regards the classification of the reaction-to-fire performance of construction products (OJ L 305, 4.11.2006, p. 8).
82. Commission Decision 2006/893/EC of 5 December 2006 on the withdrawal of the reference of standard EN 10080:2005 'Steel for the reinforcement of concrete — Weldable reinforcing steel — General' in accordance with Council Directive 89/106/EC (OJ L 343, 8.12.2006, p. 102).
83. Commission Decision 2007/348/EC of 15 May 2007 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards wood-based panels (OJ L 131, 23.5.2007, p. 21).
84. Commission Decision 2010/81/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards adhesives for ceramic tiles (OJ L 38, 11.2.2010, p. 9).

▼ M17

85. Commission Decision 2010/82/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards decorative wallcoverings in roll and panel form (OJ L 38, 11.2.2010, p. 11).
86. Commission Decision 2010/83/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards air drying jointing compounds (OJ L 38, 11.2.2010, p. 13).
87. Commission Decision 2010/85/EU-9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards cementitious screeds, calcium sulphate screeds and synthetic resin floor screeds (OJ L 38, 11.2.2010, p. 17).
88. Commission Decision 2010/679/EU of 8 November 2010 amending Decision 95/467/EC implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 292, 10.11.2010, p. 55).
89. Commission Decision 2010/683/EU of 9 November 2010 amending Decision 97/555/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders (OJ L 293, 11.11.2010, p. 60).
90. Commission Decision 2010/737/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards steel sheets with polyester coating and with plastisol coating (OJ L 317, 3.12.2010, p. 39).
91. Commission Decision 2010/738/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards fibrous gypsum plaster casts (OJ L 317, 3.12.2010, p. 42).
92. Commission Decision 2011/14/EU of 13 January 2011 amending Decision 97/556/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) (OJ L 10, 14.1.2011, p. 5).
93. Commission Decision 2011/19/EU of 14 January 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sealants for non-structural use in joints in buildings and pedestrian walkways (OJ L 11, 15.1.2011, p. 49).

▼ M17

94. Commission Decision 2011/232/EU of 11 April 2011 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, construction works and parts thereof (OJ L 97, 12.4.2011, p. 49).
95. Commission Decision 2011/246/EU of 18 April 2011 amending Decision 1999/93/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware (OJ L 103, 19.4.2011, p. 114).
96. Commission Decision 2011/284/EU of 12 May 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards power, control and communication cables (OJ L 131, 18.5.2011, p. 22).
97. Commission Implementing Decision 2012/201/EU of 26 March 2012 amending Decision 98/213/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits (OJ L 109, 21.4.2012, p. 20).
98. Commission Implementing Decision 2012/202/EU of 29 March 2012 amending Decision 1999/94/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/lightweight/autoclaved aerated concrete products (OJ L 109, 21.4.2012, p. 22).

▼ M18

- | | |
|-------------|---|
| 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) |

▼ **M17**

Section II

Conformity assessment bodies

1. For the purposes of this Chapter, and according to the Parties' legislation in Section I of this Chapter, 'Conformity assessment bodies' mean the bodies designated to carry out tasks in the process of assessment and verification of constancy of performance (AVCP) as well as *Technical Assessment Bodies (TABs)* which are members of the European Organisation for Technical Assessment (EOTA).
2. The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of this Agreement, a list of the conformity assessment bodies.

Section III

Designating authorities

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

Section IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in this Agreement.

Section V

Supplementary provisions▼ **M18**

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.

▼ **M17**

2. **Implementation**

The Parties' competent authorities and the organisations in charge of determining, in accordance with Regulation (EU) No 305/2011, the:

- essential characteristics for which the manufacturer shall declare the performance of products,
- classes of performance and threshold levels in relation to the essential characteristics of construction products,
- conditions on which a construction products shall be deemed to satisfy a certain level or class of performance, or
- AVCP-systems applicable to a given construction product,

shall mutually respect the regulatory needs of the Member States and Switzerland.

▼ **M17**

3. European harmonised standards for construction products

- (a) For the purpose of this Agreement, after their publishing in the *Official Journal of the European Union* according to Article 17(5) of the Regulation (EU) No 305/2011, Switzerland will publish the reference of the European harmonised standards for construction products, providing methods and criteria for assessing the performance of construction products, including:

— classes of performance and threshold levels in relation to the essential characteristics of construction products,

— conditions under which construction products are deemed to satisfy a certain level or class of performance without testing.

- (b) When Switzerland considers that a harmonised standard does not entirely satisfy the requirements set out in the legislation listed in Section I, the Swiss competent authority may ask the European Commission to consider the case in accordance with the procedure provided for in Article 18 of Regulation (EU) No 305/2011.

Switzerland may bring the matter before the Committee, giving its arguments. The Committee shall consider the case and may ask the European Union to act in accordance with the procedure provided for in Article 18 of Regulation (EU) No 305/2011.

4. European Technical Assessments (ETAs)

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

Procedures and decisions of EOTA shall also apply for the purpose of this Agreement.

- (b) European Assessment Documents issued by EOTA, and ETAs issued by the TABs are recognised by both Parties for the purpose of this Agreement.

- (c) Where a TAB receives a request for a ETA for a product not fully covered by a harmonised standard as in Article 21(1) of Regulation (EU) No 305/2011, it shall inform EOTA and the Commission of the content of the request and of the reference to a relevant Commission legal act for assessment and verification of constancy of performance which the TAB intends to apply for that product, or of the lack of such a legal act.

- (d) If the TABs do not agree upon the European Assessment Document within the time limits provided for, EOTA shall submit this matter to the Commission. In case of a disagreement involving a Swiss TAB, the Commission may consult the Swiss designating authority when it resolves a matter pursuant to Article 23 of Regulation (EU) No 305/2011.

- (e) When Switzerland considers that a European Assessment Document does not entirely satisfy the requirements to be met in relation to the basic requirements for construction works set out in the legislation in Section I of this Chapter, the Swiss competent authority may ask the European Commission to act in accordance with the procedure in Article 25 of Regulation (EU) No 305/2011.

▼ M17

Switzerland may bring the matter before the Committee, giving its arguments. The Committee shall consider the case and may ask the European Union to act in accordance with the procedure provided for in Article 25 of Regulation (EU) No 305/2011.

5. Information exchanges

- (a) In accordance with Article 9 of this Agreement, the Parties shall exchange information needed to ensure a proper implementation of this Chapter.
- (b) Pursuant to Article 12(3) of this Agreement, Member States and Switzerland shall designate Product Contact Points for Construction, which shall exchange relevant information upon request.
- (c) Should Switzerland have regulatory needs, it may propose the adoption of provisions, in particular so as to determine essential characteristics for which the performance shall be declared, or as to establish classes of performance, threshold levels in relation to essential characteristics of construction products, or conditions under which construction products are deemed to satisfy a certain level or class or performance without testing, as in Article 3 and Article 27 of Regulation (EU) No 305/2011.

6. Market access and technical documentation

- (a) For the purpose of this Chapter, the following definitions shall apply:
 - importer: any natural or legal person established within the European Union or Switzerland who places a construction product from a third country on the European Union or the Swiss market,
 - authorised representative: 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 in relation to specific tasks,
 - distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer who makes a construction product available on the European Union or on the Swiss market.
- (b) Pursuant to the legislation in Section I of this Chapter, manufacturers and importers shall indicate on the construction product or, where that is not possible, on its packaging or in a document accompanying it, their name, registered trade name or trade mark and their contact address.
- (c) It shall be sufficient for manufacturers, their authorised representative or importers to keep the declaration of performance and the technical documentation at the disposal of national authorities for the period required by the legislation in Section I after the date of placing the product on either Party's market.
- (d) Manufacturers, their authorised representatives, or importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the construction product with the declaration of performance and its compliance with other applicable requirements in this Chapter in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by construction products which they have placed on the market.

▼ **M17**

7. Exchange of experience

Swiss national authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 54 of Regulation (EU) No 305/2011.

8. Coordination of designated notified bodies

Swiss notified bodies may take part in the coordination and cooperation mechanisms provided for in Article 55 of Regulation (EU) No 305/2011, directly or by means of designated representatives.

9. Procedure for dealing with construction products presenting a risk caused by non-compliance that is not restricted to their 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 reasons to believe that, owing to a non-compliance with the provisions of the legislation referred to in Section I of this Chapter, a construction product presents a risk caused by non-compliance that they consider not restricted to their national territory, they shall inform each other and the European Commission without delay:

- of the results of the evaluation they have carried out and of the actions which they have required the relevant economic operator to take,
- where the relevant economic operator does not take adequate corrective action, of appropriate provisional measures taken to prohibit or restrict the making available of the construction product on their national market, to withdraw the construction product from that market or to recall it. This information shall include the details set out in Article 56(5) of Regulation (EU) No 305/2011.

Member States or Switzerland shall inform without delay 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 construction product concerned.

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

10. Safeguard procedure in case of objections against national measures

Should Switzerland or a Member State disagree with the national measure in Paragraph 9 above, it shall inform the European Commission of its objections within 15 working days of receipt of the information.

Where, on completion of the procedure set out in Paragraph 9 above, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be non-compliant with the relevant legislation referred to in Section I, the Commission shall, without delay, enter into consultation with the Member States, Switzerland and 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 construction product is withdrawn from their markets, and shall inform the Commission accordingly,

▼ M17

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

In both cases, a Party may forward the issue to the Committee, pursuant to Paragraph 12.

11. Compliant construction products which nevertheless present a risk to health and safety

Where a Member State or Switzerland finds that, although a construction product has been made available on the EU and on the Swiss market in compliance with the legislation referred to in Section I of this Chapter, the construction product presents a risk for the fulfilment of the basic requirements for construction works, to the health or 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 construction 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 the relevant economic operator(s) and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not.

A Party may forward the issue to the Committee, pursuant to Paragraph 12.

12. Safeguard clause in case of remaining disagreement between the Parties

In case of a disagreement between the Parties on measures at stake in Paragraph 10 and 11 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 it.

▼ M17

DECLARATION FROM THE EUROPEAN COMMISSION

In order to ensure the effective application and implementation of the Chapter on construction products in Annex 1 to the Agreement and in so far as Switzerland has adopted the relevant EU *acquis* or equivalent measures under the Chapter on construction products, the Commission will, in accordance with the Council Declaration on Swiss attendance of committees⁽¹⁾ and Article 100 of the Agreement on the European Economic Area, consult Swiss experts in the preparatory stages of draft measures to be submitted subsequently to the Committee established by Article 64 of Regulation (EU) No 305/2011 to assist the Commission in the exercise of its executive powers.

The Commission also notes that the Chairman of the Committee established pursuant to Article 64 of Regulation (EU) No 305/2011 may decide to invite Swiss experts to talk on particular matters, at the request of a member or on his or her own initiative, in particular in those matters of direct relevance to Switzerland.

⁽¹⁾ Declaration on Swiss attendance of committees (OJ L 114, 30.4.2002, p. 429).

▼ **M18**

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 in 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.

▼ M18

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.

▼M18**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.

▼ M18**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:

▼ M18

- (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.

▼ M17

CHAPTER 18
BIOCIDAL PRODUCTS

SCOPE AND COVERAGE

1. The provisions of this Sectoral Chapter apply to active substances, biocidal products, biocidal product families, and treated articles, as defined in Article 3 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products ('the Biocidal Products Regulation', hereinafter referred to as 'BPR'), subject to the procedures of the BPR and equivalent Swiss provisions, with the exemption of:
 - biocidal products which are or which contain genetically modified micro-organisms, and
 - avicides, piscicides and biocides for control of other vertebrates.
2. Commission implementing acts pursuant to Article 9, 14(4) and 15(1) of the BPR regarding the approval of active substances, and delegated acts pursuant to Article 28(1) and 28(3) of the BPR, regarding the inclusion of active substances into Annex I of the BPR, are part of this Chapter.
3. Switzerland is free to limit access to its market according to the requirements of its legislation existing at the date of entry into force of this Chapter concerning:
 - biocidal products containing octylphenol or its ethoxylates, and
 - aerosol dispensers containing substances stable in the air.

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

▼ M18

- | | |
|----------------|--|
| 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) |

▼ **M18**

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)

▼ **M17**

Section II

Conformity assessment bodies

For the purposes of this Chapter, ‘Conformity Assessment Bodies’ means the authorities of the European Union and competent authorities of EU Member States and of Switzerland responsible for the application of the legislation in Section I.

The contact details of the competent authorities of the Parties can be found on the websites indicated below.

European Union

Biocides:

— ‘Competent Authorities and other Contact Points’

http://ec.europa.eu/environment/chemicals/biocides/regulation/comp_authorities_en.htm

— <http://www.echa.europa.eu/regulations/biocidal-products-regulation>

Switzerland

Federal Office of Public Health, Notification Authority for Chemicals:
www.bag.admin.ch/biocide

Section III

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 Regulation (EU) No 528/2012 adopted after 10 October 2014 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. Procedures of the BPR and its implementing acts that apply between the Parties
 - (a) For the purpose of this Chapter, the subsequently specified procedures of the BPR and of its delegated and implementing acts as referred to in Section I apply as common procedures to complement provisions deemed equivalent.

In this Paragraph, a reference to ‘Member State(s)’ or their competent authorities in articles of the BPR that ‘shall apply between the Parties’ shall be understood to include, in addition to its meaning in the Regulation, Switzerland. For the purposes of this Chapter,

▼ M17

- ‘Authorisation holders’ and persons referred to in Article 95 of the BPR may be established within the European Union or Switzerland.
- Applicants shall use the Register for Biocidal Products (hereinafter ‘Register’) to submit applications and data for all procedures as foreseen in Article 71(3) of the BPR. Applicants do not need to be established within the European Union or Switzerland.

The procedures of the BPR and the implementing and delegated acts listed below shall apply between the Parties:

- Chapters II and III and Commission Delegated Regulation (EU) No 1062/2014, as regards the approval of active substances. Applicants may propose the Swiss Competent authority as the evaluating competent authority.
- Article 27 as regards biocidal products authorised according to the simplified procedure.
- Articles 32-34 and Commission Delegated Regulation (EU) No 492/2014 as regards mutual recognition of authorisations and their renewals.
- Articles 35-37 on objections and derogations.
- Articles 43-46 on Union authorisations, with the following adaptations: when the Commission grants a biocidal product a Union authorisation or renews, amends, decides not to grant the Union authorisation, cancels, or refuses to renew the Union authorisation, Switzerland shall, notwithstanding legal recourse, take a decision within 30 days in accordance with Article 14a OPBio on granting, renewing, cancelling or amending an authorisation for that product.
- Articles 47-50 and Commission Implementing Regulation (EU) No 354/2013 as regards the notification of adverse effects and rules on cancellation or amendments.
- Article 53 on parallel trade.
- Article 54 as regards the establishment of technical equivalence of active substances.
- Articles 62-63 on data sharing. In case a request has been submitted to the Swiss competent authority, the applicant shall be re-directed to the Agency and enter its request into the Register.
- Article 69(2) as regards the name and address of the authorisation holder and the authorisation number to be provided on labels.
- Article 88 as regards measures taken on the basis of new evidence.
- Article 95 (as in Regulation (EU) No 334/2014), with the transitional period in Article 95(2) up to 1 September 2016 for making the product available on the market of Switzerland.

- (b) If Switzerland intends to deviate from a decision taken pursuant to articles 36(3), 37(2), in the case of Union authorisations pursuant to articles 44(5), 46(4-5), 47-50, or decisions pursuant to article 88 of the BPR, or to adjust certain conditions specifically for its territory pursuant

▼ M17

to article 12(2) OPBio, it may take appropriate measures and shall immediately inform the Commission, giving its reasons. Where relevant, the case will be forwarded to the Joint Committee, which will decide on an appropriate course of action.

3. Information exchange

In accordance with Article 9 of this Agreement, the Parties shall in particular exchange the information needed to coordinate the procedures under this Chapter as foreseen in Article 71 of the BPR.

Pursuant to Article 29(4) of the BPR, except in cases where Commission Implementing Regulation (EU) No 414/2013 applies, Switzerland shall decline the evaluation of the application if another competent authority is examining an application relating to the same biocidal product or has already authorised it.

The Parties agree that authorisations and other decisions relating to the application of this Chapter may be notified by the competent authorities directly to the applicant in the territory of the other Party.

Information shall be protected and treated by the competent authorities of the Parties in accordance with Articles 59, 64, 66, 67 of the BPR.

4. Financial contribution for services provided by the European Chemical Agency (ECHA)

(a) Switzerland shall contribute to the Agency expenditure for activities mentioned in this chapter by an annual financial contribution to be added to the EU subsidy mentioned in Article 78(1) of the BPR. This annual financial contribution will be calculated in accordance with its Gross Domestic Product (GDP) as a percentage of the GDP of all participating States in accordance with the formula described in Appendix 1. The annual contribution will be paid to the Agency based on a debit note issued by ECHA.

(b) The financial contribution referred to in Subparagraph (a) shall be incurred as from the day following the entry into force of this Decision. The first financial contribution shall be reduced proportionally to the remaining time in year after its entry into force.

▼ M17*Appendix 1***Financial contribution of Switzerland for services provided by the European Chemical Agency (ECHA)**

1. The annual financial contribution of Switzerland to the subsidy mentioned in Article 78 of the BPR is calculated in the following way: The most updated final figures of the Gross Domestic Product (GDP) of Switzerland available on 31 March of each year shall be divided by the sum of the GDP figures of all the States participating in such activities, available for the same year. The obtained percentage will be applied to the subsidy from the Union referred to in Article 78(1)(a) of the BPR to obtain the amount of the financial contribution of Switzerland.
2. The financial contribution shall be paid in Euro.
3. Switzerland shall pay its financial contribution no later than 45 days after receiving the debit note. Any delay in payment shall give rise to the payment of default interest by Switzerland on the outstanding amount from the due date. The interest rate shall be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the *Official Journal of the European Union*, in force on the first calendar day of the month in which the deadline falls, increased by 1,5 percentage points.
4. Switzerland's financial contribution shall be adapted in case the subsidy from the European Union entered in the general budget of the European Union as defined in Article 78(1)(a) BPR is increased pursuant to Articles 26, 27 or 41 of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002. In this case, the difference shall be due 45 days after receiving the debit note.
5. In the event that the subsidy received by ECHA according to Article 78(1)(a) BPR related to a year N is not spent before 31 December of year N or that the ECHA budget of the year N has been lowered according to Articles 26, 27 or 41 of the Regulation (EU, Euratom) No 966/2012, the part of these unspent or lowered payment credits corresponding to the percentage of the contribution made by Switzerland is transferred to the budget of year N+1 of the agency. Switzerland's contribution to the Agency subsidy of year N+1 will be reduced accordingly.

▼ M17

DECLARATION FROM THE EUROPEAN COMMISSION

In order to ensure the effective application and implementation of the Chapter on Biocidal products in Annex 1 to the Agreement and in so far as Switzerland has adopted the relevant EU *acquis* or equivalent measures under the Chapter on Biocidal products, the Commission will, in accordance with the Council Declaration on Swiss attendance of committees⁽¹⁾ and Article 100 of the Agreement on the European Economic Area, consult Swiss experts in the preparatory stages of draft measures to be submitted subsequently to the Committee established by Article 82 of Regulation (EU) No 528/2012 to assist the Commission in the exercise of its executive powers.

The Commission also notes that the Chairman of the Committee established pursuant to Article 82 of Regulation (EU) No 528/2012 may decide to invite Swiss experts to talk on particular matters, at the request of a member or on his or her own initiative, in particular in those matters of direct relevance to Switzerland.

In addition, the Commission notes that Swiss experts are invited to participate in the group of Competent Authorities for the implementation of the Biocidal Products Regulation, which provides assistance to the Commission with the harmonised implementation of Regulation (EU) No 528/2012 and, as appropriate, in the Committee referred to in Article 75 of Regulation (EU) No 528/2012 and in the Coordination Group referred to in Article 35 of Regulation (EU) No 528/2012, for the matters relevant to the Chapter on biocidal products.

⁽¹⁾ Declaration on Swiss attendance of committees (OJ L 114, 30.4.2002, p. 429).

▼ **M19**

CHAPTER 19
CABLEWAY INSTALLATIONS

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|---|
| European Union | 1. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1). |
| Switzerland | 100. Federal Law of 23 June 2006 on cableway installations transporting people (RO 2006 5753) as last amended on 20 March 2009 (RO 2009 5597)

101. Ordinance of 21 December 2006 on cableway installations transporting people (RO 2007 39) as last amended on 11 October 2017 (RO 2017 5831)

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) |

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 IV of Regulation (EU) 2016/424.

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.

▼ M19

In order to avoid unnecessary duplication of obligations:

- (a) for the purpose of the obligations in Articles 11(6) and 13(3) of Regulation (EU) 2016/424 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 11(3) and 13(8) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 30 years after the subsystem or the safety component 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 keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 30 years after the subsystem or the safety component has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 11(4), second subparagraph, and 13(6) of Regulation (EU) 2016/424 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 12(2) of Regulation (EU) 2016/424 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 12(1) of Regulation (EU) 2016/424 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 subsystem or safety component 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 subsystem or safety component.

▼ M19**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 37 of Regulation (EU) 2016/424.

3. 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 Regulation (EU) 2016/424, 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 subsystems or safety components 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 subsystem or safety component covered by this Chapter presents a risk to the health or safety of persons or to 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 operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the subsystem or safety component being made available on their national market, to withdraw the subsystem or safety component 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 subsystem or safety component, 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 subsystem or safety component to meet requirements relating to the health or safety of persons or to property 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 subsystem or safety component concerned.

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

▼ M19**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 subsystem or safety component is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant subsystem or safety component 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 subsystems or safety components which nevertheless present a risk

Where a Member State or Switzerland finds that, although a subsystem or safety component 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 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 subsystem or safety component concerned, the origin and the supply chain of the subsystem or safety component, 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.

▼ M19

Where the Committee considers that the measure is:

- (a) justified, the Parties shall take the measures necessary to ensure that the subsystem or safety component is withdrawn from their market;
- (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

▼ M18

CHAPTER 20

EXPLOSIVES FOR CIVIL USE

Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- | | |
|----------------|--|
| European Union | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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) |

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.

⁽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.

▼ M18**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 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 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.

▼ M18**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

▼ M18

- 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:

▼M18

- (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;

▼ M18

- (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.



ANNEX 2

GENERAL RULES REGARDING THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES**A. General terms and conditions**

1. Under this Agreement, the designating authorities shall remain solely responsible for the competence and the capacity of the bodies they have designated and shall designate only legally identifiable bodies under their jurisdiction.
2. Designating authorities shall designate conformity assessment bodies able to demonstrate by objective means that they understand and have the requisite experience and competence to apply the requirements and certification procedures laid down in the legislative, regulatory and administrative provisions referred to in Annex I, that are applicable to the specific product, product category or sector for which they are designated.
3. Demonstration of technical competence shall cover:
 - the conformity assessment body's technical knowledge of the relevant products, processes or services which it is willing to treat;
 - the understanding of the technical standards and/or legislative, regulatory and administrative provisions for which designation is sought;
 - the physical capability to perform a given conformity assessment activity;
 - the adequate management of the activity concerned; and
 - any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed at all times.
4. The technical competence criteria shall be based as far as possible on internationally accepted documents, such as the EN 45000 series of standards or equivalents as well as on supplemented interpretative documents as appropriate. However these documents clearly need to be interpreted in such a way as to take account of the different types of requirements laid down in the applicable legislative, regulatory and administrative provisions.
5. The Parties shall encourage harmonisation of designation procedures and coordination of conformity assessment procedures through cooperation between designating authorities and conformity assessment bodies based on coordination meetings, participation in mutual recognition arrangements, and ad hoc working party meetings. The Parties shall also encourage accreditation bodies to participate in mutual recognition arrangements.

B. System for verification of conformity assessment bodies' competence

6. In order to verify the technical competence of conformity assessment bodies, the authorities concerned may use various procedures ensuring an appropriate level of trust between the Parties. If necessary, a Party shall indicate to the designating authority possible ways of demonstrating competence.

(a) Accreditation

Accreditation shall constitute a presumption of the technical competence of conformity assessment bodies in relation to the application of the requirements of the other Party provided that the competent accreditation body:

▼B

- complies with the relevant international provisions in force (EN 45000 standards or ISO/IEC guides); and
- is signatory to multilateral arrangements under which it is subject to peer evaluation, or
- takes part, under the authority of a Designating Authority, and in accordance with whatever conditions are decided on, in programmes to conduct comparisons and exchange technical experience, in the interests of ensuring continued trust in the technical competence of the accreditation and conformity-assessment bodies. Such programmes could include joint evaluations, special cooperation exercises or conformity assessment.

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

Where the criteria applicable to conformity assessment bodies require the latter to assess the conformity of products, processes or services not directly to standards or technical specifications, but to general (essential) requirements, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it incorporates elements which will enable assessment of the capacity of the conformity assessment body (technical knowledge of the product, of its use, etc.) to assess the conformity of the product to those essential requirements. Designation shall be limited to those activities of the conformity assessment body.

(b) Other means

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

- participation in regional or international mutual recognition arrangements or certification systems;
- regular peer evaluation, based on clear criteria and conducted with the appropriate expertise;
- aptitude tests; or
- comparison of conformity assessment bodies.

C. Evaluation of the verification system

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

D. Formal designation

8. When the Parties submit their proposals to the Committee on the inclusion of conformity assessment bodies in the Annexes, they shall provide the following details in respect of each body:
 - (a) its name;
 - (b) its postal address;

▼B

- (c) its fax number;
- (d) the Sectoral Chapter, product categories or products, processes and services covered by the designation;
- (e) the conformity assessment procedures covered by the designation;
- (f) the methods used to establish the body's competence.



FINAL ACT

The plenipotentiaries

of the 'EUROPEAN COMMUNITY',

and

of the SWISS CONFEDERATION,

meeting on the twenty-first day of June in the year one thousand nine hundred and ninety-nine in Luxembourg for the signature of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment have adopted the Joint Declarations mentioned below and attached to this Final Act:

Joint Declaration by the Contracting Parties on the revision of Article 4,

Joint Declaration on the mutual recognition of good clinical practice and inspections relating thereto,

Joint Declaration by the Contracting Parties on updating the Annexes,

Joint Declaration on further negotiations.

They also took note of the following Declaration annexed to this Final Act:

Declaration on Swiss attendance of Committees,

Hecho en Luxemburgo, el día veintiuno de junio del año mil novecientos noventa y nueve.

Udfærdiget i Luxembourg, den enogtyvende juni nitten hundrede og nioghalvfems.

Geschehen zu Luxemburg am einundzwanzigsten Juni neunzehnhundertneunundneunzig.

Έγινε στο Λουξεμβούργο, στις είκοσι μία Ιουνίου χίλια εννιακόσια ενενήντα εννέα.

Done at Luxembourg on the twenty-first day of June in the year one thousand nine hundred and ninety-nine.

Fait à Luxembourg, le vingt-et-un juin mil neuf cent quatre-vingt dix-neuf.

Fatto a Lussemburgo, addì ventuno giugno millenovecentonovantanove.

Gedaan te Luxemburg, de eenentwintigste juni negentienhonderd negenenneentig.

Feito no Luxemburgo, em vinte e um de Junho de mil novecentos e noventa e nove

Tehty Luxemburgissa kahdentenkymmenentenäensimmäisenä päivänä kesäkuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäyhdeksän.

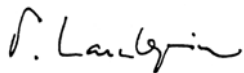
Som gjordes i Luxemburg den tjugoförsta juni nittonhundraionio.

▼B

Por la Comunidad Europea
 For Det Europæiske Fællesskab
 Für die Europäische Gemeinschaft
 Για την Ευρωπαϊκή Κοινότητα
 For the European Community
 Pour la Communauté européenne
 Per la Comunità europea
 Voor de Europese Gemeenschap
 Pela Comunidade Europeia
 Euroopan yhteisön puolesta
 På Europeiska gemenskapens vägnar




Por la Confederación Suiza
 For Det Schweiziske Edsförbund
 Für die Schweizerische Eidgenossenschaft
 Για την Ελβετική Συνομοσπονδία
 For the Swiss Confederation
 Pour la Confédération suisse
 Per la Confederazione svizzera
 Voor de Zwitserse Bondsstaat
 Pela Confederação Suíça
 Sveitsin valaliiton puolesta
 På Schweiziska edsförbundets vägnar




▼B

JOINT DECLARATION BY THE CONTRACTING PARTIES

on the Revision of Article 4

The Contracting Parties undertake to revise Article 4 of the Agreement on mutual recognition in relation to conformity assessment to include in particular products originating in other countries with which the Parties conclude agreements on mutual recognition in relation to conformity assessment, once such agreements have been concluded.

At that point the provisions of Chapter 12 in Section V of this Agreement will be revised.

▼B**JOINT DECLARATION****on the Mutual Recognition of Good Clinical Practice and Inspections
Relating thereto**

For medicinal products, the results of clinical trials carried out on the territory of the Parties to this Agreement are currently accepted for inclusion in applications for marketing authorisations and their variations or extensions. In principle, the Parties agree to continue to accept these clinical trials for the purpose of marketing authorisations applications. They agree to work towards an approximation of Good Clinical Practice, namely by implementing the current Declarations of Helsinki and Tokyo and all guidance relevant to clinical trials adopted in the framework of the International Conference on Harmonisation. However, due to legislative developments concerning inspections and authorisations of clinical trials in the European Community, detailed arrangements for the mutual recognition of the official supervision of these trials will have to be considered in the near future and laid down in a specific Chapter.

▼B

JOINT DECLARATION

by the Contracting Parties on Updating the Annexes

The Contracting Parties undertake to update the Annexes to the Agreement on mutual recognition in relation to conformity assessment not later than one month after its entry into force.

▼B

JOINT DECLARATION

on Further Negotiations

The European Community and the Swiss Confederation declare their intention of undertaking negotiations to conclude agreements in areas of common interest such as the updating of Protocol 2 to the 1972 Free Trade Agreement and Swiss participation in certain Community training, youth, media, statistical and environmental programmes. Preparatory work for these negotiations should proceed rapidly once the current bilateral negotiations have been concluded.

▼B**DECLARATION****on Swiss attendance of committees**

The Council agrees that Switzerland's representatives may, in so far as the items concern them, attend meetings of the following committees and expert working parties as observers:

- Committees of research programmes, including the Scientific and Technical Research Committee (CREST)
- Administrative Commission on Social Security for Migrant Workers
- Coordinating Group on the mutual recognition of higher-education diplomas
- Advisory committees on air routes and the application of competition rules in the field of air transport.

Switzerland's representatives shall not be present when these committees vote.

In the case of other committees dealing with areas covered by these agreements in which Switzerland has adopted either the *acquis communautaire* or equivalent measures, the Commission will consult Swiss experts by the method specified in Article 100 of the EEA Agreement.