

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 on the inclusion in Annex 1 of a new Chapter 20 on explosives for civil use, the amendment of Chapter 3 on toys and the update of legal references listed in Annex 1

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ("the Agreement") and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

- (1) The Parties to the Agreement have agreed to modify Annex 1 to the Agreement to include a new chapter on explosives for civil use;
- (2) The European Union has adopted a new Directive on the safety of toys¹ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation;
- (3) Chapter 3, Toys, of Annex 1 should be amended to reflect these developments;
- (4) It is necessary to update certain legal references in the Annex to the Agreement;
- (5) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

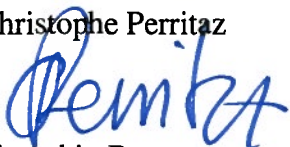
HAS DECIDED AS FOLLOWS:

1. Annex 1 to the Agreement is modified in order to include a new Chapter 20 on explosives for civil use (excluding ammunition) in accordance with the provisions set out in Attachment A annexed to this Decision.
2. Chapter 3, Toys, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.
3. Annex 1 on to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.
4. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorized to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

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).

On behalf of the Swiss Confederation

Christophe Perritaz

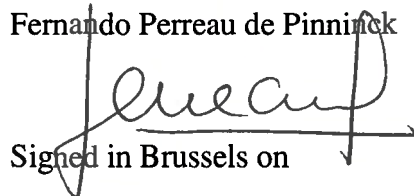


Signed in Bern on

17 December 2012

On behalf of the European Union

Fernando Perreau de Pinninck



Signed in Brussels on

12 December 2012

ATTACHMENT A

In Annex 1, Product Sectors, the following Chapter 20 on Explosives for civil use (excluding ammunition) shall be introduced:

CHAPTER 20

EXPLOSIVES FOR CIVIL USE

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

- | | |
|-----------------------|--|
| European Union | <ol style="list-style-type: none">1. Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses (in the version of OJ L 121, 15.5.1993, p. 20, corrected in OJ L 79, 7.4.1995, p. 34 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV) and in OJ L 59, 1.3.2006, p. 43 (DE)², hereinafter referred to as "Directive 93/15/EEC"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 | <ol 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) |

² 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.

101. Ordinance of 27 November 2000 on explosives (Explosives Ordinance), as last amended on 21.09.2012 (RO 2012 5315)

SECTION II

CONFORMITY ASSESSMENT BODIES

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

SECTION III

DESIGNATING AUTHORITIES

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

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Article 6(2) of Directive 93/15/EEC and its Annex III.

SECTION V

SUPPLEMENTARY PROVISIONS

1. 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.

2. 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. Controls performed pursuant to European Union law or national law in the event of transfers of the explosives governed by section V.2 shall solely be performed as part of the normal control procedures applied in a non-discriminatory fashion throughout the territory of the European Union or Switzerland.
3. 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 authorized to acquire explosives and that he is in possession of the necessary licenses or authorizations. The person responsible for the transfer must notify the competent authorities of the transit Member State or Member States or Switzerland of movements of explosives through this or these States or Switzerland, whose approval shall be required.
4. 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 will put the matter before the Committee provided for in Article 13 of Directive 93/15/EEC without delay. The European Commission shall inform Switzerland accordingly through the Committee established under Article 10 of this Agreement.
5. Where the recipient competent authority approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 7. Such a document must accompany the explosives until they arrive at their stated destination. It must be produced at the request of the relevant competent authorities. A copy of this document shall be retained by the consignee who shall present it for examination by the recipient competent authority, at the latter's request.
6. Where the competent authority of a Member State or Switzerland considers that special security requirements such as those referred to in paragraph 5 are unnecessary, explosives can be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 7. 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 5, which must accompany the explosives until they arrive at their destination, shall refer solely to the abovementioned approval.
7. 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 recipient competent authority:

- the names and addresses of the operators concerned; this information must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons in question are legally entitled to receive the consignment,
- the number and quantity of the explosives being transferred,
- a full description of the explosive in question and of the means of identification, including the United Nations identification number,
- where the explosives are to be placed on the market, information on compliance with conditions for placing on the market,
- the means of transfer and the itinerary,
- the expected dates of departure and arrival,
- where necessary, the precise points of entry to and exit from Member States or Switzerland.

Recipient competent authorities 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, in the same conditions, the particulars concerning the transfer.

8. 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 operators concerned in the explosives sector 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.
9. No supplier may transfer explosives unless the consignee has obtained the necessary authorizations for the transfer in accordance with the provisions of paragraphs 3, 5, 6 and 7.
10. For the purposes of implementing paragraph 4, where a measure provided for in Article 13 of Directive 93/15/EEC is adopted regarding products from Swiss undertakings in the explosives sector and/or Swiss manufacturers, it shall be communicated immediately to the Committee established under Article 10 of this Agreement.

If Switzerland disagrees with this measure, the application of the measure shall be deferred for three months from the date of communication. The Committee established under Article 10 of this Agreement shall hold consultations with a view to reaching a settlement. If a settlement is not reached within the period referred to in this paragraph, either Party may suspend the chapter in part or in full.

11. For the purposes of implementing paragraphs 5 and 6, the provisions of Decision 2004/388/EC shall apply.

3. 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.

4. Location of the manufacturer

For the purpose of this Chapter, it shall be sufficient that the undertaking in the explosives sector, the manufacturer, an authorized representative or, where neither of these is present, the person responsible for placing the product on the market, is established in the territory of one of the Parties.

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 3, Toys should be deleted and replaced by the following:

CHAPTER 3

TOYS

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1(2)

- | | | |
|-----------------------|------|--|
| 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 2012/7/EU (OJ L 64, 3.3.2012, p. 7) (hereinafter referred to as "Directive 2009/48/EC") |
| Switzerland | 100. | Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 9 November 2011 (RO 2011 5227) |
| | 101. | Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 22 August 2012 (RO 2012 4713) |
| | 102. | Ordinance of the Federal Department of Home Affairs (FDHA) of 15 August 2012 on the safety of toys (RO 2012 4717) |
| | 103 | Ordinance of the FDHA of 23 of November 2005 on the enforcement of foodstuff legislation (RO 2005 6555) as last amended on 15 August 2012 (RO 2012 4855) |
| | 104 | Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887) |

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 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.

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 I, 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 territory³

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.

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.

³ 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).

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.

ATTACHMENT C

Amendments to Annex 1

Chapter 1 (Machinery)

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

- "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)"

Chapter 7 (Radio Equipment and Telecommunications Terminal Equipment)

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

- "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 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 18 November 2009 (RO 2009 6243)
 102. Ordinance of 14 June 2002 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2002 2111), as last amended on 13 August 2012 (RO 2012 4337)
 103. Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115), as last amended on 21 November 2005 (RO 2005 5139)

104. List of technical standards published in the Feuille Fédérale with titles and references, as last amended on 1st May 2012 (FF 2012 4380)
105. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 9 December 2011 (RO 2012 367)"

Chapter 12 (Motor vehicles)

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

"SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1(2)

European Union

1. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Regulation (EU) No 65/2012 of the Commission of 24 January 2012 (OJ L 28, 31.1.2012, p. 24), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 2 March 2012 and amendments to the aforementioned Annex respectively to acts listed therein, accepted according to the procedure described in Section V, paragraph 1 (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 2 March 2012 (RO 2012 1909) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1
101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 11 June 2010 (RO 2010 2749) and taking into account

amendments accepted according to the procedure described in Section V, paragraph 1"

Chapter 13 (Agricultural and Forestry Tractors)

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

"SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1(2)

- European Union
1. Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)
 2. Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, as last amended by Directive 2010/52/EU of the Commission of 11 August 2010 (OJ L 213, 13.8.2010, p. 37)
 3. Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)
 4. Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81)

5. Council Directive 80/720/EEC of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors, as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p.7)
6. Council Directive 86/297/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of wheeled agricultural and forestry tractors and their protection, as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p.7)
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 (codified version) (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 (codified version) (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 (codified version) (OJ L 198, 30.7.2009, p. 4)
15. Directive 2009/59/EC of the European Parliament and the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (codified version) (OJ L 198, 30.7.2009, p. 9)
16. Directive 2009/60/EC of the European Parliament and the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors (codified version) 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 signaling devices on wheeled agricultural and forestry tractors (codified version) (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 (codified version) (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) (codified version) (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 (codified version) (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-signaling devices on wheeled agricultural or forestry tractors (codified version) (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) (codified version) (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 (codified version) (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 (codified version), as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)

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 11 June 2010 (RO 2010 2749)”

Chapter 14 (Good Laboratory Practice, GLP)

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

"Switzerland

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 19 March 2010 (RO 2010 3233)
101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197)
102. Ordinance of 18 May 2005 on protection against dangerous substances and preparations (RO 2005 2721), as last amended on 10 November 2010 (RO 2010 5223)
103. Ordinance of 18 May 2005 on the authorisation of plant protection products (RO 2005 3035), as last amended on 17 June 2011 (RO 2011 2927)
104. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 12 January 2011 (RO 2011 725)
105. Ordinance of 17 October 2001 on medicinal products (RO 2001 3420), as last amended on 8 September 2010 (RO 2010 3863)"

Chapter 15 (Medicinal products GMP Inspection and batch certification)

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

"SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1(2)

European Union

1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community

code relating to medicinal products for human use, as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34).

3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).
4. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).
5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).
6. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).
7. Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 63, 1.3.1994, p. 4) (published on website of the European Commission).
8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission).
9. Directive 2001/20/EC of 04 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the

conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

10. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).
11. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74)

Switzerland

100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 12 January 2011 (RO 2011 725)
101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 25 May 2011 (RO 2011 2561)
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 22 June 2006 (RO 2006 3587)
103. Ordinance of 17 October 2001 on clinical trials of pharmaceutical products (RO 2001 3511), as last amended on 9 May 2012 (RO 2012 2777)"

Declaration from the European Commission

In order to ensure the effective implementation of Chapter 3, Toys, and in accordance with the Council Declaration on Swiss attendance of committees⁴, the European Commission will consult Swiss experts in the preparatory stage of draft measures to be submitted subsequently to the Committee established by Article 47(1) of Directive 2009/48/EC.

⁴ OJ L114, 30.4.2002, p. 429.