ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

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

on the amendment of Chapter 16 on construction products, Chapter 18 on biocidal products and the update of legal references listed in Annex 1 [2015/1058]

THE COMMITTEE,

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

Whereas:

(1) The European Union has adopted a new Regulation on construction products (1) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent to that European Union legislation under Article 1(2) of the Agreement;

(2) Chapter 16, Construction products, of Annex 1 should be amended to reflect these developments;

(3) The European Union has adopted a new Regulation on biocidal products (2) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent to that European Union legislation under Article 1(2) of the Agreement;

(4) Chapter 18, Biocidal products, of Annex 1 should be amended to reflect these developments;

(5) It is necessary to update the legal references in Chapter 14, Good Laboratory Practice (GLP) and in Chapter 15, Medicinal products GMP Inspection and Batch Certification, of Annex 1 to the Agreement;

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

HAS DECIDED AS FOLLOWS:

1. Chapter 16, Construction products, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Chapter 18, Biocidal products, 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 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 authorised to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation  
Christophe PERRITAZ  
Signed at Berne, 14 April 2015

On behalf of the European Union  
Fernando PERREAU DE PINNINCK  
Signed at Brussels, 7 April 2015
ATTACHMENT A

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

CHAPTER 16
CONSTRUCTION PRODUCTS

SECTION I
Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2):

European Union


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

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 15.12.2014 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. 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.

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.

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.

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,

— 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.
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.'

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 18, Biocidal products should be deleted and replaced by the following:

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)

European Union


Switzerland


101. Federal Law of 7 October 1983 relating to the protection of the Environment (RO 1984 1122), as last amended on 1 August 2010 (RO 2010 3233)

102. Ordinance of 18 May 2005 concerning the making available on the market and the use of biocidal products (Ordinance on Biocidal Products, RO 2005 2821), as last amended on 15.7.2014 (RO 2014 2073) (hereinafter “OPBio”)


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”

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,

— “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 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 renew, 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 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.

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.

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.’

ATTACHMENT C

Amendments to Annex 1

Chapter 14 (Good laboratory practice (GLP))

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

'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)

European Union Food and feed


New and existing chemicals


Medicinal products


Veterinary medicinal products


Plant protection products


Biocidal products


Cosmetic products


Detergents


Switzerland

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)

102. Ordinance of 18 May 2005 on protection against dangerous substances and preparations (RO 2005 2721), as last amended on 20 June 2014 (RO 2014 2073)

103. Ordinance of 18 May 2005 on biocidal products (RO 2005 2821) as last amended on 15 July 2014 (RO 2014 2073)

104. Ordinance of 18 May 2005 on placing on the market of plant protection products (RO 2005 3035), as last amended on 11 December 2012 (RO 2013 249)

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 8 September 2010 (RO 2010 4039)

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

‘For the European Community:


In Section IV, Special rules relating to the designation of conformity assessment bodies, the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

‘European Union:


Switzerland:

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)


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)’

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


8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission)


100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 July 2013 (RO 2013 1493)

101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 January 2013 (RO 2012 3631) (1)

102. Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 1 January 2013 (RO 2012 5651)

103. Ordinance of 20 September 2013 on clinical trials in human research (RO 2013 3407) (*)

(*) Switzerland will notify the European Union without delay of the amendment corresponding to the EU Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 343, 23.11.2013, p. 1).