ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

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

of 1 April 2014

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

(2014/379/EU)

THE COMMITTEE,

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

Whereas:

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

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

(3) The European Union has adopted a new Regulation on construction products (2) (hereinafter the 'Construction Products Regulation');

(4) The Swiss legislation on construction products (Federal Law and Ordinance on construction products) is in the process of being amended; however, the Swiss ordinance on Accreditation and Designation (3), establishing the relevant framework requirements for the accreditation and designation of Swiss conformity assessment bodies is already in force;

(5) Chapter 16, Construction products, of Annex 1 should be amended, in a first step, to reflect the adoption of the Construction Products Regulation by the European Union, and, until the adoption of Swiss equivalent legislation, to enable the Parties during an interim period to grant mutual acceptance of conformity assessment results showing compliance with the Construction Products Regulation; once Swiss legislation equivalent with the Construction Products Regulation is adopted, the Parties shall replace this amendment with a subsequent one reflecting the adoption of both the Construction Products Regulation and the revised equivalent Swiss legislation. It is understood that this decision is meant to ensure continuity in the activities of conformity assessment bodies during this interim period, and is without prejudice to the application of the principles of Article 1 of the Agreement;

It is understood that this decision is meant to ensure continuity in the activities of conformity assessment bodies during this interim period, and is without prejudice to the application of the principles of Article 1 of the Agreement;


(3) Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887).
Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement.

HAS DECIDED AS FOLLOWS:

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

2. The Swiss Confederation shall accept conformity assessment results of EU recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation. The European Union shall accept conformity assessment results of Swiss recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation until the amendment of Chapter 16 following the adoption of equivalent Swiss legislation.

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

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

4. This Decision, done in duplicate, shall be signed by representatives of the Parties in the Committee who are authorized to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

   On behalf of the Swiss Confederation
   Christophe PERRITAZ
   Signed at Bern, 1 April 2014

   On behalf of the European Union
   Fernando PERREAU DE PINNINCK
   Signed at Brussels, 1 April 2014
In Annex 1, Product Sectors, Chapter 6, Pressure Vessels should be deleted and replaced by the following:

CHAPTER 6
PRESSURE VESSELS

SECTION I
Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

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 20 November 2002 on the safety of simple pressure vessels (RO 2003 107), as last amended on 19 May 2010 (RO 2010 2583)
103. Ordinance of 20 November 2002 on the safety of pressure equipment (RO 2003 38), as last amended on 19 May 2010 (RO 2010 2583)
104. Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO 2012 6607)
105. Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO 2002 4212), as last amended on 31 October 2012 (RO 2012 6535 and 6537)
106. Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway (RO 2012 6541)

SECTION II
Conformity assessment bodies

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

Designating authorities

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

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Annex II to Directive 2009/105/EC, Annexes IV or V to Directive 97/23/EC or Chapter 4 of Directive 2010/35/EU.

SECTION V

Additional provisions

1. Simple pressure vessels and pressure equipment

It shall be sufficient for manufacturers, their authorised representatives or, where neither of these is present, the person responsible for placing products on the market, to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Parties for a period of at least 10 years after the last date of manufacture of the product. The Parties undertake to forward all relevant documents to the authorities of the other Party upon request.

2. Transportable pressure equipment

1. Market access

1. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the authorised representative shall indicate its name and address on the certificate of conformity. For the purpose of this obligation, “authorised representative” shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from the manufacturer to act on his behalf in relation to specified tasks.

2. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the importer shall indicate its name and the address at which it can be contacted either on, or attached to the certificate of conformity. For the purpose of this obligation, “importer” shall mean any natural or legal person established within the European Union or Switzerland who places transportable pressure equipment or parts thereof from a third country on the European Union or on the Swiss market.

3. For the purposes of paragraphs 1 and 2, it shall be sufficient to mention either the importer or the authorised representative.

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

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

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

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

4. Mutual assistance of market surveillance authorities

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

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

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

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

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

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

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

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

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

6. Safeguard procedure

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

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

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

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

2. Disagreement between the Parties

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

Where the Committee considers that the measure is:

— justified, the Parties shall take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from their market.

— unjustified, the Member State or Switzerland shall withdraw it;

7. Free movement of transportable pressure equipment

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

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

CHAPTER 16

CONSTRUCTION PRODUCTS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraphs 1 and 2:

European Union


Implementing measures:


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)


SECTION II

Conformity assessment bodies

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

2. Conformity assessment bodies can be differentiated in three different bodies involved in the assessment and verification of constancy of performance: Product certification body, factory product control certification body and testing laboratory. For the purpose of this Agreement the definitions of Annex V Section 2 to Regulation (EU) No 305/2011 shall apply.

SECTION III

Designating authorities

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

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and with the assessment criteria set out in Article 43 of Regulation (EU) No 305/2011.

SECTION V

Supplementary provisions

1. European harmonised standards for construction products

For the purpose of this Agreement, Switzerland will publish the reference of the European harmonised standards for construction products after their publishing in the Official Journal of the European Union according to Article 17(5) of the Regulation (EU) No 305/2011.

To state the equivalence of the Swiss systems of assessment and verification of constancy of performance, Switzerland will add to every harmonised standard a conversion table. This conversion table shall ensure the comparability of the Swiss and the European systems of assessment and verification of constancy of performance describing the relevant procedures for them.

2. European Technical Assessments

(a) Switzerland shall be entitled to designate Swiss bodies to issue European Technical Assessments. It shall make sure that designated bodies become members of the European Organisation for Technical Assessment (EOTA) and participate in its work, in particular for developing and adopting European Assessment Documents (EADs) according to Article 19 of Regulation (EU) No 303/2011.

Switzerland shall notify the Committee established under Article 10 of this Agreement of the names and addresses of such bodies.

Decisions of EOTA shall also apply for the purpose of this Agreement.

European Technical Assessments are issued by the Technical Assessment Bodies and are recognised by both Parties for the purpose of this Agreement.
(b) “Technical Assessment Body” shall mean a public or private law body which is authorised to issue European Technical Assessments.

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

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of this Agreement, a list of the Technical Assessment Bodies. The Parties hereby recognise that the bodies thus listed for the purpose of this Agreement fulfil the conditions to issue European Technical Assessments.

3. Information exchanges

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

4. Technical documentation

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing products on the market to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Parties for a period of at least 10 years after the date of placing the product on either Party’s market.

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

5. Person responsible for placing the products on the market and labelling

The manufacturer shall not be obliged to designate an authorised representative or a person responsible for placing products on the market established in the territory of the other Party, nor to indicate the name and address of an authorised representative, responsible person or importer on the label, outer packaging or instructions for use.
ATTACHMENT C

Amendments to Annex 1

Chapter 1 (Machinery)

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


Chapter 2 (Personal Protective Equipment)

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


Chapter 3 (Toys)

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


Switzerland 100. Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 9 November 2011 (RO 2011 5227)

101. Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 23 October 2013 (RO 2013 3669)


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

1. European Union


Chapter 5 (Gas Appliances and Boilers)

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


Chapter 7 (Radio Equipment and Telecommunications Terminal Equipment)

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


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)

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 31 October 2012 (RO 2012 6561)

102. Ordinance of 14 June 2002 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2002 2111), as last amended on 12 August 2013 (RO 2013 2649)

103. Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115), as last amended on 21 November 2005 (RO 2005 5139)

104. List of technical standards published in the Feuille Fédérale with titles and references, as last amended on 28 December 2012 (FF 2012 9084)


Chapter 8 (Equipment and protective systems intended for use in potentially explosive atmospheres)

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

European Union


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)
Chapter 9 Electrical equipment and Electromagnetic compatibility

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

‘Switzerland

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)


102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 16 November 2011 (RO 2011 6233)

103. Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016), as last amended on 11 June 2010 (RO 2010 2749)

104. Ordinance of 18 November 2009 on electromagnetic compatibility (RO 2009 6243), as last amended on 24 August 2010 (RO 2010 3619)

105. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 31 October 2012 (RO 2012 6561)

106. List of the technical standards published in the Feuille Fédérale with titles and references, as last amended on 6 November 2012 (FF 2012 7968)'

Chapter 11 Measuring instruments and prepackages

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

‘European Union


Switzerland

100. Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended

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

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

European Union


Switzerland


103. Ordinance of 23 November 1994 on units measurement (RO 1994 3109), as last amended on 7 December 2012 (RO 2012 7193)
In Section IV, Special rules relating to the designation of conformity assessment bodies, the provision should be deleted and replaced by the following text:

‘For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Annex V to Directive 2009/23/EC and in Article 12 to Directive 2004/22/EC, as regards the products covered by those Directives.’

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

1. Information exchange

The conformity assessment bodies recognised under this Agreement shall periodically provide the Member States and the competent Swiss authorities with the information provided for in point 1.5 of Annex II to Directive 2009/23/EC.

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

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

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

3. **Marking**

3.1. For the purposes of this Agreement, the provisions of Directive 2009/34/EC of 23 April 2009 shall be read with the following adaptations:

(a) To the first indent of point 3.1 of Annex 1 and to the first indent of point 3.1.1.1(a) of Annex II, the following shall be added to the text in brackets: “CH for Switzerland”.

(b) The drawings to which point 3.2.1 of Annex II refers, are supplemented by the following drawing:

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3.2. By the way of derogation from Article 1 of this Agreement, the rules on marking for measuring instruments placed on the Swiss market are as follows:

The marking that must be affixed is the EC marking and supplementary metrology marking or the national sign of the EC Member State concerned as provided in the first indent of point 3.1 of Annex I and the first indent of point 3.1.1.1 of Annex II to Directive 2009/34/EC of 23 April 2009.

**Chapter 12 (Motor vehicles)**

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

**SECTION I**

**Legislative, regulatory and administrative provisions**

**Provisions covered by Article 1(2)**

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


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

Chapter 13 (Agricultural and Forestry Tractors)

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

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union


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)


Switzerland

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

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

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

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