

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

**DECISION No 1/2011 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT
BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL
RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT**

of 20 December 2011

**on the inclusion in Annex 1 of a new Chapter 19 on cableway installations and the update of legal
references listed in Annex 1**

(2012/162/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 Article 10(4) and (5) and Article 18(2) thereof;

Whereas 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 on product sectors to the Agreement is modified in order to include a new Chapter 19 on cableway installations in accordance with the provisions set out in Attachment A annexed to this Decision.
2. Annex 1 on product sectors to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.
3. 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.

Signed at Bern, 20 December 2011.

On behalf of the Swiss Confederation

Christophe PERRITAZ

Signed at Brussels, 14 December 2011.

On behalf of the European Union

Fernando PERREAU DE PINNINCK

ATTACHMENT A

In Annex 1, Product sectors, the following Chapter 19 on cableway installations shall be introduced:

'CHAPTER 19

CABLEWAY INSTALLATIONS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (OJ L 106, 3.5.2000, p. 21; hereinafter referred to as Directive 2000/9/EC)
Switzerland	Federal Law of 23 June 2006 on cableway installations designed to carry persons (RO 2006 5753), as last amended on 20 March 2009 (RO 2009 5597) Ordinance of 21 December 2006 on cableway installations designed to carry persons (RO 2007 39), as last amended on 11 June 2010 (RO 2010 2749)

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 VIII to Directive 2000/9/EC.

SECTION V

Supplementary provisions**1. Information exchange**

In accordance with Articles 9 and 12 of this Agreement, the Parties shall exchange information needed to ensure a proper implementation of this Chapter.

The competent authorities in Switzerland and in the Member States as well as the European Commission shall in particular exchange the information referred to in Article 11 and Article 14 of Directive 2000/9/EC.

The conformity assessment bodies designated according to Section IV of this Annex shall exchange the information referred to in Annex V to Directive 2000/9/EC, as regards Module B points 7 and 8, Module D point 6, and Module H points 6 and 7.5.

2. 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 documentation as required by Directive 2000/9/EC in the territory of one of the Parties.

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

3. *Market surveillance*

The Parties shall notify each other of the authorities established on their territory responsible for carrying out the surveillance tasks involved in the implementation of their legislation as set out in Section I.

The Parties shall notify each other of their market surveillance activities within the bodies designated for this purpose.'

ATTACHMENT B

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 and Swiss provisions should be deleted and replaced by the following text:

- | | |
|----------------|---|
| European Union | 1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) as last amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (OJ L 310, 25.11.2009, p. 29) |
| 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 19 May 2010 (RO 2010 2583) |

CHAPTER 2

PERSONAL PROTECTIVE 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 12 June 2009 on product safety (RO 2010 2573) |
| | 101. Ordinance of 19 May 2010 on product safety (RO 2010 2583) |

CHAPTER 5

GAS APPLIANCES AND BOILERS

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 | 101. Federal Law of 12 June 2009 on product safety (RO 2010 2573) |
| | 102. Ordinance of 19 May 2010 on product safety (RO 2010 2583) |

CHAPTER 6

PRESSURE VESSELS

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

- | | |
|----------------|--|
| European Union | 1. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1) |
|----------------|--|

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
102. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
 103. Ordinance of 19 May 2010 on product safety (RO 2010 2583)
 104. Ordinance of 20 November 2002 on the safety of simple pressure vessels (RO 2003 38), as last amended on 19 May 2010 (RO 2010 2583)
 105. Ordinance of 20 November 2002 on the safety of pressure equipment (RO 2003 38), as last amended on 19 May 2010 (RO 2010 2583)

CHAPTER 7

RADIO EQUIPMENT AND TELECOMMUNICATION 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 7 April 2011 (RO 2011 1391)
 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 3 May 2011 (FF 2011 0799)
 105. Ordinance of 9 March 2007 on telecommunication services (RO 2007 945), as last amended on 4 November 2009 (RO 2009 5821)

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 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)
 101. Ordinance of 2 March 1998 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 1998 963), as last amended on 11 June 2010 (RO 2010 2749)
 102. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
 103. Ordinance of 19 May 2010 on product safety (RO 2010 2583)

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)
 101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 18 November 2009 (RO 2009 6243)
 102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 8 December 1997 (RO 1998 54)
 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 18 November 2009 (RO 2009 6243)'

CHAPTER 11

MEASURING INSTRUMENTS AND PRE-PACKAGES

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
102. Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 18 June 2010 (RO 2010 5003)
 103. Ordinance of 23 November 1994 on units measurement (RO 1994 3109)
 104. Ordinance of 15 February 2006 concerning measuring instruments (RO 2006 1453), as last amended on 8 September 2010 (RO 2010 4489)
 105. Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO 2004 2093), as last amended on 2 October 2006 (RO 2006 4189)
 106. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO 2006 1433)
 107. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO 2006 1525)
 108. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring systems for liquids other than water (RO 2006 1533), as last amended on 5 October 2010 (RO 2010 4595)

109. Ordinance of the federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO 2006 1545)
110. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO 2006 1569)
111. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO 2006 1591)
112. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO 2006 1599)
113. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for the electrical energy and power (RO 2006 1613)
114. Ordinance of 15 August 1986 on weights (RO 1986 2022), as last amended on 2 October 2006 (RO 2006 4193)

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 8 September 2010 (RO 2010 4027)
 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

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 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 8 September 2010 (RO 2010 4027)

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 8 September 2010 (RO 2010 4043)

CHAPTER 17

LIFTS

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

- | | |
|----------------|---|
| European Union | 1. European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1), as last amended by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) |
| 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 23 June 1999 on the safety of lifts (RO 1999 1875), as last amended on 19 May 2010 (RO 2010 2583) |

CHAPTER 18

BIOCIDAL PRODUCTS

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 15 December 2000 for the protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197) |
| | 101. Federal Law of 7 October 1983 relating to the protection of the environment (RO 1984 1122), as last amended on 19 March 2010 (RO 2010 3233) |
| | 102. Ordinance of 18 May 2005 concerning the placing on the market and the use of biocidal products (RO 2005 2821), as last amended on 4 April 2011 (RO 2011 1403) |
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