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.

([1]) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

([2]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

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	*On behalf of the European Union*
Christophe PERRITAZ	Fernando PERREAU DE PINNINCK
Signed at Berne, 14 April 2015	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

1. Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5), as last amended by Commission Delegated Regulation (EU) No 574/2014 from 21 February 2014 (OJ L 159, 28.5.2014, p. 41), as well as implementing and delegated acts of the Commission adopted under this regulation until 15.12.2014 (hereinafter together referred to as Regulation (EU) No 305/2011)

2. Commission Decision 94/23/EC of 17 January 1994 on common procedural rules for European technical approval (OJ L 17, 20.1.1994, p. 34).

2(a). Commission Decision 94/611/EC of 9 September 1994 implementing Article 20 of Directive 89/106/EEC on construction products (OJ L 241, 16.9.1994, p. 25).

2(b). Commission Decision 95/204/EC of 31 May 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 129, 14.6.1995, p. 23).

3. Commission Decision 95/467/EC of 24 October 1995 implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 268, 10.11.1995, p. 29).

4. Commission Decision 96/577/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fixed fire-fighting systems (OJ L 254, 8.10.1996, p. 44).

5. Commission Decision 96/578/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sanitary appliances (OJ L 254, 8.10.1996, p. 49).

6. Commission Decision 96/579/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures (OJ L 254, 8.10.1996, p. 52).

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

8. Commission Decision 96/581/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards geotextiles (OJ L 254, 8.10.1996, p. 59).

9. Commission Decision 96/582/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural sealant glazing systems and metal anchors for concrete (OJ L 254, 8.10.1996, p. 62).

10. Commission Decision 96/603/EC of 4 October 1996 establishing the list of products belonging to classes A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 267, 19.10.1996, p. 23).

11. Commission Decision 97/161/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal anchors for use in concrete for fixing lightweight systems (OJ L 62, 4.3.1997, p. 41).

12. Commission Decision 97/176/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural timber products and ancillaries (OJ L 73, 14.3.1997, p. 19).

13. Commission Decision 97/177/EC of 17 February 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal injection anchors for use in masonry (OJ L 73, 14.3.1997, p. 24).

14. Commission Decision 97/462/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards wood-based panels (OJ L 198, 25.7.1997, p. 27).

15. Commission Decision 97/463/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards plastic anchors for use in concrete and masonry (OJ L 198, 25.7.1997, p. 31).

16. Commission Decision 97/464/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 198, 25.7.1997, p. 33).

17. Commission Decision 97/555/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders (OJ L 229, 20.8.1997, p. 9).

18. Commission Decision 97/556/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) (OJ L 229, 20.8.1997, p. 14).

19. Commission Decision 97/571/EC of 22 July 1997 on the general format of European Technical Approval for construction products (OJ L 236, 27.8.1997, p. 7).

20. Commission Decision 97/597/EC of 14 July 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards reinforcing and prestressing steel for concrete (OJ L 240, 2.9.1997, p. 4).

21. Commission Decision 97/638/EC of 19 September 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fasteners for structural timber (OJ L 268, 1.10.1997, p. 36).

22. Commission Decision 97/740/EC of 14 October 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards masonry and related products (OJ L 299, 4.11.1997, p. 42).

23. Commission Decision 98/143/EC of 3 February 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards systems of mechanically fastened flexible roof waterproofing membranes (OJ L 42, 14.2.1998, p. 58).

24. Commission Decision 97/808/EC of 20 November 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards floorings (OJ L 331, 3.12.1997, p. 18).

25. Commission Decision 98/213/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits (OJ L 80, 18.3.1998, p. 41).

26. Commission Decision 98/214/EC of 9 March 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural metallic products and ancillaries (OJ L 80, 18.3.1998, p. 46).

27. Commission Decision 98/279/EC of 5 December 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards non load-bearing permanent shuttering kits/systems based on hollow blocks or panels of insulating materials and, sometimes, concrete (OJ L 127, 29.4.1998, p. 26).

28. Commission Decision 98/436/EC of 22 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards roof coverings, roof lights, roof windows and ancillary products (*notified under document number C(1998) 1598*) (OJ L 194, 10.7.1998, p. 30).

29. Commission Decision 98/437/EC of 30 June 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal and external wall and ceiling finishes (OJ L 194, 10.7.1998, p. 39).

30. Commission Decision 98/456/EC of 3 July 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards post-tensioning kits for the prestressing of structures (OJ L 201, 17.7.1998, p. 112).

31. Commission Decision 98/457/EC of 3 July 1998 concerning the test of the Single Burning Item (SBI) referred to in Council Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 201, 17.7.1998, p. 114).

32. Commission Decision 98/598/EC of 9 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards aggregates (OJ L 287, 24.10.1998, p. 25)

33. Commission Decision 98/599/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid applied roof waterproofing kits (OJ L 287, 24.10.1998, p. 30).

34. Commission Decision 98/600/EC of 12 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards self-supporting translucent roof kits (except glass-based kits) (OJ L 287, 24.10.1998, p. 35).

35. Commission Decision 98/601/EC of 13 October 1998 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards road construction products (OJ L 287, 24.10.1998, p. 41).

36. Commission Decision 99/89/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated stair kits (OJ L 29, 3.2.1999, p. 34).

37. Commission Decision 1999/90/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards membranes (OJ L 29, 3.2.1999, p. 38).

38. Commission Decision 1999/91/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards thermal insulating products (OJ L 29, 3.2.1999, p. 44).

39. Commission Decision 1999/92/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards light composite wood-based beams and columns (OJ L 29, 3.2.1999, p. 49).

40. Commission Decision 1999/93/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware (OJ L 29, 3.2.1999, p. 51).

41. Commission Decision 1999/94/EC of 25 January 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/light-weight autoclaved aerated concrete products (OJ L 29, 3.2.1999, p. 55).

41a) Commission Decision 1999/453/EC of 18 June 1999 amending decision 96/579/EC and 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures and floorings respectively (OJ L 178, 14.7.1999, p. 50).

42. Commission Decision 1999/454/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fire stopping, fire sealing and fire protective products (OJ L 178, 14.7.1999, p. 52).

43. Commission Decision 1999/455/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards timber frame and log prefabricated building kits (OJ L 178, 14.7.1999, p. 56).

44. Commission Decision 1999/469/EC of 25 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards products related to concrete, mortar and grout (OJ L 184, 17.7.1999, p. 27).

45. Commission Decision 1999/470/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards construction adhesives (OJ L 184, 17.7.1999, p. 32).

46. Commission Decision 1999/471/EC of 29 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards space heating appliances (OJ L 184, 17.7.1999, p. 37).

47. Commission Decision 1999/472/EC of 1 July 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pipes, tanks and ancillaries not in contact with water intended for human consumption (OJ L 184, 17.7.1999, p. 42).

48. Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products (OJ L 50, 23.2.2000, p. 14).

49. Commission Decision 2000/245/EC of 2 February 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(4) of Council Directive 89/106/EEC as regards flat glass, profiled glass and glass block products (OJ L 77, 28.3.2000, p. 13).

50. Commission Decision 2000/273/EC of 27 March 2000 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European Technical Approvals without Guideline (OJ L 86, 7.4.2000, p. 15).

51. Commission Decision 2000/367/EC of 3 May 2000 implementing Council Directive 89/106/EEC as regards the classification of the resistance to fire performance of construction products, construction works and parts thereof (OJ L 133, 6.6.2000, p. 26).

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

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

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

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

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

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

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

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

58. Commission Decision 2002/359/EC of 13 May 2002 on the procedure for attesting the conformity of construction products in contact with water intended for human consumption, pursuant to Article 20(2) of Council Directive 89/106/EEC (OJ L 127, 14.5.2002, p. 16).

59. Commission Decision 2002/592/EC of 15 July 2002 amending Decisions 95/467/EC, 96/577/EC, 96/578/EC and 98/598/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards gypsum products, fixed fire-fighting systems, sanitary appliances and aggregates respectively (OJ L 192, 20.7.2002, p. 57).

60. Commission Decision 2003/43/EC of 17 January 2003 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 13, 18.1.2003, p. 35).

61. Commission Decision 2003/312/EC of 9 April 2003 on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks in accordance with Council Directive 89/106/EEC (OJ L 114, 8.5.2003, p. 50).

62. Commission Decision 2003/424/EC of 6 June 2003 amending Decision 96/603/EC establishing the list of products belonging to Classes A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products (OJ L 144, 12.6.2003, p. 9).

63. Commission Decision 2003/593/EC of 7 August 2003 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance of certain construction products (OJ L 201, 8.8.2003, p. 25).

64. Commission Decision 2003/629/EC of 27 August 2003 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, as regards the inclusion of smoke and heat control products (OJ L 218, 30.8.2003, p. 51).

65. Commission Decision 2003/632/EC of 26 August 2003 amending Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction-to-fire performance of construction products (OJ L 220, 3.9.2003, p. 5).

66. Commission Decision 2003/639/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pins for structural joints (OJ L 226, 10.9.2003, p. 18).

67. Commission Decision 2003/640/EC of 4 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards kits for exterior wall claddings (OJ L 226, 10.9.2003, p. 21).

68. Commission Decision 2003/655/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards watertight covering kits for wetroom floors and walls (OJ L 231, 17.9.2003, p. 12).

69. Commission Decision 2003/656/EC of 12 September 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European technical approvals without Guideline (OJ L 231, 17.9.2003, p. 15).

70. Commission Decision 2003/722/EC of 6 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid-applied bridge deck waterproofing kits (OJ L 260, 11.10.2003, p. 32).

71. Commission Decision 2003/728/EC of 3 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rockfall protection kits (OJ L 262, 14.10.2003, p. 34).

72. Commission Decision 2004/663/EC of 20 September 2004 amending Commission Decision 97/464/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 302, 29.9.2004, p. 6).

73. Commission Decision 2005/403/EC of 25 May 2005 establishing the classes of external fire performance of roofs and roof coverings for certain construction products as provided for by Council Directive 89/106/EEC (OJ L 135, 28.5.2005, p. 37).

74. Commission Decision 2005/484/EC of 4 July 2005 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cold storage building kits and cold storage building envelope kits (OJ L 173, 6.7.2005, p. 15).

75. Commission Decision 2005/610/EC of 9 August 2005 establishing the classes of reaction-to-fire performance for certain construction products (OJ L 208, 11.8.2005, p. 21).

76. Commission Decision 2005/823/EC of 22 November 2005 amending Decision 2001/671/EC implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (OJ L 307, 25.11.2005, p. 53).

77. Commission Decision 2006/190/EC of 1 March 2006 amending Decision 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards floorings (OJ L 66, 8.3.2006, p. 47).

78. Commission Decision 2006/213/EC of 6 March 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards wood flooring and solid wood panelling and cladding (OJ L 79, 16.3.2006, p. 27).

79. Commission Decision 2006/600/EC of 4 September 2006 establishing the classes of reaction-to-fire performance for certain construction products as regards double skin metal faced sandwich panels for roofs (OJ L 244, 7.9.2006, p. 24).

80. Commission Decision 2006/673/EC of 5 October 2006 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards gypsum plasterboards (OJ L 276, 7.10.2006, p. 77).

81. Commission Decision 2006/751/EC of 27 October 2006 amending Decision 2000/147/EC implementing Council Directive 89/106/EC as regards the classification of the reaction-to-fire performance of construction products (OJ L 305, 4.11.2006, p. 8).

82. Commission Decision 2006/893/EC of 5 December 2006 on the withdrawal of the reference of standard EN 10080:2005 "Steel for the reinforcement of concrete — Weldable reinforcing steel — General" in accordance with Council Directive 89/106/EC (OJ L 343, 8.12.2006, p. 102).

83. Commission Decision 2007/348/EC of 15 May 2007 amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products as regards wood-based panels (OJ L 131, 23.5.2007, p. 21).

84. Commission Decision 2010/81/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards adhesives for ceramic tiles (OJ L 38, 11.2.2010, p. 9).

85. Commission Decision 2010/82/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards decorative wallcoverings in roll and panel form (OJ L 38, 11.2.2010, p. 11).

86. Commission Decision 2010/83/EU of 9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards air drying jointing compounds (OJ L 38, 11.2.2010, p. 13).

87. Commission Decision 2010/85/EU-9 February 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards cementitious screeds, calcium sulphate screeds and synthetic resin floor screeds (OJ L 38, 11.2.2010, p. 17).

88. Commission Decision 2010/679/EU of 8 November 2010 amending Decision 95/467/EC implementing Article 20(2) of Council Directive 89/106/EEC on construction products (OJ L 292, 10.11.2010, p. 55).

89. Commission Decision 2010/683/EU of 9 November 2010 amending Decision 97/555/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders (OJ L 293, 11.11.2010, p. 60).

90. Commission Decision 2010/737/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards steel sheets with polyester coating and with plastisol coating (OJ L 317, 3.12.2010, p. 39).

91. Commission Decision 2010/738/EU of 2 December 2010 establishing the classes of reaction-to-fire performance for certain construction products as regards fibrous gypsum plaster casts (OJ L 317, 3.12.2010, p. 42).

92. Commission Decision 2011/14/EU of 13 January 2011 amending Decision 97/556/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) (OJ L 10, 14.1.2011, p. 5).

93. Commission Decision 2011/19/EU of 14 January 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sealants for non-structural use in joints in buildings and pedestrian walkways (OJ L 11, 15.1.2011, p. 49).

94. Commission Decision 2011/232/EU of 11 April 2011 amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, construction works and parts thereof (OJ L 97, 12.4.2011, p. 49).

95. Commission Decision 2011/246/EU of 18 April 2011 amending Decision 1999/93/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware (OJ L 103, 19.4.2011, p. 114).

96. Commission Decision 2011/284/EU of 12 May 2011 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards power, control and communication cables (OJ L 131, 18.5.2011, p. 22).

97. Commission Implementing Decision 2012/201/EU of 26 March 2012 amending Decision 98/213/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits (OJ L 109, 21.4.2012, p. 20).

98. Commission Implementing Decision 2012/202/EU of 29 March 2012 amending Decision 1999/94/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/lightweight/autoclaved aerated concrete products (OJ L 109, 21.4.2012, p. 22).

Switzerland

100. Federal law of 21 March 2014 on construction products (RO 2014 2867)

101. Ordinance of 27 August 2014 on construction products (RO 2014 2887)

102. Ordinance of the Federal office for Building and Logistics on the designation of European implementing and delegated acts regarding construction products of 10 September 2014 as last amended on 2 February 2015 (RO 2015 515)

103. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 July 2014 (RO 2014 1411)

104. Accord intercantonal sur l'élimination des entraves techniques au commerce du 23 octobre 1998 (RO 2003 270)

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.'

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

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	1. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) (OJ L 167, 27.6.2012, p. 1), as last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 (OJ L 103, 5.4.2014, p. 22), as well as implementing and delegated acts of the Commission adopted under this regulation until 10.10.2014.
Switzerland	100. Federal Law of 15 December 2000 for the protection against dangerous substances and preparations (RO 2004 4763), as last amended on 13 June 2006 (RO 2006 2197)
	101. Federal Law of 7 October 1983 relating to the protection of the Environment (RO 1984 1122), as last amended on 1 August 2010 (RO 2010 3233)
	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")
	103. Ordinance of 15 August 2014 of the Department of Home Affairs on implementing rules related to the Ordinance on Biocidal Products (RO 2014 2755).

SECTION II

Conformity assessment bodies

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

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

European Union

Biocides:

— "Competent Authorities and other Contact Points"

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

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

Switzerland

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

SECTION III

Supplementary provisions

1. Amendments to legislative, regulatory and administrative provisions of Section I

Without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of implementing and delegated acts of the Commission under Regulation (EU) No 528/2012 adopted after 10 October 2014 without delay after their publication in the *Official Journal of the European Union*.

Switzerland shall notify the European Union without delay of the relevant amendments of the Swiss legislation.

2. Procedures of the BPR and its implementing acts that apply between the Parties

(a) For the purpose of this Chapter, the subsequently specified procedures of the BPR and of its delegated and implementing acts as referred to in Section I apply as common procedures to complement provisions deemed equivalent.

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

— "Authorisation holders" and persons referred to in Article 95 of the BPR may be established within the European Union or Switzerland.

— Applicants shall use the Register for Biocidal Products (hereinafter "Register") to submit applications and data for all procedures as foreseen in Article 71(3) of the BPR. Applicants do not need to be established within the European Union or Switzerland.

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

— Chapters II and III and Commission Delegated Regulation (EU) No 1062/2014, as regards the approval of active substances. Applicants may propose the Swiss Competent authority as the evaluating competent authority.

— Article 27 as regards biocidal products authorised according to the simplified procedure.

— Articles 32-34 and Commission Delegated Regulation (EU) No 492/2014 as regards mutual recognition of authorisations and their renewals.

— Articles 35-37 on objections and derogations.

— Articles 43-46 on Union authorisations, with the following adaptations: when the Commission grants a biocidal product a Union authorisation or renews, amends, decides not to grant the Union authorisation, cancels, or refuses to renew the Union authorisation, Switzerland shall, notwithstanding legal recourse, take a decision within 30 days in accordance with Article 14a OPBio on granting, renewing, cancelling or amending an authorisation for that product.

— Articles 47-50 and Commission Implementing Regulation (EU) No 354/2013 as regards the notification of adverse effects and rules on cancellation or amendments.

— Article 53 on parallel trade.

— Article 54 as regards the establishment of technical equivalence of active substances.

— Articles 62-63 on data sharing. In case a request has been submitted to the Swiss competent authority, the applicant shall be re-directed to the Agency and enter its request into the Register.

— Article 69(2) as regards the name and address of the authorisation holder and the authorisation number to be provided on labels.

— Article 88 as regards measures taken on the basis of new evidence.

— Article 95 (as in Regulation (EU) No 334/2014), with the transitional period in Article 95(2) up to 1 September 2016 for making the product available on the market of Switzerland.

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

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

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

1. Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

2. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 64, 11.3.2011, p. 15), as last amended by Commission implementing Regulation (EU) No 562/2012 (OJ L 168, 28.6.2012, p. 21).

3. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1).

New and existing chemicals

4. Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended by Council Directive 92/32/EEC of 30 April 1992 (OJ L 154, 5.6.1992, p. 1).

5. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), as last amended by Commission Regulation (EU) No 895/2014 of 14 August 2014 (OJ L 244, 19.8.2014, p. 6).

6. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), as last amended by Commission Regulation (EU) No 605/2014 of 5 June 2014 (OJ L 167, 6.6.2014, p. 36).

7. Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1), as last amended by Directive 2006/08/EC of 23 January 2006 (OJ L 19, 24.1.2006, p. 12).

8. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

Medicinal products

9. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ L 299, 27.10.2012, p. 1). NB: Directive 2001/83/EC has been amended and the GLP requirement is now contained in the Introduction and General Principles chapter of Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).

10. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Veterinary medicinal products

11. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), as last amended by Commission Directive 2009/9/EC of 10 February 2009 (OJ L 44, 14.2.2009, p. 10).

Plant protection products

12. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

13. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

14. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

Biocidal products

15. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

Cosmetic products

16. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

Detergents

17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1).

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)

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 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:

http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice/index_en.htm'

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:

1. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

2. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28).

Switzerland:

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 22 March 2013 (FF 2012 8671)

101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197)

102. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137)

103. Ordinance of 18 May 2005 on Good Laboratory Practice (RO 2005 2795) as last amended on 11 November 2012 (RO 2012 6103)'

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) as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38).

2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1).

3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

4. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) as last amended by Directive 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 343, 23.11.2013, p. 1).

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

9. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

10. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

11. Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1).

Switzerland

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

([1]) 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).