ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2010 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 18 October 2010

on the amendment of Chapter 12 on Motor vehicles of Annex 1 and on the inclusion in Annex 1 of a new Chapter 18 on Biocidal products

(2011/115/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 framework directive on motor vehicle type approval [1] and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent pursuant to Article 1(2) of the Agreement to the abovementioned European Union legislation.

(2) Chapter 12, Motor vehicles, of Annex 1 should be amended to reflect these developments.

(3) 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 12, Motor vehicles, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Annex 1 on Product Sectors to the Agreement is modified in order to include a new Chapter 18 on Biocidal products 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, 18 October 2010.
On behalf of the Swiss Confederation
Heinz HERTIG

Signed at Brussels, 12 October 2010.
On behalf of the European Union
Fernando PERREAU DE PINNINCK

[1] Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007, p. 1).

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 12, Motor vehicles, the text should be deleted and replaced by the following one:

'CHAPTER 12

MOTOR VEHICLES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1.	Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 (OJ L 200, 31.7.2009, p. 1), and taking into account the acts listed in Annex IV to Directive 2007/46/EC, as amended until 14 October 2009 and amendments to the aforementioned Annex respectively to acts listed therein, accepted according to the procedure described in Section V, paragraph 1 (hereinafter together referred to as "Framework Directive 2007/46/EC")
Switzerland	100.	Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as amended until 14 October 2009 (RO 2009 5705) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1
	101.	Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 14 October 2009 (RO 2009 5805) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1

SECTION II

Conformity assessment bodies

The Committee established pursuant to 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 pursuant to 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 refer to their respective legislative, regulatory and administrative provisions as listed in Section I.

SECTION V

Supplementary provisions

The provisions of this Section shall apply exclusively to relations between Switzerland and the European Union.

1. *Amendments to Annex IV respectively to acts listed in Annex IV to Directive 2007/46/EC*

The legislation adopted in the European Union and listed in Annex IV to Directive 2007/46/EC after 14 October 2009 shall be considered to be part of the provisions covered by Article 1(2) of this Agreement after the accomplishment of the following procedure:

(a) without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of the changes to Annex IV to Directive 2007/46/EC respectively to acts listed therein without delay after their publication in the *Official Journal of the European Union*;

(b) Switzerland shall notify the European Union of the acceptance of the new provisions and of the adoption of the corresponding Swiss legislation before those changes apply in the European Union;

(c) the changes in the legislative provisions shall be deemed to be included in Section I on the date of the notification by Switzerland.

The Joint Committee will take regular note of the abovementioned changes. The introduction of these changes will be made publicly available.

2. *Information exchange*

The competent type-approval authorities in Switzerland and the Member States shall in particular exchange the information referred to in Article 8(5) to (8) of the Framework Directive 2007/46/EC.

In the event of refusal by Switzerland or a Member State to grant type-approval in accordance with Article 8(3) of the Framework Directive 2007/46/EC, it shall immediately send the other Member States, Switzerland and the Commission a detailed file explaining the reasons for its decision and setting out the evidence for its findings.

3. *Recognition of vehicle type-approval*

Switzerland shall also recognise vehicle type-approval granted before the entry into force of this Agreement in accordance with Council Directive 70/156/EEC of 6 February 1970 (OJ L 42, 23.2.1970, p. 1), as last amended by Commission Directive 2007/37/EC of 21 June 2007 (OJ L 161, 22.6.2007, p. 60), by the authorities responsible for type-approval where that approval is still valid in the European Union.

The European Union shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of the Framework Directive 2007/46/EC.

Recognition of Swiss-issued type-approval shall be suspended should Switzerland fail to adapt its legislation to all the European Union type-approval legislation in force.

4. *Safeguard clauses*

1. Vehicles, systems, components or separate technical units in compliance with the applicable legislation

1. If a Member State or Switzerland finds that new vehicles, systems, components or separate technical units, albeit in compliance with the applicable requirements or properly marked, present a serious risk to road safety, or seriously harm the environment or public health, that State may, for a maximum period of 6 months, refuse to register such vehicles or to permit the sale or entry into service in its territory of such vehicles, components or separate technical units.

In such cases, the Member State concerned or Switzerland shall immediately notify the manufacturer, the other Member States, Switzerland and the Commission accordingly, stating the reasons on which its decision is based.

2. The Commission and Switzerland shall consult the Parties concerned as soon as possible and, in particular, their respective approval authorities that granted the type-approval. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with the view to reaching a settlement.

2. Vehicles, systems, components or separate technical units not in conformity with the approved type

1. If a Member State or Switzerland which has granted a type-approval finds that new vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the type it has approved, it shall take the necessary measures, including, where necessary, the withdrawal of type-approval, to ensure that production vehicles, systems, components or separate technical units, as the case may be, are brought into conformity with the approved type. The approval authority of that Member State or Switzerland shall advise the approval authorities of the other Member States and/or Switzerland of the measures taken.

2. For the purposes of paragraph 1, deviations from the particulars in the type-approval certificate or the information package shall be deemed to constitute failure to conform to the approved type.

A vehicle shall not be deemed to deviate from the approved type where tolerances are permitted by the relevant regulatory acts and those tolerances are respected.

3. If a Member State or Switzerland demonstrates that new vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, it may ask the Member State or Switzerland which granted the type-approval to verify that vehicles, systems, components or separate technical units in production continue to conform to the approved type. On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action as soon as possible and in any case within 6 months of the date of the request.

4. The approval authority shall request the Member State or Switzerland which granted the system, component, separate technical unit or incomplete vehicle type-approval to take the necessary action to ensure that vehicles in production are brought back into conformity with the approved type in the following cases:

   (a) in relation to a vehicle type-approval, where the non-conformity of a vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit;

   (b) in relation to a multi-stage type-approval, where the non-conformity of a completed vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit being part of the incomplete vehicle, or of the incomplete vehicle itself.

   On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action, if necessary in conjunction with the Member State making the request or Switzerland, as soon as possible and in any case within 6 months of the date of the request. Where a failure to conform is established, the approval authority of the Member State or Switzerland which granted the system, component or separate technical unit type-approval or the approval of the incomplete vehicle shall take the measures set out in paragraph 1.

5. The approval authorities shall inform each other within 20 working days of any withdrawal of type-approval and of the reasons therefor.

6. If the Member State or Switzerland that granted type-approval disputes the failure to conform notified to it, the Member States concerned and Switzerland shall endeavour to settle the dispute. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with a view to reaching a settlement.'

ATTACHMENT B

In Annex 1, Product Sectors, the following Chapter 18 on Biocidal products shall be introduced:

'CHAPTER 18

BIOCIDAL PRODUCTS

SCOPE AND COVERAGE

The provisions of this Sectoral Chapter apply to biocidal products as defined in Directive 98/8/EC, with the exemption of:

— biocidal products which are or which contain genetically modified or pathogenic micro-organisms, and

— avicides, piscicides and biocides for control of other vertebrates.

Commission Directives to include active substances to the Annex I, IA or IB are part of this Chapter.

Switzerland will be 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.

The Parties shall jointly review the situation in 2013.

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1), as last amended by Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 (OJ L 262, 6.10.2009, p. 40), hereinafter referred to as "Directive 98/8/EC"

2. Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products (OJ L 228, 8.9.2000, p. 6)

3. Commission Regulation (EC) No 1687/2002 of 25 September 2002 on an additional period for notification of certain active substances already on the market for biocidal use as established in Article 4(1) of Regulation (EC) No 1896/2000 (OJ L 258, 26.9.2002, p. 15)

4. Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3)

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 20 March 2008 (RO 2008 3437)

102. Ordinance of 18 May 2005 concerning the placing on the market and the use of biocidal products (Ordinance on Biocidal Products) (RO 2005 2821), as last amended on 2 November 2009 (RO 2009 5401)

SECTION II

Conformity assessment bodies

For the purposes of this Chapter, "Conformity Assessment Bodies" means the competent authorities of the Member States of the European Union and Switzerland for placing biocidal products on the market.

The contact details of the competent authorities of the Member States and of Switzerland can be found on the websites indicated below.

Member States

Biocides: "Competent Authorities and other Contact Points" http://ec.europa.eu/environment/biocides/pdf/ca_contact.pdf

Switzerland

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

SECTION III

Supplementary provisions

For the purpose of paragraphs 2-5 of this Section, any reference to Directive 98/8/EC shall, as far as Switzerland is concerned, be understood to equally refer to the equivalent Swiss provisions.

1. *Inclusion of active substances in Annex I, IA or IB*

Article 11 of Directive 98/8/EC shall apply between the Parties with the following adaptations:

inclusion or subsequent changes to the inclusion, of an active substance in Annex I, IA or IB shall also be considered where an applicant has forwarded the required dossier to the competent authority of Switzerland, and where the receiving competent authority has sent the required evaluation to the Commission.

2. *Mutual recognition of authorisations between Member States and Switzerland*

1. Without prejudice to Article 12 of Directive 98/8/EC, a biocidal product that has already been authorised or registered in one Member State or in Switzerland shall be authorised or registered in another Member State or in Switzerland within 120 days, or 60 days respectively, of an application being received by the other Member State or by Switzerland, provided that the active substance of the biocidal product is included in Annex I or IA to Directive 98/8/EC and conforms to the requirements thereof. For the mutual recognition of authorisations, the application shall include a summary of the dossier as required in Article 8(2)(a) and Annex IIB, Section X of Directive 98/8/EC and a certified copy of the first authorisation granted. For mutual recognition of registration of low-risk biocidal products, the application shall include the data requirements of Article 8(3) of Directive 98/8/EC, except for the efficacy data for which a summary shall suffice.

   The authorisation may be subject to provisions resulting from the implementation of other measures in accordance with the Parties' law, relating to the conditions for distribution and use of biocidal products intended to protect the health of the distributors, users and workers concerned.

   This mutual recognition procedure shall be without prejudice to measures taken by Member States and by Switzerland pursuant to the Parties' law intended to protect the health of workers.

2. If, in accordance with Article 5 of Directive 98/8/EC, a Member State or Switzerland establishes that:

   (a) the target species is not present in harmful quantities;

   (b) unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated; or

   (c) the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the Member State where the biocidal product was first authorised or in Switzerland, and an unchanged authorisation may therefore present unacceptable risks to humans or the environment,

   the Member State or Switzerland may request that certain conditions referred to in Article 20(3)(e), (f), (h), (j) and (l) of Directive 98/8/EC be adjusted to the different circumstances, so that conditions for issue of an authorisation laid down in Article 5 of Directive 98/8/EC are satisfied.

3. Where a Member State or Switzerland believes that a low-risk biocidal product which has been registered by another Member State or by Switzerland does not comply with the definition provided for in Article 2(1)(b) of Directive 98/8/EC, it may provisionally refuse registration thereof and shall immediately communicate its concerns to the competent authority responsible for the verification of the dossier.

   If, within a maximum period of 90 days, an agreement is not reached between the authorities concerned, the matter will be forwarded to the Commission for a decision in accordance with the procedure laid down in paragraph 4.

4. Notwithstanding paragraphs 2 and 3, where a Member State or Switzerland believes a biocidal product authorised by another Member State or Switzerland cannot meet the conditions set out pursuant to Article 5(1) of Directive 98/8/EC and consequently proposes to refuse the authorisation or the registration or to restrict the authorisation under certain conditions, it shall notify the Commission, other Member States, Switzerland and the applicant and shall provide them with an explanatory document containing the name of the product and its specification and setting out the grounds on which it proposes to refuse or to restrict the authorisation.

   The Commission shall prepare a proposal on these matters in accordance with Article 27 of Directive 98/8/EC for a decision in accordance with the procedure laid down in Article 28(2) of Directive 98/8/EC.

5. If the procedure laid down in paragraph 4 leads to the confirmation of a refusal of a second or subsequent registration by a Member State or by Switzerland, the Member State that had previously registered the low-risk biocidal product or Switzerland shall, where deemed appropriate by the Standing Committee, take this refusal into consideration and review its registration according to Article 6 of Directive 98/8/EC.

   If this procedure confirms the initial registration, the Member State or Switzerland having introduced the procedure shall register the low-risk biocidal product concerned.

6. By way of derogation from paragraph 1, Member States or Switzerland may refuse mutual recognition of authorisations granted for product types 15, 17 and 23 of Annex V to Directive 98/8/EC provided that such a limitation can be justified and does not jeopardise the purpose of this Chapter.

   Member States and Switzerland shall inform each other and the Commission of any decision taken in this respect and indicate the reasons therefor.

3. *Market access*

   The applicant shall indicate his name or trade name and address on the label of biocidal products. It will be sufficient, for the purposes of Article 8 of Directive 98/8/EC, if the applicant for an authorisation has a permanent office either within the European Union or Switzerland. 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.

4. *Information exchange*

   In accordance with Article 9 of this Agreement, the Parties shall in particular exchange information referred to in Article 18 of Directive 98/8/EC. Confidential information shall be defined and treated in accordance with Article 19 of Directive 98/8/EC.

5. *Safeguard clause*

   Where a Member State or Switzerland has valid reasons to consider that a biocidal product which it has authorised, registered or is bound to authorise or register pursuant to Article 3 or 4 of Directive 98/8/EC constitutes an unacceptable risk to human or animal health or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. It shall immediately inform the Commission, the other Member States and Switzerland of such action and give reasons for its decisions. A decision shall be taken on the matter within 90 days in accordance with the procedure laid down in Article 28(3). If Switzerland disagrees with the Commission Decision, the case will be forwarded to the Joint Committee, which will decide on an appropriate course of action, including the possibility to call an expert meeting. If a settlement is not reached within 90 days, either party may suspend the Biocidal products Chapter in part or in full.

   Recourse to this safeguard clause should be an exception.

6. *Transitional period*

   Article 16(1) of Directive 98/8/EC shall apply between the Parties, with the transitional period up to 14 May 2014 for Switzerland.'

DECLARATION FROM THE EUROPEAN COMMISSION

In order to ensure the effective application and implementation of the Biocidal products Chapter to be included in Annex 1 to the Agreement and in so far as Switzerland has adopted the relevant *acquis communautaire* 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 28 of Directive 98/8/EC to assist the Commission in the exercise of its executive powers.

In addition, the Commission notes that Swiss experts are invited to participate in the expert group of Competent Authorities for Biocidal Products, which provides assistance to the Commission with the harmonised implementation of Directive 98/8/EC. The Commission also notes that the Chairman of the Committee established pursuant to Article 28 of Directive 98/8/EC 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 cases where discussions on the application of Articles 4 and 11 of Directive 98/8/EC are of direct relevance to Switzerland.

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