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I

(Legislative acts)

DECISIONS

COUNCIL DECISION No 376/2014/EU

of 12 June 2014

authorising Portugal to apply a reduced rate of excise duty in the autonomous region of Madeira on locally produced and consumed rum and liqueurs and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 349 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Parliament,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) Council Decision 2009/831/EC ⁽¹⁾, adopted on the basis of Article 299(2) of the EC Treaty (now Article 349 of the Treaty on the Functioning of the European Union (TFEU)), authorised Portugal to apply a reduced rate of excise duty in the autonomous region of Madeira on locally produced and consumed rum and liqueurs and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie which may be lower than the minimum rate of excise duty set by Council Directive 92/84/EEC ⁽²⁾, but not more than 75 % lower than the standard national excise duty on alcohol.
- (2) On 30 July 2013, the Portuguese authorities asked the Commission to submit a proposal for a Council Decision extending Decision 2009/831/EC, under the same conditions, until 31 December 2020. This request was modified on 19 November 2013, when Portugal requested an extension of Decision 2009/831/EC for six months, until 30 June 2014, to coincide with the current regional aid guidelines that would be followed by a new extension covering the period from 1 July 2014 to 31 December 2020.
- (3) The granting of the new authorisation is justified in order to avoid endangering the development of those outermost regions. Faced with difficulties in exporting outside the regions, the regional markets are the only possible outlets to sell those products.
- (4) In the autonomous regions of the Azores and Madeira, raw materials of agricultural origin are more expensive than under normal conditions of production, due to the small size, fragmented nature and low mechanisation of agricultural holdings. In the case of Madeira, in addition, output from the processing of sugar cane is lower than in other outermost regions, due to the topography, climate, soil and artisanal production. The transport to the islands of certain raw and packaging materials not produced locally leads to additional cost, as compared to the

⁽¹⁾ Council Decision 2009/831/EC of 10 November 2009 authorising Portugal to apply a reduced rate of excise duty in the autonomous region of Madeira on locally produced and consumed rum and liqueurs and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie (OJ L 297, 13.11.2009, p. 9).

⁽²⁾ Council Directive 92/84/EEC of 19 October 1992 on the approximation of the rates of excise duty on alcohol and alcoholic beverages (OJ L 316, 31.10.1992, p. 29).

transport of only the finished product. In the case of the Azores, the insularity is twofold, since the islands are widely spread. Transport and the installation of equipment in those remote and insular regions further increase the additional costs. The same applies to certain necessary travels and shipments to the mainland. Additional costs are also required for the storage of finished products as local consumption does not absorb output as it materialises, but stretches throughout the year. The small size of the regional market increases per unit costs in various ways, notably through the unfavourable relationship between fixed costs and output, both as regards equipment and costs necessary to meet environmental norms. Moreover, rum producers in Madeira have to treat waste from the processing of sugar cane, whereas producers in other regions can recycle those products. Finally, the producers concerned also bear extra costs generally borne by the local economies, in particular increased labour and energy costs.

- (5) The detailed calculations provided in the reports referred to in Article 4 of Decision 2009/831/EC confirm that the reduction of 75 % of the rate of excise duty does not offset completely the competitive disadvantage which distilled alcoholic beverages produced in Madeira and the Azores face as a result of higher production and marketing costs. Therefore, a reduction of the rate of excise duty should continue to be authorised at the level requested.
- (6) A careful examination of the situation confirms that it is necessary to grant Portugal's request in order to ensure that the alcohol industry is maintained in the outermost regions concerned.
- (7) Since the tax advantage does not go beyond what is necessary to offset additional costs, and since the volumes at stake remain modest and the tax advantage limited to consumption in the regions concerned, the measure does not undermine the integrity and coherence of the Union legal order.
- (8) The submission of a mid-term report should be required, so that the Commission can assess whether the conditions justifying the granting of such derogation continue to be fulfilled.
- (9) This Decision is without prejudice to the possible application of Articles 107 and 108 TFEU,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from Article 110 TFEU, Portugal is hereby authorised to apply a rate of excise duty lower than the full rate on alcohol laid down in Article 3 of Directive 92/84/EEC in the autonomous region of Madeira on locally produced and consumed rum and liqueurs, and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie.

Article 2

The derogation referred to in Article 1 shall be confined:

1. in Madeira

- (a) to rum as defined in category 1 of Annex II to Regulation (EC) No 110/2008 of the European Parliament and of the Council ⁽¹⁾, having the geographical indication 'Rum da Madeira' referred to in category 1 of Annex III to that Regulation;
- (b) to liqueurs and 'crème de' as defined in categories 32 and 33 respectively of Annex II to Regulation (EC) No 110/2008 produced from regional fruit or plants;

2. in the Azores

- (a) to liqueurs and 'crème de' as defined in categories 32 and 33 respectively of Annex II to Regulation (EC) No 110/2008 produced from regional fruit or raw materials;
- (b) to eaux-de-vie made from wine or grape marc having the characteristics and qualities defined in categories 4 and 6 of Annex II to Regulation (EC) No 110/2008.

⁽¹⁾ Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

Article 3

The reduced rate of excise duty applicable to the products referred to in Article 1 may be lower than the minimum rate of excise duty on alcohol set by Directive 92/84/EEC, but may not be more than 75 % lower than the standard national excise duty on alcohol.

Article 4

By 30 September 2017 at the latest, Portugal shall send the Commission a report to enable it to assess whether the reasons which justified the granting of the reduced rate still exist.

Article 5

This Decision shall apply from 1 July 2014 to 31 December 2020.

Article 6

This Decision is addressed to the Portuguese Republic.

Done at Luxembourg, 12 June 2014.

For the Council
The President
Y. MANIATIS

COUNCIL DECISION No 377/2014/EU
of 12 June 2014
on the AIEM tax applicable in the Canary Islands

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 349 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) Pursuant to Article 349 of the Treaty on the Functioning of the European Union (TFEU), the Council, taking into account the structural social and economic situation of the outermost regions, which is compounded by their remoteness, insularity, small size, difficult topography and climate, and economic dependence on a few products, adopts specific measures aimed, in particular, at laying down the conditions of application of the Treaties to those regions, including common policies.
- (2) Specific measures should therefore be adopted in order to establish the conditions for applying the TFEU to those regions. Such measures are to take account of the special characteristics and constraints of those regions, without undermining the integrity and coherence of the Union legal order, including the internal market and common policies.
- (3) The most significant handicap identified in the Canary Islands is the high dependence of their economy on the services sector, in particular tourism, together with the small share of industry in the Canary Islands' GDP.
- (4) Second to that is the isolation inherent in an archipelago which hinders the free movement of persons, goods and services. Dependence on certain modes of transport, air transport and maritime transport is increased, since those are modes of transport which have not yet been fully liberalised. Furthermore, production costs are greater because those modes of transport are less efficient and are more expensive than road or rail.
- (5) As a further consequence of this isolation, higher production costs result from dependence in terms of raw materials and energy, from the obligation to build up stocks and from difficulties affecting the supply of production equipment.
- (6) The small size of the market and the low level of export activity, the geographical fragmentation of the archipelago, and the obligation to maintain diversified but small production lines in order to meet the requirements of a small market restrict the opportunities for economies of scale.
- (7) It is in many cases more difficult or more expensive to obtain specialised and maintenance services, and training for managers and technicians, or to subcontract or promote business expansion beyond the Canary Islands' market. The narrow range of distribution methods also results in overstocking.
- (8) As regards the environment, the disposal of industrial waste and the treatment of toxic waste give rise to higher environmental costs. Those costs are higher because there are no recycling plants, other than for certain products, and waste has to be transported to the mainland and toxic waste has to be treated outside the Canary Islands.
- (9) On the basis of the above and of the notification from the Spanish authorities to the Commission on 4 March 2013, the authorisation concerning the application of a tax to a list of products for which exemptions for local products may be allowed should be renewed.

- (10) Council Decision 2002/546/EC ⁽¹⁾, adopted on the basis of Article 299 of the EC Treaty, initially authorised Spain, up to 31 December 2011, to apply exemptions from or reductions in the tax known as 'Arbitrio sobre Importaciones y Entregas de Mercancías en las Islas Canarias' ('AIEM') to certain products produced locally in the Canary Islands. The Annex to that Decision contains a list of products to which tax exemptions and reductions may be applied. The difference between the taxation of locally manufactured products and the taxation of other products may not exceed 5, 15 or 25 percentage points, depending on the product.
- (11) Council Decision No 895/2011/EU ⁽²⁾ amended Decision 2002/546/EC, extending its period of application to 31 December 2013.
- (12) Council Decision No 1413/2013/EU ⁽³⁾ further amended Decision 2002/546/EC, extending its period of application to 30 June 2014.
- (13) The AIEM tax serves the objectives of autonomous development of the Canary Islands' industrial production sectors and of diversifying the Canary Islands' economy.
- (14) The maximum exemptions which may be applied to the industrial products in question vary from 5 % to 15 %, depending on sector and product.
- (15) The maximum exemption applicable to finished tobacco products is nevertheless higher, as the tobacco sector is an exceptional case. The tobacco industry, which had greatly expanded in the Canary Islands, has been declining markedly for a number of years. The traditional handicaps of insularity described above are at the root of the decline in local tobacco production in the Canary Islands. There are grounds for keeping a substantial exemption for tobacco. Exemption from taxation is directly related to the objective of maintaining production in the Canary Islands.
- (16) The objectives of promoting the socioeconomic development of the Canary Islands are reflected at national level in the purpose of the tax and the allocation of the revenue it generates. The incorporation of the revenue from this tax in the resources of the Canary Islands' economic and tax system and its use for an economic and social development strategy involving the promotion of local activities is a legal obligation.
- (17) The exemptions from or reductions in the AIEM tax should apply for 6,5 years. It will, nevertheless, be necessary to evaluate the results of such exemptions or reductions. Therefore, the Spanish authorities should present to the Commission by 30 September 2017 at the latest a report on the application of the AIEM tax exemptions or reductions, in order to check the impact of the measures taken and their contribution to promoting or maintaining local economic activities, account being taken of the handicaps affecting the outermost regions. On this basis, the scope and the exemptions authorised under Union rules will be revised, if necessary.
- (18) The fiscal advantage granted by the AIEM needs to remain proportionate so as not to undermine the integrity and the coherence of the Union legal order, including safeguarding undistorted competition in the internal market and State aid policies.
- (19) This Decision is without prejudice to the possible application of Articles 107 and 108 TFEU,

HAS ADOPTED THIS DECISION:

Article 1

1. By way of derogation from Articles 28, 30 and 110 TFEU, the Spanish authorities shall be authorised until 31 December 2020 to lay down, in respect of the products listed in the Annex that are produced locally in the Canary Islands, total exemptions from or partial reductions in the tax known as 'Arbitrio sobre las Importaciones y Entregas de Mercancías en las Islas Canarias' (AIEM). Those exemptions or reductions must form part of the strategy for economic and social development of the Canary Islands and must contribute to the promotion of local activities.

⁽¹⁾ Council Decision 2002/546/EC of 20 June 2002 on the AIEM tax applicable in the Canary Islands (OJ L 179, 9.7.2002, p. 22).

⁽²⁾ Council Decision No 895/2011/EU of 19 December 2011 amending Decision 2002/546/EC as regards its period of application (OJ L 345, 29.12.2011, p. 17).

⁽³⁾ Council Decision No 1413/2013/EU of 17 December 2013 amending Decision 2002/546/EC as regards its period of application (OJ L 353, 28.12.2013, p. 13).

2. Application of the total exemptions or reductions referred to in paragraph 1 shall not lead to differences in excess of:
- (a) 5 % for the products listed in Section A of the Annex;
 - (b) 10 % for the products listed in Section B of the Annex;
 - (c) 15 % for the products listed in Section C of the Annex;
 - (d) 25 % for the products listed in Section D of the Annex. Nevertheless, the Spanish authorities may establish a minimum tax on cigarettes of not more than EUR 18 per 1 000 cigarettes, applicable only if the AIEM tax resulting from the application of general types of taxation is below this figure.

Article 2

The Spanish authorities shall present to the Commission by 30 September 2017 at the latest a report on the application of the measures referred to in Article 1, in order to check the impact of the measures taken and their contribution to the promotion or maintenance of local economic activities, account being taken of handicaps affecting the outermost regions.

On that basis, the Commission shall present a report to the Council comprising a full analysis of the economic and social aspects and, where appropriate, a proposal for adapting the provisions of this Decision.

Article 3

This Decision shall be applicable from 1 July 2014.

Article 4

This Decision is addressed to the Kingdom of Spain.

Done at Luxembourg, 12 June 2014.

For the Council
The President
Y. MANIATIS

ANNEX

A. List of products referred to in point (a) of Article 1(2) according to the classification of the Common Customs Tariff nomenclature

Agricultural and fishery products:

0207 11/0207 13

Minerals:

2516 90 00 00/6801/6802

Building materials:

3816/3824 40 00 00/3824 50/3824 90 45 00/3824 90 70 00/3824 90 97 99/6809

Chemicals:

2804 30 00 00/2804 40 00 00/3105 20 90 00/3208/3209/3210/3212 90 00 00/3213/3214/3304 99 00 00/
3925 90 80 00/3401/3402/3406/3814 00 90/3923 90 00 00/4012 11 00/4012 12 00/4012 13/4012 19

Metal-working industries:

7604/7608

Food industry:

0210 12 11 00/0210 12 19 00/0210 19 40 00/0210 19 81/0305 41 00/0305 43 00 90/

0901 22 00 00/1101/1102/1601/1602/1704 90 30 00/1704 90 51 00/1704 90 55 00/

1704 90 75 00/1704 90 71 00/1806/1901 20 00 00/1901 90 91 00/1901 90 99/

1904 10 10/1905/2005 20 20/2006 00 31 00/2008 11 96 00/2008 11 98 00/2008 19 92/

2008 19 93/2008 19 95/2008 19 99/2309

Beverages:

2009 11/2009 12 00/2009 19/2009 41/2009 49/2009 50/2009 61/2009 71/2009 79/2009 89/2009 90/2201/
2202/2204

Textiles and leather:

6112 31/6112 41

Paper:

4818 90 90 00/4823 90 85 90

Graphic arts and publishing:

4910

B. List of products referred to in point (b) of Article 1(2) according to the classification of the Common Customs Tariff nomenclature

Agricultural and fishery products:

0203 11/0203 12/0203 19/0701 90/0703

Building materials:

2523 29 00 00/

Food industry:

0210 11 11 00/0210 11 31 00/1905/2105

Paper:

4808/4819/4823 90 40 00

C. **List of products referred to in point (c) of Article 1(2) according to the classification of the Common Customs Tariff nomenclature**

Agricultural and fishery products:

0407 21 00 00/0407 29 10 00/0407 90 10 00

Building materials:

2523 90/7010

Chemicals:

3809 91 00/3917 21/3917 23/3917 32 00/3917 33 00/3917 39 00/3917 40 00/3923 10 00/3923 21 00/
3923 30 10/3924 10 00

Metal-working industries:

7309 00/7610 10 00 00/9403 20 80 90

Food industry:

0403/0901 21/1902/2103 20 00 00/2103 30/2103 90 90/2106 90 98/

Beverages:

2203/2208 40

Textiles and leather:

6302

Paper:

4818 10/4818 20/4818 30/4821

Graphic arts and publishing:

4909/4911

D. **List of products referred to in point (d) of Article 1(2) according to the classification of the Common Customs Tariff nomenclature**

Tobacco:

2402

COUNCIL DECISION No 378/2014/EU**of 12 June 2014****amending Decision 2004/162/EC concerning the dock dues in the French overseas departments, as regards its period of application**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 349 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Parliament,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) Council Decision 2004/162/EC ⁽¹⁾ authorises France to apply exemptions or reductions to dock dues for products produced locally in the French overseas departments and listed in the Annex to that Decision. The difference between the taxation of locally manufactured products and that of other products may not exceed 10, 20 or 30 percentage points, depending on the product. Those exemptions or reductions constitute specific measures designed to offset the specific constraints facing the outermost regions provided for in Article 349 of the Treaty on the Functioning of the European Union (TFEU) which increase production costs for local companies and make it difficult for their products to compete with the same products imported from metropolitan France and other Member States or non-Member States. The exemptions from or reductions in the dues applicable to local products support the creation, maintenance and development of local production. Pursuant to Decision 2004/162/EC, the French authorities are authorised until 1 July 2014 to apply those exemptions and reductions.
- (2) France is of the view that the handicaps suffered by the French outermost regions persist, and has submitted a request to the Commission that a system of differentiated taxation similar to the current system be maintained after 1 July 2014, until 31 December 2020.
- (3) Analysing the lists of the products to which France has requested the application of differentiated taxation is a lengthy process requiring verification, for each product, of the reasons for differential taxation and its proportionality, so as to ensure that such differentiated taxation does not undermine the integrity and the coherence of the Union legal order, including the internal market and common policies.
- (4) Such analysis has not yet been completed, due to the large number of products involved and the quantity of information to be collected, in particular the quantification of the higher production costs that handicap local products and the structure of the product markets concerned.
- (5) Failure to adopt a proposal before 1 July 2014 could create a legal vacuum, as the application of any differentiated taxation in the French outermost regions after 1 July 2014 would not be possible.
- (6) An additional period of six months is required to complete the analysis of the products to which France requests the application of differentiated taxation, and to give the Commission time to present a balanced proposal that takes account of the various interests at stake.
- (7) Decision 2004/162/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1(1) of Decision 2004/162/EC, the date '1 July 2014' is replaced by the date '31 December 2014'.

⁽¹⁾ Council Decision 2004/162/EC of 10 February 2004 concerning the dock dues in the French overseas departments and extending the period of validity of Decision 89/688/EEC (OJ L 52, 21.2.2004, p. 64).

Article 2

This Decision shall apply from 1 July 2014.

Article 3

This Decision is addressed to the French Republic.

Done at Luxembourg, 12 June 2014.

For the Council
The President
Y. MANIATIS

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 681/2014**of 20 June 2014****amending Regulation (EU) No 37/2010, as regards the substance ‘rafoxanide’****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit (hereinafter ‘MRL’) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾.
- (3) Rafoxanide is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine and ovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.
- (4) A request for an opinion on the extrapolation of the existing entry for rafoxanide applicable to bovine milk has been submitted to the European Medicines Agency.
- (5) The Committee for Medicinal Products for Veterinary Use has recommended the establishment of a provisional MRL for rafoxanide for bovine and ovine milk and the removal of the prohibition to use that substance in animals from which milk is produced for human consumption.
- (6) The entry for rafoxanide in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the recommended provisional MRL for bovine and ovine milk and to remove the prohibition to use that substance from animals from which milk is produced for human consumption.
- (7) The provisional MRL for rafoxanide set out in that Table should expire on 31 December 2015.

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

- (8) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 19 August 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'rafoxanide' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Rafoxanide	Rafoxanide	Bovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antiparasitic agents/ Agents against endoparasites'
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney		
		Bovine, ovine	10 µg/kg	Milk	Provisional MRL shall expire on 31 December 2015	

COMMISSION IMPLEMENTING REGULATION (EU) No 682/2014
of 20 June 2014
amending Regulation (EU) No 37/2010, as regards the substance ‘closantel’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit (hereinafter ‘MRL’) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾.
- (3) Closantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine and ovine species, applicable to muscle, fat, liver, kidney and milk. The provisional maximum residue limits for that substance set out for bovine and ovine milk expired on 1 January 2014.
- (4) Additional data were provided and assessed by the Committee for Medicinal Products for Veterinary Use who recommended that the provisional MRLs for closantel for bovine and ovine milk should be set as definitive.
- (5) The entry for closantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'closantel' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Closantel'	Closantel	Bovine	1 000 µg/kg 3 000 µg/kg 1 000 µg/kg 3 000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/ Agents against endo- parasites'
		Ovine	1 500 µg/kg 2 000 µg/kg 1 500 µg/kg 5 000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk		

COMMISSION IMPLEMENTING REGULATION (EU) No 683/2014
of 20 June 2014
amending Regulation (EU) No 37/2010, as regards the substance ‘clorsulon’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit (hereinafter ‘MRL’) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾.
- (3) Clorsulon is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine species, applicable to muscle, liver, kidney and milk. The provisional maximum residue limits for that substance set out for bovine milk expired on 1 January 2014.
- (4) Additional data were provided and assessed by the Committee for Medicinal Products for Veterinary Use who recommended that the provisional MRLs for clorsulon for bovine milk should be set as definitive.
- (5) The entry for clorsulon in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'clorsulon' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Clorsulon	Clorsulon	Bovine	35 µg/kg 100 µg/kg 200 µg/kg 16 µg/kg	Muscle Liver Kidney Milk	NO ENTRY	Antiparasitic agents/ Agents against endo- parasites'

COMMISSION IMPLEMENTING REGULATION (EU) No 684/2014**of 20 June 2014****concerning the authorisation of canthaxanthin as a feed additive for breeder hens (holder of the authorisation DSM Nutritional products Ltd)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a canthaxanthin. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of canthaxanthin as a feed additive for breeder hens to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 December 2012 ⁽²⁾ that, under the proposed conditions of use, the preparation of canthaxanthin does not have an adverse effect on animal health, human health or the environment, and that it has a potential to stabilise the reproductive performance of breeder hens. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of canthaxanthin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1***Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(1):3047.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum residues limits in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Category of zootechnical additives. Functional group: other zootechnical additives (stabilisation of reproductive performance)										
4d161g	DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.	Canthaxanthin	<i>Additive composition</i> Preparation containing minimum: 10 % of canthaxanthin; ≤ 2,2 % ethoxyquin; dichloromethane: ≤ 10 mg/kg additive. <i>Characterisation of the active substance</i> canthaxanthin C ₄₀ H ₅₂ O ₂ CAS No: 514-78-3 Assay: Minimum 96 % Produced by chemical synthesis <i>Analytical method</i> ⁽¹⁾ — For the determination of canthaxanthin in the feed additive: spectrophotometry (426 nm) — For the determination of canthaxanthin in premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to VIS detection (NP-HPLC-VIS, 466 nm)	Breeder hens	—	6	6	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heat processing. 2. The mixture of different sources of canthaxanthin shall not exceeded 6 mg canthaxanthin/kg of complete feedingstuff. 3. The mixture of this preparation with canthaxanthin and other carotenoids is allowed provided that the total concentration of the mixture does not exceed 80 mg/kg of complete feedingstuff. 4. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	10 July 2024	15 mg canthaxanthin/kg liver (wet tissue) and 2,5 mg canthaxanthin/kg skin/fat (wet tissue)

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives

COMMISSION REGULATION (EU) No 685/2014**of 20 June 2014****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) On 13 September 2011, an application was submitted for authorisation of the use of polyvinyl alcohol-polyethylene glycol-graft-co-polymer (PVA-PEG *graft* co-polymer) in aqueous instant-release film coatings for food supplements. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The European Food Safety Authority evaluated the safety of PVA-PEG *graft* co-polymer when used as a food additive and concluded that its use in food supplements as film coating is of no safety concern for the proposed uses ⁽⁴⁾.
- (6) PVA-PEG *graft* co-polymer is intended for use in aqueous instant-release film coatings for food supplements. It protects against unpleasant tastes or odours, improves appearance, makes tablets easier to swallow, gives a distinctive appearance, and protects sensitive active ingredients. A specific property of the substance is that it is extremely flexible, has low viscosity, and dissolves rapidly in acidic, neutral, and alkaline aqueous media. It is therefore appropriate to authorise the use of PVA-PEG *graft* co-polymer as a glazing agent in solid food supplements and to assign E 1209 as E-number to that additive.
- (7) The specifications for PVA-PEG *graft* co-polymer should be included in Regulation (EU) No 231/2012 when it is included in the Union lists of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (8) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA Journal 2013; 11(8):3303.

- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) in Part B, point 3 'Additives other than colours and sweeteners', the following new entry is inserted after the entry for food additive E 1208 Polyvinylpyrrolidone-vinyl acetate copolymer:

E 1209	Polyvinyl alcohol-polyethylene glycol- <i>graft</i> -co-polymer'
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- (2) in Part E, in food category 17.1 'Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms', the following new entry is inserted after the entry for food additive E 1208:

	E 1209	Polyvinyl alcohol-polyethylene glycol- <i>graft</i> -co-polymer	100 000'		
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for E 1208 (Polyvinyl-pyrrolidone-vinyl acetate copolymer):

‘E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-GRAFT-COPOLYMER

Synonyms	Macrogol poly(vinyl alcohol) grafted co-polymer; poly(ethan-1,2-diol-graft-ethanol); ethenol, polymer with oxirane, graft; oxirane, polymer with ethanol, graft; ethylene oxide-vinyl alcohol graft co-polymer
Definition	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer is a synthetic co-polymer that consists of approximately 75 % PVA units and 25 % PEG units.
CAS number	96734-39-3
Chemical name	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer
Chemical formula	
Weight Average Molecular Weight	40 000 to 50 000 g/mol
Description	White to faintly yellow powder
Identification	
Solubility	Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides; practically insoluble in ethanol, acetic acid, acetone, and chloroform
IR Spectrum	Must comply
pH value	5,0-8,0
Purity	
Ester Value	10 to 75 mg/g KOH
Dynamic viscosity	50 to 250 mPa·s
Loss on drying	Not more than 5 %
Sulphated Ash	Not more than 2 %
Vinyl Acetate	Not more than 20 mg/kg
Acetic acid/Total Acetate	Not more than 1,5 %
Ethylene glycol	Not more than 50 mg/kg
Diethylene glycol	Not more than 50 mg/kg
1,4-Dioxane	Not more than 10 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg'

COMMISSION REGULATION (EU) No 686/2014**of 20 June 2014****amending Regulations (EC) No 983/2009 and (EU) No 384/2010 as regards the conditions of use of certain health claims related to the lowering effect of plant sterols and plant stanols on blood LDL-cholesterol****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 17(3) thereof,

Whereas:

- (1) Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims are to be sent to the national competent authority of the respective Member State. The national competent authority is to forward those applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'. The Authority is to give an opinion on the health claim and to forward it to the Commission who is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority.
- (2) Pursuant to Article 16(4) of Regulation (EC) No 1924/2006, an opinion of the Authority in favour of authorising a health claim may include specific conditions of use of the claim.
- (3) The authorisation of health claims may be amended following a request by the applicant or user according to Article 19(1) of Regulation (EC) No 1924/2006 or following an opinion of the Authority issued on its own initiative or following a request from a Member State or from the Commission according to Article 19(2) of Regulation (EC) No 1924/2006.
- (4) Following the opinion of the Authority, based on a request of the Commission and a similar request from France, regarding the possibility to indicate a quantitative effect in health claims related to the lowering effects of plant sterols/plant stanol esters on blood LDL-cholesterol (Question No EFSA-Q-2009-00530 and Q-2009-00718) ⁽²⁾, the Commission amended, by Regulation (EU) No 376/2010 ⁽³⁾, the conditions of use of two health claims related to the lowering effects of plant sterols and plant stanol esters on blood cholesterol, as laid down in Commission Regulation (EC) No 983/2009 ⁽⁴⁾, by indicating a quantitative effect. Moreover, based on the same opinion of the Authority, the Commission authorised, by Regulation (EU) No 384/2010 ⁽⁵⁾, a health claim related to the lowering effects of plant sterols/plant stanol esters on blood LDL-cholesterol, establishing conditions of use related to the indication of a quantitative effect.
- (5) Following an application from Raisio Nutrition Ltd, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the lowering effects of plant stanols as plant stanol esters on blood LDL-cholesterol concentrations (Question No EFSA-Q-2011-00851) ⁽⁶⁾. The claim proposed by the applicant was worded as follows: 'The daily consumption of 3 g plant stanols in ester form has been shown to reduce blood cholesterol by 12 %. High cholesterol is a risk factor in the

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2009; 1175, 1-9.⁽³⁾ Commission Regulation (EU) No 376/2010 of 3 May 2010 amending Regulation (EC) No 983/2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ L 111, 4.5.2010, p. 3).⁽⁴⁾ Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ L 277, 22.10.2009, p. 3).⁽⁵⁾ Commission Regulation (EU) No 384/2010 of 5 May 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health (OJ L 113, 6.5.2010, p. 6).⁽⁶⁾ EFSA Journal 2012; 10(5):2692.

development of coronary heart disease'. The applicant further requested that the minimum duration to obtain the effect be stated to be one to two weeks, and that an authorisation be given for claims for an extended range of foods, including yellow fat spreads, dairy products, cheese, rye bread, oatmeal, fermented soy milk based products (drinkable and spoonable yoghurt-type products), and oat-based milk drinks.

- (6) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 16 May 2012, that plant stanol esters at a daily intake of 3 g (range 2,7-3,3 g) lower blood LDL-cholesterol by 11,4 % (95 % Confidence Interval (CI): 9,8-13,0), and that the minimum duration required to achieve the maximum effect of plant stanols on blood LDL-cholesterol lowering is two to three weeks. Moreover, the Authority concluded that while plant stanol esters added to foods such as margarine-type spreads, mayonnaise, salad dressings and to dairy products such as milk, yoghurts including low-fat yoghurts, and cheese have been shown consistently to lower blood LDL-cholesterol levels, the extent of the cholesterol-lowering effect of plant stanols added to other food formats is less well established.
- (7) Unilever PLC and Unilever NV submitted an application pursuant to Article 19 of Regulation (EC) No 1924/2006, for the modification of the conditions of use of the health claims related to the lowering effects of plant sterols and plant stanols on blood LDL-cholesterol (Question No EFSA-Q-2011-01241) ⁽¹⁾. The modification concerns the magnitude of the lowering effect on blood LDL-cholesterol (7-12 %) for a daily intake of plant sterols and plant stanols between 1,5 and 3 g. The applicant further requested that the minimum duration to obtain the effect be stated to be one to two weeks.
- (8) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 16 May 2012, that plant sterols and plant stanol esters at a daily intake of 3 g (range 2,6-3,4 g) lower blood LDL-cholesterol by 11,3 % (95 % Confidence Interval (CI): 10,0-12,5), and that the minimum duration required to achieve the maximum effect of plant sterols and plant stanols on LDL-cholesterol is two to three weeks. The Authority also noted in its assessment that plant sterols and plant stanols at daily intakes ranging from 1,5 to 3 g have a similar efficacy on lowering blood LDL-cholesterol.
- (9) The conditions of use of the authorised health claims on plant sterols, plant stanol esters and plant sterols/plant stanol esters, as laid down in Regulations (EC) No 983/2009 and (EU) No 384/2010, provide that reference to the magnitude of the cholesterol-lowering effect of those substances may be made for foods falling within certain categories. According to those conditions, when reference is made to the magnitude of the cholesterol-lowering effect, consumers are to be informed that plant sterols and/or plant stanol esters at daily intakes ranging from 1,5 to 2,4 g lower blood LDL-cholesterol by 7 % to 10 % within two to three weeks. Since new evidence has shown that an additional effect is achieved with higher intakes of those substances of up to 3 g per day, it is necessary to amend those conditions of use as regards the consumer information on the magnitude of the effect and the required daily intake, taking into account the scientific opinions of the Authority.
- (10) In order to ensure that the claims authorised by Regulations (EC) No 983/2009 and (EU) No 384/2010 do not confuse or mislead the consumer, the conditions of use concerning consumer information on the magnitude of the cholesterol-lowering effect should be set in a coherent way. Since plant sterols and plant stanols at daily intakes ranging from 1,5 to 3 g have a similar efficacy, it is appropriate to indicate the same magnitude of the effect for plant sterols, plant stanol esters and plant sterols/plant stanol esters. Commission Regulation (EC) No 608/2004 ⁽²⁾ provides that the consumption of more than 3 g of plant sterols and plant stanols should be avoided. It is therefore appropriate to only provide ranges of intakes up to 3 g in the conditions of use.
- (11) Regulations (EC) No 983/2009 and (EU) No 384/2010 should therefore be amended accordingly.
- (12) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ EFSA Journal 2012; 10(5):2693.

⁽²⁾ Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters (OJ L 97, 1.4.2004, p. 44).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 983/2009

Annex I to Regulation (EC) No 983/2009 is amended as follows:

- (1) the first entry (concerning the health claim: 'Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease'), is amended as follows:

- (a) the text in the fifth column (conditions of use of the claim) is replaced by the following:

'Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.';

- (b) the text in the seventh column (EFSA opinion reference) is replaced by the following:

'Q-2008-085

Q-2009-00530 and Q-2009-00718

Q-2011-01241';

- (2) the second entry (concerning the health claim: 'Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease') is amended as follows:

- (a) the text in the fifth column (conditions of use of the claim), is replaced by the following:

'Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant stanols or the range "10 %-12,5 %" for foods that provide a daily intake of 2,5-3 g plant stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.';

- (b) the text in the seventh column (EFSA opinion reference) is replaced by the following:

'Q-2008-118

Q-2009-00530 and Q-2009-00718

Q-2011-00851

Q-2011-01241.'

Article 2

Amendments to Regulation (EU) No 384/2010

The first entry of Annex I to Regulation (EU) No 384/2010 (concerning the health claim: 'Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease') is amended as follows:

- (a) the text in the fifth column (conditions of use of the claim) is replaced by the following:

'Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols/stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols/stanols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols/stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.';

(b) the text in the seventh column (EFSA opinion reference) is replaced by the following:

‘Q-2008-779

Q-2009-00530 and Q-2009-00718

Q-2011-01241.’

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 687/2014**of 20 June 2014****amending Regulation (EU) No 185/2010 as regards clarification, harmonisation and simplification of aviation security measures, equivalence of security standards and cargo and mail security measures****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 ⁽¹⁾, and in particular Article 4(3) thereof,

Whereas:

- (1) Experience with the implementation of Commission Regulation (EU) No 185/2010 ⁽²⁾ has shown the need for amendments to the implementing modalities of certain common basic standards.
- (2) Certain specific aviation security measures should be clarified, harmonised or simplified in order to improve legal clarity, so as to avoid diverging interpretations of the legislation and further ensure the best implementation of the common basic standards on aviation security.
- (3) The amendments concern the implementation of a limited number of measures in relation to prohibited articles, aircraft security, security controls for cargo, mail, in-flight and airport supplies and security equipment.
- (4) In accordance with Commission Regulation (EC) No 272/2009 ⁽³⁾, the Commission should recognise the equivalence of aviation security standards of third countries and other countries and territories to which Title VI of the TFEU does not apply under the condition that the criteria set out in that Regulation are met.
- (5) The Commission has verified that airports located in Guernsey, Isle of Man and Jersey fulfil the criteria set out in Part E of the Annex to Regulation (EC) No 272/2009.
- (6) Regulation (EU) No 185/2010 lists in its Annex the third countries and other countries and territories to which Title VI of the TFEU does not apply recognised as applying security standards equivalent to the common basic standards that Regulation (EC) No 272/2009 establishes.
- (7) Commission Regulation (EEC) No 2454/93 ⁽⁴⁾ and Regulation (EU) No 185/2010 both lay down similar security requirements for entities operating in the cargo and mail supply chain.
- (8) The security requirements for the aviation security regulated agent and known consignor programme defined in Regulation (EU) No 185/2010 and for the customs Authorized Economic Operator programme defined in Regulation (EEC) No 2454/93 should be further aligned in order to allow for mutual recognition to facilitate the concerned industry and government authorities while at the same time maintaining current security levels.
- (9) Regulation (EU) No 185/2010 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Civil Aviation Security,

⁽¹⁾ OJ L 97, 9.4.2008, p. 72.

⁽²⁾ Commission Regulation (EU) No 185/2010 of 4 March 2010 laying down detailed measures for the implementation of the common basic standards on aviation security (OJ L 55, 5.3.2010, p. 1).

⁽³⁾ Commission Regulation (EC) No 272/2009 of 2 April 2009 supplementing the common basic standards on civil aviation security laid down in the Annex to Regulation (EC) No 300/2008 of the European Parliament and of the Council (OJ L 91, 3.4.2009, p. 7).

⁽⁴⁾ Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 185/2010 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Point 5(o) of the Annex shall apply as of 1 July 2014.

Points 10(b) and 11(b) of the Annex shall apply from 1 March 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

The Annex to Regulation (EU) No 185/2010 is amended as follows:

(1) Chapter 1 is amended as follows:

(a) the following point 1.0.5 is added:

‘1.0.5. References to third countries in this chapter and where applicable in a separate Commission Decision include other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply.’;

(b) point 1.3.1.7 is deleted;

(c) the following point 1.6 is added:

‘1.6. PROHIBITED ARTICLES

1.6.1. Persons other than passengers shall not be permitted to carry into security restricted areas the articles listed in Attachment 1-A.

1.6.2. An exemption to point 1.6.1 may be granted on condition that the person is authorised to carry prohibited articles into security restricted areas in order to undertake tasks that are essential for the operation of airport facilities or of aircraft, or for performing in-flight duties.

1.6.3. In order to allow reconciliation of the person authorised to carry one or more articles as listed in Attachment 1-A with the article carried:

(a) the person shall have an authorisation and shall carry it. The authorisation shall either be indicated on the identification card that grants access to security restricted areas or on a separate declaration in writing. The authorisation shall indicate the article(s) that may be carried, either as a category or as a specific article. If the authorisation is indicated on the identification card, then it shall be recognisable on a need-to-know basis; or

(b) a system shall be in place at the security checkpoint indicating which persons are authorised to carry which article(s), either as a category or as a specific article.

Reconciliation shall be performed before the person is allowed to carry the article(s) concerned into security restricted areas or on board an aircraft, or upon being challenged by persons performing surveillance or patrols under point 1.5.1 (c).

1.6.4. Articles as listed in Attachment 1-A may be stored in security restricted areas provided they are kept in secure conditions. Articles as listed in points (c), (d) and (e) of Attachment 4-C may be stored in security restricted areas provided they are not accessible to passengers.’;

(d) the following Attachment 1-A is added:

‘ATTACHMENT 1-A

PERSONS OTHER THAN PASSENGERS

LIST OF PROHIBITED ARTICLES

(a) *guns, firearms and other devices that discharge projectiles* — devices capable, or appearing capable, of being used to cause serious injury by discharging a projectile, including:

- firearms of all types, such as pistols, revolvers, rifles, shotguns,
- toy guns, replicas and imitation firearms capable of being mistaken for real weapons,
- component parts of firearms, excluding telescopic sights,
- compressed air and CO₂ guns, such as pistols, pellet guns, rifles and ball bearing guns,

- signal flare pistols and starter pistols,
 - bows, cross bows and arrows,
 - harpoon guns and spear guns,
 - slingshots and catapults;
- (b) *stunning devices* — devices designed specifically to stun or immobilise, including:
- devices for shocking, such as stun guns, tasers and stun batons,
 - animal stunners and animal killers,
 - disabling and incapacitating chemicals, gases and sprays, such as mace, pepper sprays, capsicum sprays, tear gas, acid sprays and animal repellent sprays;
- (c) *explosives and incendiary substances and devices* — explosives and incendiary substances and devices capable, or appearing capable, of being used to cause serious injury or to pose a threat to the safety of aircraft, including:
- ammunition,
 - blasting caps,
 - detonators and fuses,
 - replica or imitation explosive devices,
 - mines, grenades and other explosive military stores,
 - fireworks and other pyrotechnics,
 - smoke-generating canisters and smoke-generating cartridges,
 - dynamite, gunpowder and plastic explosives;
- (d) any other article capable of being used to cause serious injury and which is not commonly used in security restricted areas, e.g. martial arts equipment, swords, sabres, etc.;
- (2) Chapter 3 is amended as follows:
- (a) the following point 3.0.6 is added:
- ‘3.0.6. References to third countries in this chapter and where applicable in a separate Commission Decision include other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply.’;
- (b) point 3.2.1.1 is replaced by the following:
- ‘3.2.1.1. Regardless of where an aircraft is parked at an airport, each of its external doors shall be protected against unauthorised access by:
- (a) ensuring that persons seeking to gain unauthorised access are challenged promptly; or
 - (b) having the external door closed. Where the aircraft is in a critical part, external doors that are not accessible by a person from the ground shall be considered closed if access aids have been removed and placed sufficiently far from the aircraft as to reasonably prevent access by a person; or
 - (c) having electronic means which will immediately detect unauthorised access; or;
 - (d) having an electronic airport identification card access system at all doors leading directly to the passenger boarding bridge, adjacent to an open aircraft door, which only allows access for persons that are trained in accordance with point 11.2.3.7. Such persons must ensure that unauthorised access is prevented, during their use of the door.’;

- (c) Attachment 3-B is replaced by the following:

‘ATTACHMENT 3-B

AIRCRAFT SECURITY

THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, RECOGNISED AS APPLYING SECURITY STANDARDS EQUIVALENT TO THE COMMON BASIC STANDARDS.

As regards aircraft security, the following third countries, as well as other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union Title VI of that Treaty does not apply, have been recognised as applying security standards equivalent to the common basic standards:

United States of America

Faroe Islands, in regard to Vagar airport

Greenland, in regard to Kangerlussuaq airport

Guernsey

Jersey

Isle of Man

The Commission shall notify without delay the appropriate authorities of the Member States if it has information indicating that security standards applied by the third country or other country or territory concerned with a significant impact on overall levels of aviation security in the Union are no longer equivalent to the common basic standards of the Union.

The appropriate authorities of the Member States shall be notified without delay when the Commission has information about actions, including compensatory measures, confirming that the equivalency of relevant security standards applied by the third country or other country or territory concerned is re-established.’;

- (3) Chapter 4 is amended as follows:

- (a) the following point 4.0.5 is added:

‘4.0.5. References to third countries in this chapter and where applicable in a separate Commission Decision include other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply.’;

- (b) Attachment 4-B is replaced by the following:

‘ATTACHMENT 4-B

PASSENGERS AND CABIN BAGGAGE

THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, RECOGNISED AS APPLYING SECURITY STANDARDS EQUIVALENT TO THE COMMON BASIC STANDARDS.

As regards passengers and cabin baggage, the following third countries, as well as other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union Title VI of that Treaty does not apply, have been recognised as applying security standards equivalent to the common basic standards.

United States of America

Faroe Islands, in regard to Vagar airport

Greenland, in regard to Kangerlussuaq airport

Guernsey

Jersey**Isle of Man**

The Commission shall notify without delay the appropriate authorities of the Member States if it has information indicating that security standards applied by the third country or other country or territory concerned with a significant impact on overall levels of aviation security in the Union are no longer equivalent to the common basic standards of the Union.

The appropriate authorities of the Member States shall be notified without delay when the Commission has information about actions, including compensatory measures, confirming that the equivalency of relevant security standards applied by the third country or other country or territory concerned is re-established.;

(4) Chapter 5 is amended as follows:

(a) the following point 5.0.5 is added:

‘5.0.5. References to third countries in this chapter and where applicable in a separate Commission Decision include other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply.’;

(b) Attachment 5-A is replaced by the following:

‘ATTACHMENT 5-A**HOLD BAGGAGE**

THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, RECOGNISED AS APPLYING SECURITY STANDARDS EQUIVALENT TO THE COMMON BASIC STANDARDS.

As regards hold baggage, the following third countries, as well as other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply, have been recognised as applying security standards equivalent to the common basic standards.

United States of America**Faroe Islands, in regard to Vagar airport****Greenland, in regard to Kangerlussuaq airport****Guernsey****Jersey****Isle of Man**

The Commission shall notify without delay the appropriate authorities of the Member States if it has information indicating that security standards applied by the third country or other country or territory concerned with a significant impact on overall levels of aviation security in the Union are no longer equivalent to the common basic standards of the Union.

The appropriate authorities of the Member States shall be notified without delay when the Commission has information about actions, including compensatory measures, confirming that the equivalency of relevant security standards applied by the third country or other country or territory concerned is re-established.;

(5) Chapter 6 is amended as follows:

(a) the following point 6.0.3 is added:

‘6.0.3. References to third countries in this chapter and where applicable in a separate Commission Decision include other countries and territories to which, in accordance with Article 355 of the Treaty on the Functioning of the European Union, Title VI of that Treaty does not apply.’;

- (b) point 6.3.1.2 (b) is replaced by the following:

‘(b) the appropriate authority or an EU aviation security validator acting on its behalf shall examine the security programme and then make an on-site verification of the sites specified in order to assess whether the applicant complies with the requirements of Regulation (EC) No 300/2008 and its implementing acts.

Except for the requirements laid down in point 6.2, an examination of the site of the applicant by the relevant customs authority in accordance with Article 14n of Commission Regulation (EEC) No 2454/93 (*) shall be considered as an on-site verification if it took place not earlier than 3 years before the date on which the applicant seeks approval as a regulated agent. The AEO certificate and the relevant assessment of the customs authorities shall be made available by the applicant for further inspection.

(*) Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).;

- (c) in point 6.3.1.4, the following paragraph is added:

‘Except for the requirements laid down in point 6.2, an examination of the site of the regulated agent by the relevant customs authority in accordance with Article 14n of Regulation (EEC) No 2454/93 shall be considered as an on-site verification.’;

- (d) point 6.3.1.5 is replaced by the following:

‘6.3.1.5. If the appropriate authority is no longer satisfied that the regulated agent complies with the requirements of Regulation (EC) No 300/2008 and its implementing acts, it shall withdraw the status of regulated agent for the specified site(s).

If the entity is no longer a holder of an AEO certificate referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93 or if this AEO certificate is suspended due to non-compliance with Article 14k of that Regulation, the appropriate authority shall undertake appropriate action to satisfy itself that the regulated agent complies with the requirements of Regulation (EC) No 300/2008.

The entity shall inform the appropriate authority of any changes related to its AEO certificate referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93.

Immediately after withdrawal, and in all cases within 24 hours, the appropriate authority shall ensure that the former regulated agent’s change of status is indicated in the “Union database on supply chain security”.’;

- (e) the following point 6.3.1.8 is added:

‘6.3.1.8. The appropriate authority shall make available to the customs authority any information related to the status of a regulated agent which could be relevant in respect of holding an AEO certificate as referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93. This shall include the information related to new approvals of regulated agents, withdrawal of the regulated agent status, revalidation and inspections, verification schedules and outcomes of these assessments.

By 1 March 2015 at the latest, the modalities for this exchange of information shall be established between the appropriate authority and the national customs authorities.’;

- (f) point 6.3.2.3 is replaced by the following:

‘6.3.2.3 The regulated agent shall ensure that consignments to which not all required security controls have previously been applied are:

- (a) screened in accordance with point 6.2; or
- (b) accepted for storage under the regulated agent’s exclusive responsibility, not identifiable as shipment for carriage on an aircraft before selection, and selected autonomously without any intervention of the consignor or any person or entity other than those appointed and trained by the regulated agent for that purpose.

Point (b) may only be applied if it is unpredictable for the consignor that the consignment is to be transported by air.’;

(g) point 6.3.2.6 (e) is replaced by the following:

‘(e) the reason that the security status was issued, stating:

- “KC”, meaning received from known consignor, or
- “AC”, meaning received from account consignor, or
- “RA”, meaning selected by a regulated agent, or
- the means or method of screening used, or
- the grounds for exempting the consignment from screening;’

(h) point 6.4.1.2 is replaced by the following:

‘6.4.1.2. The appropriate authority of each Member State shall define in its national civil aviation security programme as referred to in Article 10 of Regulation (EC) No 300/2008 the responsibilities for the implementation of the following procedure on the approval of known consignors:

- (a) the applicant shall seek approval from the appropriate authority of the Member State in which its site is located.

The applicant shall be provided with the “Guidance for known consignors” as contained in Attachment 6-B and the “Validation checklist for known consignors” as contained in Attachment 6-C;

- (b) the appropriate authority, or the EU aviation security validator acting on its behalf, shall make an on-site verification of the sites specified in order to assess whether the applicant complies with the requirements of Regulation (EC) No 300/2008 and its implementing acts.

In order to assess whether the applicant complies with these requirements, the appropriate authority, or the EU aviation security validator acting on its behalf, shall make use of the “Validation checklist for known consignors” as contained in Attachment 6-C. This checklist includes a declaration of commitments which shall be signed by the applicant’s legal representative or by the person responsible for security at the site.

Once the validation checklist is completed, the information contained in the checklist shall be handled as classified information.

The signed declaration shall be retained by the appropriate authority concerned or retained by the EU aviation security validator and made available on request to the appropriate authority concerned;

- (c) an examination of the site of the applicant by the relevant customs authority in accordance with Article 14n of Regulation (EEC) No 2454/93 shall be considered as an on-site verification if it took place not earlier than 3 years before the date on which the applicant seeks approval as a known consignor. In those cases, the applicant shall complete the information required in Part One of the “Validation checklist for known consignors” as contained in Attachment 6-C and send it to the appropriate authority jointly with the declaration of commitments which shall be signed by the applicant’s legal representative or by the person responsible for security at the site.

The AEO certificate and the relevant assessment of the customs authorities shall be made available by the applicant for further inspection.

The signed declaration shall be retained by the appropriate authority concerned or retained by the EU aviation security validator and made available on request to the appropriate authority concerned;

- (d) if the appropriate authority is satisfied with the information provided under points (a) and (b) or (a) and (c), as applicable, it shall ensure that the necessary details of the consignor are entered into the “Union database on supply chain security” not later than the next working day. When making the database entry the appropriate authority shall give each approved site a unique alphanumeric identifier in the standard format.

If the appropriate authority is not satisfied with the information provided under points (a) and (b) or (a) and (c), as applicable, then the reasons shall promptly be notified to the entity seeking approval as a known consignor;

- (e) a known consignor shall not be considered as approved until its details are listed in the “Union database on supply chain security”;

- (i) in point 6.4.1.4, the following paragraph is added:

‘An examination of the site of the known consignor by the relevant customs authority in accordance with Article 14n of Regulation (EEC) No 2454/93 shall be considered as an on-site verification.’;

- (j) point 6.4.1.5 is replaced by the following:

‘6.4.1.5 If the appropriate authority is no longer satisfied that the known consignor complies with the requirements of Regulation (EC) No 300/2008 and its implementing acts, it shall withdraw the status of known consignor for the specified site(s).

If the entity is no longer a holder of an AEO certificate referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93 or if this AEO certificate is suspended due to non-compliance with article 14k of that Regulation, the appropriate authority shall undertake appropriate action to satisfy itself that the known consignor complies with the requirements of Regulation (EC) No 300/2008.

The entity shall inform the appropriate authority of any changes related to its AEO certificate referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93.

Immediately after withdrawal, and in all cases within 24 hours, the appropriate authority shall ensure that the former known consignor’s change of status is indicated in the “Union database on supply chain security”;

- (k) the following point 6.4.1.7 is added:

‘6.4.1.7. The appropriate authority shall make available to the customs authority any information related to the status of a known consignor which could be relevant in respect of holding an AEO certificate as referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93. This includes information related to new approvals of known consignors, withdrawal of the known consignor status, revalidation and inspections, verification schedules and outcomes of these assessments.

By 1 March 2015 at the latest, the modalities for this exchange of information shall be established between the appropriate authority and the national customs authorities.’;

- (l) point 6.6.1.1 (c) is replaced by the following:

‘(c) the haulier declaration as contained in Attachment 6-E shall be agreed by the haulier who has entered into the transport agreement with the regulated agent, known consignor or account consignor, unless the haulier is itself approved as a regulated agent.

The signed declaration shall be retained by the regulated agent, known consignor or account consignor on whose behalf the transport is carried out. On request, a copy of the signed declaration shall also be made available to the regulated agent or air carrier receiving the consignment or to the appropriate authority concerned; or’;

- (m) point 6.8.2.3 is replaced by the following:

‘6.8.2.3 The appropriate authority may designate an air carrier as ACC3 for a limited period, ending on 30 June 2016 at the latest, in the case where an EU aviation security validation could not take place for objective reasons which are beyond the responsibility of the air carrier. Where such a designation is granted for a period of more than six months, the appropriate authority shall have verified that the air carrier applies an internal security quality assurance programme that is equivalent to EU aviation security validation.’;

(n) point 6.8.3.1 (c) is replaced by the following:

‘(c) the required security controls have been applied to the consignment by an account consignor under the responsibility of the ACC3 or of an EU aviation security validated regulated agent, the consignment has been protected from unauthorised interference from the time that those security controls were applied and until loading, and it is not carried on a passenger aircraft; or’;

(o) point 6.8.3.2 is replaced by the following:

‘6.8.3.2. Cargo and mail carried into the Union shall be screened by one of the means and methods listed in point 6.2.1 to a standard sufficient to reasonably ensure that it contains no prohibited articles.’;

(p) Point 6.8.3.3 (a) is replaced by the following:

‘(a) transfer and transit cargo or mail that screening in accordance with point 6.8.3.2 or security controls have been applied by itself or by an EU aviation security validated entity at the point of origin or elsewhere in the supply chain and such consignments have been protected from unauthorised interference from the time that those security controls were applied and until loading’;

(q) in point 6.8.4.1, the introductory sentence is replaced by the following:

‘6.8.4.1. In order to become an EU aviation security validated regulated agent or known consignor, entities located in third countries shall be validated according to one of the following two options and be listed in the database of the ACC3(s) to which they directly deliver cargo or mail for carriage into the Union’;

(r) the following points 6.8.4.4 to 6.8.4.6 are added:

‘6.8.4.4. An air cargo or mail entity operating a network of different sites in third countries may obtain a single designation as EU aviation security validated regulated agent covering all sites of the network, provided that:

- (a) the relevant aviation security operations of the network, including transport services between sites, are covered by a single security programme or by standardised security programmes; and
- (b) the implementation of the security programme(s) shall be subject to a single internal security quality assurance programme that is equivalent to EU aviation security validation; and
- (c) before designation of the network as EU aviation security regulated agent, the following sites of the entity have been subjected to an EU aviation security validation:
 - (i) the site(s) from which cargo or mail is directly delivered to an ACC3, and
 - (ii) at least two or 20 % of the sites of the network, whichever is the higher, from which cargo or mail is fed to site(s) mentioned in point (i), and
 - (iii) all sites located in third countries listed in Attachment 6-I of the Annex to Commission Decision C(2010) 774.

In order to maintain EU aviation security validated regulated agent designation for all sites of the network not yet validated until 30 June 2018 at the latest, during every year after the year of designation, at least a further two or 20 %, whichever is the higher, of the sites from which cargo or mail is fed to the site(s) mentioned in point (c)(i) shall be subjected to an EU aviation security validation, until all sites are validated.

An EU aviation security validator shall establish the roadmap listing the order of the locations to be validated each year selected on a random basis. The roadmap shall be established independently from the entity operating the network and may not be changed by that entity. This roadmap shall constitute an integral part of the validation report on the basis of which the network is designated as a third country EU validated regulated agent.

Once it has been subjected to an EU aviation security validation, a site of the network shall be considered as an EU aviation security validated regulated agent in accordance with point 6.8.4.2 (a).

6.8.4.5. If the EU aviation security validation of a site of the network referred to in point 6.8.4.4 (c) ii. concludes that the site has failed to comply with the objectives referred to in the checklist in Attachment 6-C2, cargo and mail from that site shall be screened at a site validated in accordance with 6.8.4.2 (a) until an EU aviation security validation confirms compliance with the objectives of the checklist.

6.8.4.6. Points 6.8.4.4 to 6.8.4.6 expire on 30 June 2018.'

(6) Attachment 6-B is amended as follows:

(a) the following paragraph is inserted before the section 'Introduction':

'If you are a holder of an AEO certificate referred to in point (b) or (c) of Article 14a(1) of Regulation (EEC) No 2454/93 (so called AEOF and AEOS certificates) and if the site for which you are requesting the known consignor status has been successfully examined by customs authorities at a date not earlier than 3 years before the date of requesting the known consignor status, you are required to fill out and have signed by a legal representative of your company Part 1, concerning the organisation and responsibilities, as well as the declaration of commitments of the "Validation checklist for known consignors" as contained in attachment 6-C.';

(b) the section 'Organisation and responsibilities' is replaced by the following:

'Organisation and responsibilities'

You will be required to provide details about your organisation (name, VAT or Chamber of Commerce number or Corporate registration number if applicable, AEO certificate number and the date of the last examination of this site by customs authorities, if applicable), address of the site to be validated and main address of organisation (if different from the site to be validated). The date of the previous validation visit and last unique alphanumeric identifier (if applicable) are required, as well as of the nature of the business, the approximate number of employees on site, name and title of the person responsible for air cargo/air mail security and contact details.';

(7) in Attachment 6-C, Part 1 is replaced by the following:

'Part 1: Organisation and responsibilities

1.1 Date of validation (*)

dd/mm/yyyy	
------------	--

1.2 Date of previous validation and Unique Identifier where applicable

dd/mm/yyyy	
------------	--

UNI	
-----	--

1.3 Name of organisation to be validated (*)

Name

VAT/Chamber of Commerce number/Corporate registration number (if applicable)

1.4 Information on AEOF or AEOS certificate, where applicable

AEO certificate number	
------------------------	--

Date when customs authorities have last examined this site	
--	--

1.5 Address of site to be validated (*)

Number/Unit/Building	
----------------------	--

Street	
--------	--

Town	
Postcode	
Country	

1.6 Main address of organisation (if different from site to be validated, provided that it is in the same country)

Number/Unit/Building	
Street	
Town	
Postcode	
Country	

1.7 Nature of Business(es) — types of cargo processed

1.8 Is the applicant responsible for:

(a) Production (b) Packing (c) Storage (d) Dispatch (e) Other, please specify	
---	--

1.9 Approximate number of employees on site

--	--

1.10 Name and title of person responsible for air cargo/air mail security (*)

Name	
Job title	

1.11 Contact telephone number

Tel. No	
---------	--

1.12 E-mail address (*)

E-mail;	
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(8) in Attachment 6-E, the seventh indent of the second paragraph is replaced by the following:

‘— Transport will not be subcontracted to a third party, unless the third party:

- (a) has a haulier agreement with the regulated agent, known consignor or account consignor responsible for the transport [same name as above]; or
- (b) is approved or certified by the appropriate authority; or
- (c) has a haulier agreement with the undersigned haulier requiring that the third party will not subcontract further and implements the security procedures contained in this declaration. The undersigned haulier retains full responsibility for the entire transport on behalf of the regulated agent, known consignor or account consignor; and;

- (9) Attachment 6-F is replaced by the following:

‘ATTACHMENT 6-F

CARGO AND MAIL

6-Fi

THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, RECOGNISED AS APPLYING SECURITY STANDARDS EQUIVALENT TO THE COMMON BASIC STANDARDS.

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THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, FOR WHICH ACC3 DESIGNATION IS NOT REQUIRED ARE LISTED IN A SEPARATE COMMISSION DECISION.

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VALIDATION ACTIVITIES OF THIRD COUNTRIES, AS WELL AS OTHER COUNTRIES AND TERRITORIES TO WHICH, IN ACCORDANCE WITH ARTICLE 355 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, TITLE VI OF THAT TREATY DOES NOT APPLY, RECOGNISED AS EQUIVALENT TO EU AVIATION SECURITY VALIDATION.’;

- (10) Chapter 8 is amended as follows:

- (a) Point 8.0.4 is replaced by the following:

‘8.0.4. The list of prohibited articles in in-flight supplies is the same as the one set out in Attachment 1-A. Prohibited articles shall be handled in accordance with point 1.6.’;

- (b) Point 8.1.4 is replaced by the following as of 1 March 2015:

‘8.1.4. Designation of known suppliers

8.1.4.1. Any entity (“the supplier”) that ensures the security controls as referred to in point 8.1.5 and delivers in-flight supplies, but not directly to aircraft, shall be designated as a known supplier by the operator or the entity to whom it delivers (“the designating entity”). This shall not apply to a regulated supplier.

8.1.4.2. In order to be designated as a known supplier, the supplier must provide the designating entity with:

- (a) the “Declaration of commitments — known supplier of in-flight supplies” as contained in Attachment 8-B. This declaration shall be signed by the legal representative; and
- (b) the security programme covering the security controls as referred to in point 8.1.5.

8.1.4.3. All known suppliers must be designated on the basis of validations of:

- (a) the relevance and completeness of the security programme in respect of point 8.1.5; and
- (b) the implementation of the security programme without deficiencies.

If the appropriate authority or the designating entity is no longer satisfied that the known supplier complies with the requirements of point 8.1.5, the designating entity shall withdraw the status of known supplier without delay.

8.1.4.4. The appropriate authority shall define in its national civil aviation security programme as referred to in Article 10 of Regulation (EC) No 300/2008 if the validations of the security programme and its implementation shall be performed by a national auditor, an EU aviation security validator, or a person acting on behalf of the designating entity appointed and trained for that purpose.

Validations must be recorded and if not otherwise stated in this legislation, must take place before designation and repeated every 2 years thereafter.

If the validation is not done on behalf of the designating entity any record thereof must be made available to it.

8.1.4.5. The validation of the implementation of the security programme confirming the absence of deficiencies shall consist of either:

- (a) an on-site visit of the supplier every 2 years; or
- (b) regular checks upon reception of supplies delivered by that known supplier, starting after the designation, including:
 - a verification that the person delivering supplies on behalf of the known supplier was properly trained; and
 - a verification that the supplies are properly secured; and
 - screening of the supplies in the same way as supplies coming from an unknown supplier.

These checks must be carried out in an unpredictable manner and take place at least either, once every three months or on 20 % of the known supplier's deliveries to the designating entity.

Option b) may only be used if the appropriate authority defined in its national civil aviation security programme that the validation shall be performed by a person acting on behalf of the designating entity.

8.1.4.6. The methods applied and procedures to be followed during and after designation shall be laid down in the security programme of the designating entity.

8.1.4.7. The designating entity shall keep:

- (a) a list of all known suppliers it has designated indicating the expiry date of their designation, and
- (b) the signed declaration, a copy of the security programme, and any reports recording its implementation for each known supplier, at least until 6 months after the expiry of its designation.

Upon request, these documents shall be made available to the appropriate authority for compliance monitoring purposes.;

(11) Chapter 9 is amended as follows:

(a) Point 9.0.4 is replaced by the following:

‘9.0.4. The list of prohibited articles in airport supplies is the same as the one set out in Attachment 1-A. Prohibited articles shall be handled in accordance with point 1.6.’;

(b) Point 9.1.3 is replaced by the following as of 1 March 2015:

‘9.1.3. **Designation of known suppliers**

9.1.3.1. Any entity (“the supplier”) that ensures the security controls as referred to in point 9.1.4 and delivers airport supplies shall be designated as a known supplier by the airport operator.

9.1.3.2. In order to be designated as a known supplier, the supplier must provide the airport operator with:

- (a) the “Declaration of commitments — known supplier of airport supplies” as contained in Attachment 9-A. This declaration shall be signed by the legal representative; and
- (b) the security programme covering the security controls as referred to in point 9.1.4.

9.1.3.3. All known suppliers must be designated on the basis of validations of:

- (a) the relevance and completeness of the security programme in respect of point 9.1.4; and
- (b) the implementation of the security programme without deficiencies.

If the appropriate authority or the airport operator is no longer satisfied that the known supplier complies with the requirements of point 9.1.4, the airport operator shall withdraw the status of known supplier without delay.

- 9.1.3.4. The appropriate authority shall define in its national civil aviation security programme as referred to in Article 10 of Regulation (EC) No 300/2008 if the validations of the security programme and its implementation shall be performed by a national auditor, an EU aviation security validator, or a person acting on behalf of the airport operator appointed and trained for that purpose.

Validations must be recorded and if not otherwise stated in this legislation, must take place before designation and repeated every 2 years thereafter.

If the validation is not done on behalf of the airport operator any record thereof must be made available to it.

- 9.1.3.5. The validation of the implementation of the security programme confirming the absence of deficiencies shall consist of either:

- (a) an on-site visit of the supplier every 2 years; or
- (b) regular checks upon access to the security restricted area of supplies delivered by that known supplier, starting after the designation, including:
 - a verification that the person delivering supplies on behalf of the known supplier was properly trained; and
 - a verification that the supplies are properly secured; and
 - screening of the supplies in the same way as supplies coming from an unknown supplier.

These checks must be carried out in an unpredictable manner and take place at least either, once every three months or on 20 % of the known supplier's deliveries to the airport operator.

Option b) may only be used if the appropriate authority defined in its national civil aviation security programme that the validation shall be performed by a person acting on behalf of the airport operator.

- 9.1.3.6. The methods applied and procedures to be followed during and after designation shall be laid down in the security programme of the airport operator.

- 9.1.3.7. The airport operator shall keep:

- (a) a list of all known suppliers it has designated indicating the expiry date of their designation, and
- (b) the signed declaration, a copy of the security programme, and any reports recording its implementation for each known supplier, at least until 6 months after the expiry of its designation.

Upon request, these documents shall be made available to the appropriate authority for compliance monitoring purposes.;

- (12) Chapter 12 is amended as follows:

- (a) Point 12.4.2 '**Standards for EDS**' is replaced by the following:

12.4.2. Standards for EDS

12.4.2.1. All EDS installed before 1 September 2014 shall at least meet standard 2.

12.4.2.2. Standard 2 shall expire on 1 September 2020.

12.4.2.3. The appropriate authority may permit standard 2 EDS installed between 1 January 2011 and 1 September 2014 to continue to be used until 1 September 2022 at the latest.

12.4.2.4. The appropriate authority shall inform the Commission when it grants permission to permit standard 2 EDS to continue to be used as of 1 September 2020.

12.4.2.5. All EDS installed as from 1 September 2014 shall meet standard 3.

12.4.2.6. All EDS shall meet standard 3 as from 1 September 2020 at the latest, unless point 12.4.2.3 applies.;

- (b) The list of attachments after point 12.11 is replaced by the following:

‘ATTACHMENT 12-A

Detailed provisions for performance requirements for WTMD are laid down in a separate Commission Decision

ATTACHMENT 12-B

Detailed provisions for performance requirements for EDS are laid down in a separate Commission Decision.

ATTACHMENT 12-C

Detailed provisions for performance requirements for equipment for the screening of liquids, aerosols and gels (LAGS) are laid down in a separate Commission Decision.

ATTACHMENT 12-D

Detailed provisions for performance requirements for an EDD are laid down in a separate Commission Decision.

ATTACHMENT 12-E

Detailed provisions for approval procedures of an EDD are laid down in a separate Commission Decision.

ATTACHMENT 12-F

Detailed provisions for approval test areas and test conditions for an EDD are laid down in a separate Commission Decision.

ATTACHMENT 12-G

Detailed provisions for quality control requirements for an EDD are laid down in a separate Commission Decision.

ATTACHMENT 12-H

Detailed provisions for “Free Running EDD — Standards for deployment methodology” are laid down in a separate Commission Decision.

ATTACHMENT 12-I

Detailed provisions for “Remote Explosive Scent Tracing EDD — Standards for deployment methodology” are laid down in a separate Commission Decision.

ATTACHMENT 12-J

Detailed provisions for performance requirements for MDE are laid down in a separate Commission Decision.

ATTACHMENT 12-K

Detailed provisions for performance requirements for security scanners are laid down in a separate Commission Decision.

ATTACHMENT 12-L

Detailed provisions for performance requirements for Explosive Trace Detection (ETD) are laid down in a separate Commission Decision.’

COMMISSION IMPLEMENTING REGULATION (EU) No 688/2014**of 20 June 2014****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.
- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
Director-General for Agriculture and Rural Development

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MK	113,4
	TR	83,5
	ZZ	98,5
0707 00 05	MK	50,7
	TR	90,3
	ZZ	70,5
0709 93 10	TR	107,9
	ZZ	107,9
0805 50 10	AR	100,3
	TR	141,7
	ZA	140,7
	ZZ	127,6
0808 10 80	AR	125,1
	BR	105,7
	CA	102,6
	CL	92,4
	CN	130,3
	NZ	133,9
	US	223,4
	ZA	126,2
	ZZ	130,0
0809 10 00	TR	250,6
	ZZ	250,6
0809 29 00	TR	338,2
	ZZ	338,2
0809 30	MK	87,8
	ZZ	87,8

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DIRECTIVE 2014/79/EU

of 20 June 2014

amending Appendix C of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards TCEP, TCPP and TDCP

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ⁽¹⁾, and in particular Article 46(2) thereof,

Whereas:

- (1) The substance tris(2-chloroethyl) phosphate (TCEP), CAS No 115-96-8, is a phosphate ester used as a flame-retardant plasticiser in polymers. The main industrial branches in which TCEP has been used are the building industry, the furniture and the textile industry. TCEP is classified under 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 ⁽²⁾ as carcinogenic category 2 and toxic for reproduction category 1B.
- (2) Directive 2009/48/EC establishes general requirements for substances which are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008. Such substances may not be used in toys, in components of toys or in micro-structurally distinct parts of toys, except if inaccessible to children, permitted by a Commission decision or contained in individual concentrations equal to or smaller than the relevant concentrations established for the classification of mixtures containing them as CMRs. In the absence of any specific requirements, TCEP can thus be contained in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it as CMRs, namely 0,5 % as from 20 July 2013 and 0,3 % as from 1 June 2015 respectively.
- (3) TCEP was comprehensively evaluated in 2009 under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽³⁾. The risk assessment report, entitled 'European Union Risk assessment on TCEP', shows that TCEP easily migrates, and, when ingested, results in toxicity in the kidney, liver and brain, causing health damages and potentially cancer.
- (4) The risk assessment report also shows that since 2001 there is no EU TCEP production. Its use in the EU had also declined, TCEP being replaced progressively by other flame retardants. Nevertheless, the presence of TCEP in toys cannot be excluded, as most toys available on the EU market are imported, thus manufactured outside the EU.
- (5) To assess the health effects of TCEP in toys and the appropriateness of Directive 2009/48/EC's generic limits for TCEP as a CMR substance, the Commission sent a request for an opinion to the Scientific Committee on Health and Environmental Risks (SCHER). In its opinion, adopted on 22 March 2012 and entitled 'Opinion on tris (2-chloroethyl) phosphate (TCEP) in toys', SCHER notes that health effects (in particular kidney effects) have been observed after repeated exposure to 12 mg of TCEP/kg body weight per day. SCHER also notes that the TCEP content found by the Danish Environmental Protection Agency (Danish EPA) in toys (0,5-0,6 %), as reported in the Danish EPA's 'Survey and risk assessment of perfume and flavours in toys and childcare articles. Survey of chemical substances in consumer products', corresponds to a risk for children, even without considering other exposures. When considering TCEP exposure from other sources than toys (e.g. air, dust), SCHER concludes that

⁽¹⁾ OJ L 170, 30.6.2009, p. 1.

⁽²⁾ OJ L 353, 31.12.2008, p. 1.

⁽³⁾ OJ L 84, 5.4.1993, p. 1.

no additional exposure from toys can be considered as safe, and recommends setting the limit for TCEP in toys at the detection limit of a sufficiently sensitive analytical method.

- (6) In the light of the above, the generic limit values of 0,5 % and 0,3 % referred to by Directive 2009/48/EC appear to be inappropriate for protecting children's health. Following a stakeholder consultation, the 'detection limit of a sufficiently sensitive analytical method' for TCEP was set at 5 mg/kg. As this limit refers to a detection level, it is not based on a toxicological approach.
- (7) In addition to TCEP, SCHER also assessed TCEP's halogenated alternatives, namely tris[2-chloro-1-(chloromethyl) ethyl] phosphate (TDCP), CAS No 13674-87-8, and tris(2-chloro-1-methylethyl) phosphate (TCPP), CAS No 13674-84-5, in the above-mentioned opinion of 22 March 2012. These alternatives were assessed in 2008 under Regulation (EEC) No 793/93.
- (8) In its opinion SCHER agrees with the conclusion of the alternatives' risk assessments that there is sufficient information from the structures, physical-chemical properties, toxicokinetics and mutagenic profiles of TCEP, TDCP and TCPP to support a qualitative read-across, indicating a potential concern for carcinogenicity for TCPP by a non-genotoxic mechanism. The read-across implies, according to SCHER, that considerations given for TCEP could be applied to its halogenated alternatives as well, if used in toy manufacturing.
- (9) TDCP is classified under Regulation (EC) No 1272/2008 as carcinogenic category 2, and for TCPP, although not classified, SCHER identified a potential concern for carcinogenicity. In line with the above considerations for TCEP and the SCHER opinion, limit values for TDCP and TCPP should therefore also be set at 5 mg/kg.
- (10) Directive 2009/48/EC foresees that, to further protect children's health, specific limit values for chemicals can be set out, when appropriate, for toys intended for use by children under three years old or other toys intended to be placed in the mouth.
- (11) Directive 2009/48/EC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Committee established in Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Appendix C of Annex II to Directive 2009/48/EC is replaced by the following:

'Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2)

Substance	CAS No	Limit value
TCEP	115-96-8	5 mg/kg (content limit)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)

Article 2

1. Member States shall adopt and publish, by 21 December 2015 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 21 December 2015.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 June 2014.

For the Commission
The President
José Manuel BARROSO

COMMISSION DIRECTIVE 2014/80/EU**of 20 June 2014****amending Annex II to Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration ⁽¹⁾, and in particular Article 8 thereof,

Whereas:

- (1) Based on the first review under Article 10 of Directive 2006/118/EC, not enough information is available to set new groundwater quality standards in Annex I to that Directive for any pollutants, but technical adaptations in accordance with Article 8 of that Directive are necessary in its Annex II.
- (2) Common principles for the determination of background levels need to be applied in order to improve the comparability of threshold values.
- (3) There is considerable potential for nitrogen and phosphorus in groundwater to present a eutrophication risk to associated surface waters and to directly dependent terrestrial ecosystems. Besides nitrates, already included in Annex I to Directive 2006/118/EC, and ammonium, included in Annex II to that Directive, nitrites, as a contributor to total nitrogen, and total phosphorus, either as such or as phosphates, should also be considered by Member States when establishing threshold values.
- (4) The need to obtain and respond to new information on other substances posing a potential risk should be acknowledged. Therefore, a watch list for pollutants of groundwater should be established under the Common Implementation Strategy for Directive 2000/60/EC of the European Parliament and of the Council ⁽²⁾ to increase the availability of monitoring data on substances posing a risk or potential risk to bodies of groundwater, and thereby facilitate the identification of substances, including emerging pollutants, for which groundwater quality standards or threshold values should be set.
- (5) The information provided by Member States on the pollutants and indicators for which threshold values have been established, in particular as regards the methodologies related to groundwater chemical status assessment, proved insufficient in the first river basin management plans to enable proper understanding and comparison of the results. The relevant requirements regarding the information to be provided should be clarified and complemented in order to ensure the transparency of that assessment. The information provided would also facilitate comparison of the chemical status assessment results across the Member States and contribute to a potential future harmonisation of methodologies for establishing groundwater threshold values.
- (6) Directive 2006/118/EC should therefore be amended accordingly.
- (7) The measures provided for in this Directive are in accordance with the opinion of the Committee under Article 9 of Directive 2006/118/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2006/118/EC is amended in accordance with the Annex to this Directive.

⁽¹⁾ OJ L 372, 27.12.2006, p. 19.

⁽²⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 24 months from the date of entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex II to Directive 2006/118/EC is amended as follows:

(1) in Part A, point 3 is replaced by the following:

- ‘3) wherever elevated background levels of substances or ions or their indicators occur due to natural hydro-geological reasons, those background levels in the relevant body of groundwater shall be taken into account when establishing threshold values. When determining background levels, the following principles should be taken into account:
- (a) The determination of background levels should be based on the characterisation of groundwater bodies in accordance with Annex II to Directive 2000/60/EC and on the results of groundwater monitoring in accordance with Annex V to that Directive. The monitoring strategy and interpretation of the data should take account of the fact that flow conditions and groundwater chemistry vary laterally and vertically;
 - (b) Where only limited groundwater monitoring data are available, more data should be gathered and in the meantime background levels should be determined based on those limited monitoring data, where appropriate by a simplified approach using a subset of samples for which indicators show no influence of human activity. Information on geochemical transfers and processes should also be taken account of, where available;
 - (c) Where insufficient groundwater monitoring data are available and the information on geochemical transfers and processes is poor, more data and information should be gathered and in the meantime background levels should be estimated, where appropriate based on statistical reference results for the same type of aquifers in other areas having sufficient monitoring data.’

(2) in point 1 of Part B, the following entries are added:

‘Nitrites

Phosphorus (total)/Phosphates (*)

‘(*) Member States may decide to establish threshold values either for phosphorus (total) or for phosphates.’

(3) Part C is replaced by the following:

‘Part C

Information to be provided by Member States with regard to the pollutants and their indicators for which threshold values have been established

Member States shall include in the river basin management plans to be submitted in accordance with Article 13 of Directive 2000/60/EC information on the way the procedure set out in Part A of this Annex has been followed.

In particular, Member States shall provide:

- (a) information on each of the bodies or groups of bodies of groundwater characterised as being at risk, including the following:
 - (i) the size of the bodies;
 - (ii) each pollutant or indicator of pollution which characterises bodies of groundwater as being at risk;
 - (iii) the environmental quality objectives to which the risk is related, including the actual or potential legitimate uses or functions of the groundwater body, and the relationship between the bodies of groundwater and the associated surface waters and directly dependent terrestrial ecosystems;
 - (iv) in the case of naturally-occurring substances, the natural background levels in the bodies of groundwater;
 - (v) information on the exceedances where threshold values are exceeded.
- (b) the threshold values, whether they apply at the national level, at the level of the river basin district or the part of the international river basin district falling within the territory of the Member State, or at the level of a body or a group of bodies of groundwater;

- (c) the relationship between the threshold values and each of the following:
 - (i) in the case of naturally-occurring substances, the background levels;
 - (ii) associated surface waters and directly dependent terrestrial ecosystems;
 - (iii) the environmental quality objectives and other standards for water protection that exist at national, Union or international level;
 - (iv) any relevant information concerning the toxicology, eco-toxicology, persistence, bioaccumulation potential, and dispersion tendency of the pollutants.
- (d) the methodology for determining background levels based on the principles set out in point 3 of Part A.
- (e) the reasons for not having established threshold values for any of the pollutants and indicators identified in Part B.
- (f) key elements of the groundwater chemical status assessment, including the level, method and period of aggregation of monitoring results, the definition of the acceptable extent of exceedance, and the method for calculating it, in accordance with Article 4(2)(c)(i) and point 3 of Annex III.

Where any of the data referred to in points (a) to (f) are not included in the river basin management plans, Member States shall provide the reasons for this in those plans.'

RULES OF PROCEDURE

RULES OF PROCEDURE OF THE SUPERVISORY BOARD OF THE EUROPEAN CENTRAL BANK

THE SUPERVISORY BOARD OF THE EUROPEAN CENTRAL BANK,

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions ⁽¹⁾, and in particular Article 26(12) thereof,

Having regard to Decision ECB/2004/2 of 19 February 2004 adopting the Rules of Procedure of the European Central Bank ⁽²⁾, and in particular Article 13d thereof,

HAS ADOPTED THESE RULES OF PROCEDURE:

PRELIMINARY CHAPTER

Article 1

Supplementary nature

These Rules of Procedure shall supplement the Rules of Procedure of the European Central Bank. The terms used in these Rules of Procedure shall have the same meaning as in the Rules of Procedure of the European Central Bank.

CHAPTER I

SUPERVISORY BOARD

Article 2

Supervisory Board meetings

2.1. The Supervisory Board shall decide on the dates of its meetings on a proposal from the Chair. The Supervisory Board shall, in principle, meet regularly following a schedule that it shall determine in good time before the start of each calendar year.

2.2. The Chair shall convene a meeting of the Supervisory Board if a request for a meeting is submitted by at least three of its members.

2.3. The Chair may also convene meetings of the Supervisory Board whenever he/she deems it necessary. In such cases, this shall be specified in a cover note.

2.4. At the request of the Chair, the deliberations of the Supervisory Board may also take place by means of teleconferencing, unless at least three members of the Supervisory Board object.

Article 3

Attendance at Supervisory Board meetings

3.1. Except as provided herein, attendance at meetings of the Supervisory Board shall be restricted to its members and, where the national competent authority is not the national central bank, to the representative of the national central bank.

⁽¹⁾ OJ L 287, 29.10.2013, p. 63.

⁽²⁾ OJ L 80, 18.3.2004, p. 33.

3.2. Each representative of the national competent authority may normally be accompanied by one person. If the national competent authority is not the national central bank, this paragraph shall apply to the representative having the voting right. This paragraph shall also apply in the case of the attendance by an alternate, as provided in Article 3.3.

3.3. If a representative of a national competent authority or, where the national competent authority is not the national central bank, a representative of the national central bank, is unable to attend, he/she may appoint, in writing, an alternate to attend and to exercise their voting right as applicable, unless otherwise stipulated in the written communication. This written communication shall be sent to the Chair in due time before the meeting.

3.4. In the absence of both the Chair and the Vice-Chair, the Supervisory Board shall be chaired by the most senior member of the Supervisory Board in terms of the length of his/her membership in the first instance, and by age in the event of two or more members having equal standing in terms of the length of membership.

3.5. Upon invitation of the Chair, a representative of the European Commission and/or a representative of the European Banking Authority may participate in the meetings as observers. The Chair shall invite the representatives of the Commission and the European Banking Authority if a request for such an invitation is submitted by at least three members of the Supervisory Board. Applying the same rules, the Supervisory Board may also invite other persons to attend its meetings if it deems it appropriate to do so.

Article 4

Organisation of Supervisory Board meetings

4.1. The Supervisory Board shall adopt the agenda for each meeting. A provisional agenda shall be drawn up by the Chair and shall be sent, together with the related documents, to the members of the Supervisory Board at least five working days before the relevant meeting, except in emergencies, in which case the Chair shall act appropriately having regard to the circumstances. The Supervisory Board may decide to remove items from or add items to the provisional agenda on a proposal from the Chair or from any other member of the Supervisory Board. Except in emergencies, an item shall be removed from the provisional agenda at the request of at least three members of the Supervisory Board if the related documents were not submitted to the members of the Supervisory Board in due time.

4.2. The proceedings of Supervisory Board meetings shall be submitted to its members for approval at the subsequent meeting (or if necessary earlier by written procedure) and shall be signed by the Chair.

Article 5

Access to information

All the members of the Supervisory Board shall have regular access to updated information on the institutions deemed significant under Regulation (EU) No 1024/2013. The information made available to the members of the Supervisory Board should include key items of information that enable a meaningful understanding of such institutions. The Supervisory Board may adopt internal templates for sharing information for this purpose.

Article 6

Voting

6.1. For the purposes of this Article, the representatives of the authorities of any participating Member State shall together be considered as one member.

6.2. Unless explicitly indicated otherwise in writing by the national competent authority, the voting right shall be exercised by the representative of the national competent authority or their alternate in accordance with Article 3.3.

6.3. In order for the Supervisory Board to vote, there shall be a quorum of two-thirds of its members having a voting right. If the quorum is not met, the Chair may convene an extraordinary meeting at which members of the Supervisory Board may vote without regard to the quorum.

6.4. The Supervisory Board shall proceed to vote at the request of the Chair. The Chair shall also initiate a voting procedure upon request from three members of the Supervisory Board.

6.5. Except where otherwise provided by Regulation (EU) No 1024/2013, the Supervisory Board shall act by a simple majority of its members having a voting right. Each member shall have one vote. In case of a draw, the Chair shall have the casting vote. In the cases set out in Article 26(7) of Regulation (EU) No 1024/2013, the voting rules as laid down in Article 13c of the Rules of Procedure of the European Central Bank apply.

6.6. The Chair may initiate a secret ballot if requested by at least three members of the Supervisory Board having a voting right.

6.7. Voting may also take place by written procedure, unless at least three members of the Supervisory Board having a voting right object. In such case, the item shall be put on the agenda of the subsequent Supervisory Board meeting. A written procedure shall require normally not less than five working days for consideration by each member of the Supervisory Board and a record of any such deliberations in the proceedings of the subsequent Supervisory Board meeting. The absence of an explicit vote by a member of the Supervisory Board in a written procedure shall be deemed as approval.

Article 7

Emergencies

7.1. In case of emergencies, the Chair or, in his/her absence, the Vice-Chair shall convene a meeting of the Supervisory Board in time to take the necessary decisions, as appropriate also by means of teleconferencing by way of derogation from Article 2.4. When convening such a meeting, the Chair or, in his/her absence, the Vice-Chair shall make clear in the invitation letter that, by way of derogation from Article 6.3, if a quorum of 50 % for emergency decisions were not to be met, the meeting will be closed and immediately thereafter an extraordinary meeting, at which decisions may be taken without regard to the quorum, will be opened.

7.2. The Supervisory Board may lay down further internal rules on the adoption of decisions and other measures in situations of emergency.

Article 8

Delegation of power

8.1. The Supervisory Board may authorise the Chair or the Vice-Chair to take, on its behalf and under its responsibility, clearly defined management or administrative measures, including the use of instruments in preparation for a decision to be taken collectively by the members of the Supervisory Board at a later point in time and instruments implementing final decisions taken by the Supervisory Board.

8.2. The Supervisory Board may also ask the Chair or the Vice-Chair to adopt (i) the definitive text of any instrument as defined in Article 8.1 on condition that the substance of such instrument has already been determined in discussion, and/or (ii) final decisions, where such delegation involves limited and clearly defined executive powers, the exercise of which is subject to strict review in the light of objective criteria established by the Supervisory Board.

8.3. The delegations and decisions adopted in accordance with Articles 8.1 and 8.2 shall be recorded in the proceedings of the Supervisory Board meetings.

CHAPTER II

STEERING COMMITTEE

Article 9

The Steering Committee

In accordance with Article 26(10) of Regulation (EU) No 1024/2013, the Steering Committee of the Supervisory Board is hereby established.

*Article 10***Mandate**

10.1. The Steering Committee shall support the activities of the Supervisory Board and shall be responsible for preparing the meetings of the Supervisory Board.

10.2. The Steering Committee shall execute its preparatory tasks in the interest of the European Union as a whole and shall work in full transparency with the Supervisory Board.

*Article 11***Composition and appointment of members**

11.1. The Steering Committee shall be composed of eight members of the Supervisory Board: the Chair and the Vice-Chair of the Supervisory Board, one representative of the European Central Bank (ECB) and five representatives of the national competent authorities.

11.2. The Steering Committee shall be chaired by the Chair of the Supervisory Board or, in the exceptional absence of the Chair, the Vice-Chair.

11.3. The Supervisory Board shall appoint the representatives of the national competent authorities, ensuring a fair balance and rotation between the national competent authorities. The Supervisory Board shall follow a rotation system in accordance with which the national competent authorities shall be allocated to four groups, according to a ranking based on the total consolidated banking assets in the relevant participating Member State. Each group shall have as a minimum one member on the Steering Committee. The Supervisory Board shall review the grouping on an annual basis or whenever a Member State adopts the euro or establishes a close cooperation with the ECB. The rotation of members within each group shall follow the alphabetical order of the names of the participating Member States in their national languages. The classification of the national competent authorities into groups and the assignment of seats on the Steering Committee to the groups are laid down in the Annex.

11.4. The terms of office of the representatives of the national competent authorities as members of the Steering Committee shall be one year.

11.5. The President of the ECB shall appoint the representative of the ECB in the Steering Committee from among the four ECB representatives on the Supervisory Board and determine the respective term of office.

11.6. The list of members of the Steering Committee shall be published and updated regularly.

*Article 12***Steering Committee meetings**

12.1. The dates of the meetings shall be decided by the Steering Committee on a proposal from the Chair. The Chair may also convene meetings whenever he/she deems it necessary. At the request of the Chair, the Steering Committee may also convene by means of teleconferencing, unless at least two members of the Steering Committee object.

12.2. The agenda for each Steering Committee meeting shall be proposed by the Chair and adopted at the beginning of the meeting by the Steering Committee. All members of the Steering Committee may propose items and documents to the Chair for consideration by the Steering Committee.

12.3. The agenda of any meeting of the Steering Committee shall be made available before such meeting to all members of the Supervisory Board. The proceedings of any meeting of the Steering Committee shall be made available to all members of the Supervisory Board prior to the subsequent meeting of the Supervisory Board.

12.4. On a proposal by the Chair, the Steering Committee may decide to invite one or more other members of the Supervisory Board to attend all or part of one of its meetings. When specific issues related to an individual credit institution are discussed, the representative of the national competent authority of the participating Member State in which that credit institution is located shall be invited.

CHAPTER III

FINAL PROVISION

Article 13

Entry into force

These Rules of Procedure shall enter into force on 1 April 2014.

Done at Frankfurt am Main, 31 March 2014.

The Chair of the Supervisory Board

Danièle NOUY

ANNEX

ROTATION SYSTEM

For the purposes of Article 11.3, the following rotation system shall apply, on the basis of the data as at 31 December 2012:

Group	Member State	Number of seats on the Steering Committee
1	DE FR	1
2	ES IT NL	1
3	BE IE EL LU AT PT FI	2
4	EE CY LV MT SI SK	1

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

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

of 1 April 2014

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

(2014/379/EU)

THE COMMITTEE,

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

Whereas:

- (1) The European Union has adopted a new Directive on the transportable pressure equipment ⁽¹⁾ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation;
- (2) Chapter 6, Pressure vessels, of Annex 1 should be amended to reflect these developments;
- (3) The European Union has adopted a new Regulation on construction products ⁽²⁾ (hereinafter the 'Construction Products Regulation');
- (4) The Swiss legislation on construction products (Federal Law and Ordinance on construction products) is in the process of being amended; however, the Swiss ordinance on Accreditation and Designation ⁽³⁾, establishing the relevant framework requirements for the accreditation and designation of Swiss conformity assessment bodies is already in force;
- (5) Chapter 16, Construction products, of Annex 1 should be amended, in a first step, to reflect the adoption of the Construction Products Regulation by the European Union, and, until the adoption of Swiss equivalent legislation, to enable the Parties during an interim period to grant mutual acceptance of conformity assessment results showing compliance with the Construction Products Regulation; once Swiss legislation equivalent with the Construction Products Regulation is adopted, the Parties shall replace this amendment with a subsequent one reflecting the adoption of both the Construction Products Regulation and the revised equivalent Swiss legislation. It is understood that this decision is meant to ensure continuity in the activities of conformity assessment bodies during this interim period, and is without prejudice to the application of the principles of Article 1 of the Agreement;

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

⁽²⁾ 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).

⁽³⁾ Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887).

- (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 6, Pressure vessels, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.
2. The Swiss Confederation shall accept conformity assessment results of EU recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation. The European Union shall accept conformity assessment results of Swiss recognised conformity assessment bodies assessing conformity in accordance with the requirements of the Construction Products Regulation until the amendment of Chapter 16 following the adoption of equivalent Swiss legislation.

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

3. Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.
4. This Decision, done in duplicate, shall be signed by representatives of the Parties in the Committee who are authorized to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation

Christophe PERRITAZ

Signed at Bern, 1 April 2014

On behalf of the European Union

Fernando PERREAU DE PINNINCK

Signed at Brussels, 1 April 2014

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 6, Pressure Vessels should be deleted and replaced by the following:

‘CHAPTER 6

PRESSURE VESSELS

SECTION I

Legislative, regulatory and administrative provisions*Provisions covered by Article 1(2)*

- | | |
|----------------|---|
| European Union | <ol style="list-style-type: none"> 1. Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels (OJ L 264, 8.10.2009, p. 12), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12) 2. Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1), as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) 3. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1), hereinafter referred to as “Directive 2010/35/EU” 4. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13) |
| Switzerland | <ol style="list-style-type: none"> 100. Federal Law of 12 June 2009 on product safety (RO 2010 2573) 101. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631) 102. Ordinance of 20 November 2002 on the safety of simple pressure vessels (RO 2003 107), as last amended on 19 May 2010 (RO 2010 2583) 103. Ordinance of 20 November 2002 on the safety of pressure equipment (RO 2003 38), as last amended on 19 May 2010 (RO 2010 2583) 104. Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO 2012 6607) 105. Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO 2002 4212), as last amended on 31 October 2012 (RO 2012 6535 and 6537) 106. Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway (RO 2012 6541) |

SECTION II

Conformity assessment bodies

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

SECTION III

Designating authorities

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

SECTION IV

Special rules relating to the designation of conformity assessment bodies

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

SECTION V

Additional provisions*1. Simple pressure vessels and pressure equipment*

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

*2. Transportable pressure equipment**1. Market access*

1. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the authorised representative shall indicate its name and address on the certificate of conformity. For the purpose of this obligation; “authorised representative” shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from the manufacturer to act on his behalf in relation to specified tasks.
2. Pursuant to Directive 2010/35/EU or, respectively, the relevant Swiss legislation, the importer shall indicate its name and the address at which it can be contacted either on, or attached to the certificate of conformity. For the purpose of this obligation, “importer” shall mean any natural or legal person established within the European Union or Switzerland who places transportable pressure equipment or parts thereof from a third country on the European Union or on the Swiss market.
3. For the purposes of paragraphs 1 and 2, it shall be sufficient to mention either the importer or the authorised representative.

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

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

3. *Identification of economic operators*

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

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

4. *Mutual assistance of market surveillance authorities*

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

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

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

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

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

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

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

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

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

6. *Safeguard procedure*

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

1. Objections against national measures

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

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

2. Disagreement between the Parties

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

Where the Committee considers that the measure is:

- justified, the Parties shall take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from their market.
- unjustified, the Member State or Switzerland shall withdraw it;

7. *Free movement of transportable pressure equipment*

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

ATTACHMENT B

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

CHAPTER 16

CONSTRUCTION PRODUCTS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraphs 1 and 2:

European Union 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)

Implementing measures:

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. 8)
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 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)
24. 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)
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 (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 1999/89/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/EEC 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/EEC (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 of 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)
99. Commission Implementing Regulation (EU) No 1062/2013 of 30 October 2013 on the format of the European Technical Assessment for construction products (OJ L 289, 31.10.2013, p. 42)

SECTION II

Conformity assessment bodies

1. The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of this Agreement, a list of the conformity assessment bodies.
2. Conformity assessment bodies can be differentiated in three different bodies involved in the assessment and verification of constancy of performance: Product certification body, factory product control certification body and testing laboratory. For the purpose of this Agreement the definitions of Annex V Section 2 to Regulation (EU) No 305/2011 shall apply.

SECTION III

Designating authorities

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

SECTION IV

Special rules relating to the designation of conformity assessment bodies

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

SECTION V

Supplementary provisions**1. *European harmonised standards for construction products***

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

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

2. *European Technical Assessments*

- (a) Switzerland shall be entitled to designate Swiss bodies to issue European Technical Assessments. It shall make sure that designated bodies become members of the European Organisation for Technical Assessment (EOTA) and participate in its work, in particular for developing and adopting European Assessment Documents (EADs) according to Article 19 of Regulation (EU) No 305/2011.

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

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

European Technical Assessments are issued by the Technical Assessment Bodies and are recognised by both Parties for the purpose of this Agreement.

- (b) “Technical Assessment Body” shall mean a public or private law body which is authorised to issue European Technical Assessments.

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

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

3. *Information exchanges*

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

4. *Technical documentation*

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

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

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

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

ATTACHMENT C

Amendments to Annex 1**Chapter 1 (Machinery)**

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

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

Chapter 2 (Personal Protective Equipment)

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

- 'European Union 1. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12)'

Chapter 3 (Toys)

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

- 'European Union 1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1), as last amended by Commission Regulation (EU) No 681/2013 (OJ L 195, 18.7.2013, p. 16) (hereinafter referred to as "Directive 2009/48/EC")
- Switzerland 100. Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 9 November 2011 (RO 2011 5227)
101. Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 23 October 2013 (RO 2013 3669)
102. Ordinance of the Federal Department of Home Affairs (FDHA) of 15 August 2012 on the safety of toys (RO 2012 4717) as last amended on 25 November 2013 (RO 2013 5297)
103. Ordinance of the FDHA of 23 of November 2005 on the enforcement of foodstuff legislation (RO 2005 6555) as last amended on 15 August 2012 (RO 2012 4855)
104. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887)'

Chapter 4 (Medical devices)

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

- European Union
1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)
 2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)
 3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)
 4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17)
 5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43)
 6. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 22, 9.8.2012, p. 3)
 7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41)
 8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98)
 9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21)
 10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63)
 11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50)
 12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)
 13. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45)

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| | 14. | Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28) |
| | 15. | Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8) |
| Switzerland | 100. | Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 14 December 2012 (RO 2013 1493) |
| | 101. | Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 et RS 4 798), as last amended on 20 March 2008 (RO 2008 3437) |
| | 102. | Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2011 (RO 2012 6235) |
| | 103. | Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 10 December 2004 (RO 2004 5391) |
| | 104. | Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 11 June 2010 (RO 2010 2749) |
| | 105. | Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847), as last amended on 4 September 2013 (RO 2013 3041) |
| | 106. | Ordinance of 17 June 1996 on Accreditation and Designation of Conformity Assessment Bodies (RO 1996 1904), as last amended on 15 June 2012 (RO 2012 3631) |
| | 107. | Federal Act on Data Protection of 19 June 1992 (RO 1992 1945), as last amended on 30 September 2011 (RO 2013 3215) |

Chapter 5 (Gas Appliances and Boilers)

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

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| European Union | 1. | Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10) |
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Chapter 7 (Radio Equipment and Telecommunications Terminal Equipment)

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

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|----------------|----|--|
| European Union | 1. | Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) |
| | 2. | Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers (OJ L 97, 19.4.2000, p. 13) |

3. Commission Decision 2000/637/EC of 22 September 2000 on the application of Article 3(3)(e) of Directive 1999/5/EC to radio equipment covered by the regional arrangement concerning radiotelephone service on inland waterways (OJ L 269, 21.10.2000, p. 50)
 4. Commission Decision 2001/148/EC of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons (OJ L 55, 24.2.2001, p. 65)
 5. Commission Decision 2005/53/EC of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS) (OJ L 22, 26.1.2005, p. 14)
 6. Commission Decision 2005/631/EC of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services (OJ L 225, 31.8.2005, p. 28)
 7. Commission Decision 2013/638/EU of 12 August 2013 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS) (OJ L 296, 7.11.2013, p. 22)
- Switzerland
100. Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187), as last amended on 12 June 2009 (RO 2010 2617)
 101. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 31 October 2012 (RO 2012 6561)
 102. Ordinance of 14 June 2002 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2002 2111), as last amended on 12 August 2013 (RO 2013 2649)
 103. Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115), as last amended on 21 November 2005 (RO 2005 5139)
 104. List of technical standards published in the Feuille Fédérale with titles and references, as last amended on 28 December 2012 (FF 2012 9084)
 105. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 9 December 2011 (RO 2012 367)

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

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

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|----------------|------|--|
| European Union | 1. | Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres, as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12) |
| Switzerland | 100. | Federal law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 20 March 2008 (RO 2008 3437) |

101. Ordinance of 2 March 1998 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 1998 963), as last amended on 11 June 2010 (RO 2010 2749)
102. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
103. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631)

Chapter 9 Electrical equipment and Electromagnetic compatibility

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

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| ‘Switzerland | <ol style="list-style-type: none"> 100. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 20 March 2008 (RO 2008 3437) 101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 16 November 2011 (RO 2011 6243) 102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 16 November 2011 (RO 2011 6233) 103. Ordinance of 9 April 1997 on electrical low voltage equipment (RO 1997 1016), as last amended on 11 June 2010 (RO 2010 2749) 104. Ordinance of 18 November 2009 on electromagnetic compatibility (RO 2009 6243), as last amended on 24 August 2010 (RO 2010 3619) 105. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 31 October 2012 (RO 2012 6561) 106. List of the technical standards published in the Feuille Fédérale with titles and references, as last amended on 6 November 2012 (FF 2012 7968) |
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Chapter 11 Measuring instruments and prepackages

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

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|-----------------|--|
| ‘European Union | <ol style="list-style-type: none"> 1. Council Directive 71/347/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain (OJ L 239, 25.10.1971, p. 1), as subsequently amended 2. Council Directive 76/765/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholmeters and alcohol hydrometers (OJ L 262, 27.9.1976, p. 143), as subsequently amended 3. Council Directive 86/217/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (OJ L 152, 6.6.1986, p. 48), as subsequently amended |
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4. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14), as subsequently amended
 5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1), as subsequently amended
 6. Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17) applicable as from 11 April 2009
- Switzerland
100. Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended
 101. Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and pre-packaged products (RS 941.204.1), as subsequently amended

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

- European Union
1. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (Recast) (OJ L 106, 28.4.2009, p. 7)
 2. Council Directive 71/317/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 to 10 kilogramme medium accuracy cylindrical weights (OJ L 202, 6.9.1971, p. 14)
 3. Council Directive 74/148/EEC of 4 March 1974 on the approximation of the laws of the Member States relating to weights of from 1 mg to 50 kg of above-medium accuracy (OJ L 84, 28.3.1974, p. 3)
 4. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40) as last amended by Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009 (OJ L 114, 7.5.2009, p. 10)
 5. Council Directive 76/766/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (OJ L 262, 27.9.1976, p. 149)
 6. Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments (OJ L 122, 16.5.2009, p. 6), as last amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 316, 14.11.2012, p. 12)
 7. European Parliament and Council Directive 2004/22/EC of 31 March 2004 on measuring instruments (2004/22/EC) (OJ L 135, 30.4.2004, p. 1)
- Switzerland
102. Federal Law of 17 June 2011 on metrology (RO 2012 6235)
 103. Ordinance of 23 November 1994 on units measurement (RO 1994 3109), as last amended on 7 December 2012 (RO 2012 7193)

104. Ordinance of 15 February 2006 concerning measuring instruments (RO 2006 1453), as last amended on 7 December 2012 (RO 2012 7207)
105. Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO 2004 2093), as last amended on 7 December 2012 (RO 2012 7183)
106. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO 2006 1433), as last amended on 7 December 2012 (RO 2012 7183)
107. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO 2006 1525), as last amended on 7 December 2012 (RO 2012 7183)
108. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring systems for liquids other than water (RO 2006 1533), as last amended on 7 December 2012 (RO 2012 7183)
109. Ordinance of the federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO 2006 1545), as last amended on 7 December 2012 (RO 2012 7183)
110. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO 2006 1569), as last amended on 7 December 2012 (RO 2012 7183)
111. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO 2006 1591), as last amended on 7 December 2012 (RO 2012 7183)
112. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO 2006 1599), as last amended on 7 December 2012 (RO 2012 7183)
113. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for the electrical energy and power (RO 2006 1613), as last amended on 7 December 2012 (RO 2012 7183)
114. Ordinance of 15 August 1986 on weights (RO 1986 2022), as last amended on 7 December 2012 (RO 2012 7183)

In Section IV, Special rules relating to the designation of conformity assessment bodies, the provision should be deleted and replaced by the following text:

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

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

‘1. *Information exchange*

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

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

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 (EU) No 195/2013 of the Commission of 7 March 2013 (OJ L 65, 8.3.2013, p. 1), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 1 December 2013 (hereinafter together referred to as “Framework Directive 2007/46/EC”)
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| 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 30 November 2012 (RO 2012 7137)

101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 7 December 2012 (RO 2012 7065) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1' |
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Section V, paragraph 1, Amendments to Annex IV respectively to acts listed in Annex IV of Directive 2007/46/EC should be deleted and replaced by the following:

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

Without prejudice to article 12(2), the European Union shall notify Switzerland of amendments to Annex IV and to acts listed in Annex IV of Directive 2007/46/EC after 1 December 2013 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, at the latest by the date of application of these amendments in the European Union.'

Chapter 13 (Agricultural and Forestry Tractors)

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

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

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| European Union | 1. Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)

2. Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, as last amended by Directive 2010/52/EU of the Commission of 11 August 2010 (OJ L 213, 13.8.2010, p. 37)

3. Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)

4. Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81) |
|----------------|--|

5. Council Directive 80/720/EEC of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors, as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
6. Council Directive 86/297/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of wheeled agricultural and forestry tractors and their protection, as last amended by Directive 2012/24/EU of the Commission of 8 October 2012 (OJ L 274, 9.10.2012, p. 24)
7. Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
8. Council Directive 86/415/EEC of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
9. Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, as last amended by Directive 2010/22/EU of the Commission of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
10. Directive 2000/25/EC of the European Parliament and of the Council of 22 May 2000 on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors and amending Council Directive 74/150/EEC as last amended by Directive 2011/87/EU of the European Parliament and the Council of 16 November 2011 (OJ L 301, 18.11.2011, p. 1)
11. Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, as last amended by 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
12. Directive 2008/2/EC of the European Parliament and the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (OJ L 24, 29.1.2008, p. 30)
13. Directive 2009/57/EC of the European Parliament and the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors (OJ L 261, 3.10.2009, p. 1)
14. Directive 2009/58/EC of the European Parliament and the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors (OJ L 198, 30.7.2009, p. 4)
15. Directive 2009/59/EC of the European Parliament and the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (OJ L 198, 30.7.2009, p. 9)
16. Directive 2009/60/EC of the European Parliament and the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors as last amended by Directive 2010/62/EU of the Commission of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)
17. Directive 2009/61/EC of the European Parliament and the Council of 13 July 2009 relating to the installation of lighting and light signalling devices on wheeled agricultural and forestry tractors (OJ L 203, 5.8.2009, p. 19)

18. Directive 2009/63/EC of the European Parliament and the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors (OJ L 214, 19.8.2009, p. 23)
 19. Directive 2009/64/EC of the European Parliament and the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility) (OJ L 216, 20.8.2009, p. 1)
 20. Directive 2009/66/EC of the European Parliament and the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 11)
 21. Directive 2009/68/EC of the European Parliament and the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (OJ L 203, 5.8.2009, p. 52)
 22. Directive 2009/75/EC of the European Parliament and the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (OJ L 261, 3.10.2009, p. 40)
 23. Directive 2009/76/EC of the European Parliament and the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (OJ L 201, 1.8.2009, p. 18)
 24. Directive 2009/144/EC of the European Parliament and the Council of 30 November 2009 on certain components and characteristics of wheeled agricultural or forestry tractors, as last amended by Directive 2013/8/EU of the Commission of 26 February 2013 (OJ L 56, 28.2.2013, p. 8)
 25. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1)
- Switzerland
100. Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 2 March 2012 (RO 2012 1915)
 101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 7 December 2012 (RO 2012 7065)

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 63, 1.3.1994, p. 4) (published on website of the European Commission)
 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 04 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)
- Switzerland
100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 July 2013 (RO 2013 1493)
 101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 January 2013 (RO 2012 3631)
 102. Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 1 January 2013 (RO 2012 5651)
 103. Ordinance of 20 September 2013 on clinical trials in human research (RO 2013 3407)
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