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⁽¹⁾ Text with EEA relevance

I

(Legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) No 55/2013

of 17 December 2012

concerning the extension of the scope of Regulation (EU) No 1214/2011 of the European Parliament and of the Council on the professional cross-border transport of euro cash by road between euro area Member States

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 352 thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

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

Having regard to the opinion of the European Central Bank ⁽¹⁾,

Acting in accordance with a special legislative procedure,

Whereas:

(1) Regulation (EU) No 1214/2011 of the European Parliament and of the Council ⁽²⁾ aims to facilitate the cross-border transport of euro cash between Member States. However, that Regulation only applies to the territory of those Member States which have adopted the euro as their single currency.

(2) In the run-up to the euro changeover in a Member State, there is a need for euro cash to be transported from existing euro area Member States, since euro banknotes needed for the changeover are usually transported from existing euro area stocks, and euro coins are often fully or partly minted abroad.

(3) It is therefore necessary that Regulation (EU) No 1214/2011 apply also to Member States that are preparing to adopt the euro. It should apply from the date of the decision of the Council to abrogate the derogations of the Member States concerned to participate in the euro.

(4) Since the objective of this Regulation, namely to facilitate the professional cross-border transport of euro cash by road between current euro area Member States and Member States about to introduce the euro, cannot be sufficiently achieved by the Member States due to the very detailed and diverging national regulatory regimes on the matter, and can therefore, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1214/2011 shall apply to the territory of a Member State that has not yet adopted the euro as from the date of the decision of the Council to abrogate the derogation of the Member State concerned to participate in the euro, taken in accordance with Article 140(2) of the Treaty on the Functioning of the European Union.

Article 2

This Regulation shall enter into force 12 months after its publication in the *Official Journal of the European Union*.

⁽¹⁾ Opinion of 5 October 2010 (OJ C 278, 15.10.2010, p. 1).

⁽²⁾ OJ L 316, 29.11.2011, p. 1.

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

Done at Brussels, 17 December 2012.

For the Council

The President

S. ALETRARIS

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 56/2013

of 16 January 2013

amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies**(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular the first paragraph of Article 23 thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.
- (2) Article 7(1) of Regulation (EC) No 999/2001 provides that the feeding to ruminants of protein derived from animals is prohibited. Article 7(2) of that Regulation extends that prohibition to animals other than ruminants and restricts that prohibition, as regards the feeding of those animals with products of animal origin, in accordance with Annex IV to that Regulation.
- (3) Annex IV to Regulation (EC) No 999/2001 extends the prohibition provided for in Article 7(1) to the feeding to non-ruminant farmed animals, with the exception of the feeding to carnivorous fur-producing animals, of, inter alia, processed animal protein (PAP). By way of derogation, and under specific conditions, Annex IV authorises certain PAP to be fed to non-ruminant farmed animals.

- (4) Article 11 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) ⁽²⁾ prohibits the feeding of terrestrial animals of a given species other than fur animals with PAP derived from the bodies or parts of bodies of animals of the same species. That Article also prohibits the feeding of farmed fish with PAP derived from the bodies or parts of bodies of farmed fish of the same species.
- (5) The Communication from the Commission to the European Parliament and the Council — The TSE Road Map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015 ⁽³⁾ was adopted on 16 July 2010. It outlines areas where future possible changes to Union legislation on TSEs could be made. It also emphasises that any review of the TSE rules should be primarily driven by scientific advice and technical issues related to the control and enforcement of the new measures.
- (6) That Communication, inter alia, addresses the revision of the current feed ban rules laid down in Union legislation. Based on the contents of two scientific opinions issued by the Panel on Biological Hazards (BIOHAZ) of the European Food Safety Authority (EFSA) on 24 January 2007 ⁽⁴⁾ and on 17 November 2007 ⁽⁵⁾ respectively, the Communication acknowledges that no TSE have been identified as occurring in non-ruminant farmed animals

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.⁽²⁾ OJ L 300, 14.11.2009, p. 1.⁽³⁾ COM/2010/0384.⁽⁴⁾ Opinion of the Scientific Panel on Biological Hazards on a request from the European Parliament on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE, *The EFSA Journal* (2007), 443, 1-26.⁽⁵⁾ Opinion of the Scientific Panel on Biological Hazards on a request from the European Parliament on Certain Aspects related to the Feeding of Animal Proteins to Farm Animals, *The EFSA Journal* (2007) Journal number 576, 1-41.

under natural conditions and that the transmission risk of bovine spongiform encephalopathy (BSE) from non-ruminants to non-ruminants is negligible as long as intra-species recycling is avoided. Consequently, the Communication concludes that a lifting of the ban on the use of PAP from non-ruminants in non-ruminant feed could be considered, but without lifting the existing prohibition on intra-species recycling and only if validated analytical techniques to determine the species origin of PAP are available and a correct channelling of PAP from different species is in place.

- (7) On 29 November 2010, the Council adopted conclusions on that Communication⁽¹⁾. Those conclusions recognise the fundamental importance of the ban on using PAP in feed for farmed animals in preventing the circulation of BSE via the feed chain and thus playing a key role in the reduction of the incidence of that disease in the bovine population. Furthermore, those conclusions consider that it should be a prerequisite of any possible reintroduction of the use of non-ruminant PAPs to feed for other non-ruminant species that effective and validated tests are available to distinguish between PAP originating from different species and also that there has been a careful analysis of the risks of relaxation, regarding animal and public health.
- (8) On 9 December 2010, the BIOHAZ Panel of EFSA adopted a scientific opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs)⁽²⁾. It concluded that 'on the basis of 2009 BSE surveillance data in the Union, assuming a 0,1 % contamination (the limit of detection for PAP in feed) with non-ruminant PAP and according to EFSA's QRA PAP model, the estimated mean total BSE infectivity load that could enter in cattle feed per year in the Union would be equivalent to 0,2 cattle oral infectious dose 50 %'. It estimated that 'this would mean that less than one additional BSE infected animal could be expected in the Union cattle population per year with an upper 95 % confidence'.
- (9) European Parliament resolution of 8 March 2011 on the EU protein deficit: what solution for a long-standing problem⁽³⁾, calls on the Commission to submit a legislative proposal to the Parliament and the Council authorising the use of PAP from slaughtered offal for the production of feed for monogastric animals (pigs and poultry), provided that the ingredients stem from meat

which was approved for human consumption, and that the ban on intra-species recycling and forced cannibalism is fully implemented and controlled.

- (10) European Parliament resolution of 6 July 2011 on EU legislation on Transmissible Spongiform Encephalopathies (TSE) and on related feed and food controls — implementation and outlook⁽⁴⁾ supports, particularly in the light of the existing protein deficit in the Union, the Commission intention to remove the feed ban provisions in Union legislation banning the feeding of PAP to non-ruminants, provided that it applies to non-herbivores, and under certain conditions.
- (11) That resolution calls for the production and sterilisation methods used for processed animal protein to comply with highest safety standards and with the rules laid down in Regulation (EC) No 1069/2009 and the use of the latest and safest technology available. It calls for the existing prohibitions on intra-species recycling to remain in place, that production channels of PAP derived from different species be completely separated, and that the separation of such production channels be controlled by the competent authorities in the Member States and audited by the Commission. In addition, it states that before the lifting of the feed ban is implemented, a reliable species specific method is in place to identify the species origin of the proteins in animal feed containing PAP so that intra-species recycling and the presence of PAP can be excluded, that the production of PAP from category 1 or category 2 material be prohibited and that only category 3 material fit for human consumption be used for the production of PAP. That resolution rejects the use of PAP derived from non-ruminants or ruminants in feed for ruminants.
- (12) On 9 March 2012, the European Union Reference Laboratory for Animal Proteins in feedingstuffs (EURL-AP) validated a new diagnostic DNA-based method which is able to detect very low level of ruminant material that may be present in feed⁽⁵⁾. That method can be used for performing routine controls on PAP and compound feed containing PAP in order to verify the absence of proteins of ruminant origin.
- (13) There is currently no diagnostic method validated which is able to detect the presence of porcine or poultry material in feed. Therefore, it would not be possible to control the correct implementation of the prohibition on

⁽¹⁾ <http://register.consilium.europa.eu/pdf/en/10/st13/st13889-ad01re01.en10.pdf>

⁽²⁾ Opinion of the Scientific Panel on Biological Hazards on a revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal protein (PAPs), *The EFSA Journal* 2011;9(1):1947.

⁽³⁾ Text adopted, P7_TA(2011)0084.

⁽⁴⁾ Text adopted, P7_TA(2011)0328.

⁽⁵⁾ <http://eurl.craw.eu/index.php?page=24&id=10>

intra-species recycling should the use of PAP of porcine origin in poultry feed and the use of poultry PAPs in pig feed be reauthorised.

- (14) Aquaculture production does not present any concern regarding compliance with the intra-species recycling ban as current channelling requirements for the use of fishmeal in feed for aquaculture animals have already proven to be effective.
- (15) With the exception of fishmeal and compound feed containing fishmeal, which are already permitted for feeding non-ruminant animals, PAP from non-ruminant animals and feedingstuffs containing such PAP should therefore be reauthorised for feeding aquaculture animals. Strict requirements during the collection, transport and processing of those products should apply in order to avoid any risk of cross-contamination with ruminant protein. In addition, regular sampling and analysis of the PAP and the compound feed containing this PAP should be performed in order to verify the absence of cross-contamination with ruminant proteins.
- (16) The prohibition to feed aquaculture animals with PAP from non-ruminant animals as laid down in Annex IV to Regulation (EC) No 999/2001 should therefore be deleted. In the interests of clarity of Union legislation, it is appropriate to replace the whole Annex IV by the Annex IV set out in the Annex to this Regulation.
- (17) Point 1 of Annex I to Regulation (EC) No 999/2001 refers to definitions of feedingstuffs and animal by-products not intended for human consumption set out in Union legal acts that have since been repealed. For the

sake of clarity of Union legislation, those references should be replaced by references to the respective definitions contained in legal acts in force. Annex I to Regulation (EC) No 999/2001 should therefore be amended in accordance with the Annex to this Regulation.

- (18) As Member States and the economic operators of the feeding sector need sufficient time to adapt their control procedures to the new requirements introduced by this Regulation, this Regulation should not apply immediately after its entry into force.
- (19) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (20) 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

Annexes I and IV to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

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*.

It shall apply from 1 June 2013.

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

Done at Brussels, 16 January 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annexes I and IV to Regulation (EC) No 999/2001 are amended as follows:

(1) Annex I, point 1 is replaced by the following:

‘1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*), Commission Regulation (EU) No 142/2011 (**), Regulation (EC) No 178/2002 of the European Parliament and of the Council (***), Regulation (EC) No 767/2009 of the European Parliament and of the Council (****) and Council Directive 2006/88/EC (*****) shall apply:

(a) the definition of “farmed animal” in Article 3(6) of Regulation (EC) No 1069/2009;

(b) the following definitions in Annex I to Regulation (EU) No 142/2011:

(i) “fur animals” in point 1;

(ii) “blood products” in point 4;

(iii) “processed animal protein” in point 5;

(iv) “fishmeal” in point 7;

(v) “collagen” in point 11;

(vi) “gelatine” in point 12;

(vii) “hydrolysed proteins” in point 14;

(viii) “canned petfood” in point 16;

(ix) “petfood” in point 19;

(x) “processed petfood” in point 20;

(c) the definition of “feed” in Article 3(4) of Regulation (EC) No 178/2002;

(d) Regulation (EC) No 767/2009:

(i) “feed materials” in Article 3(2)(g);

(ii) “compound feed” in Article 3(2)(h);

(iii) “complete feed” in Article 3(2)(i);

(e) Directive 2006/88/EC:

(i) “aquaculture animal” in Article 3(1)(b);

(ii) “aquatic animal” in Article 3(1)(e).

(*) OJ L 300, 14.11.2009, p. 1.

(**) OJ L 54, 26.2.2011, p. 1.

(***) OJ L 31, 1.2.2002, p. 1.

(****) OJ L 229, 1.9.2009, p. 1.

(*****) OJ L 328, 24.11.2006, p. 14.’;

(2) Annex IV is replaced by the following:

‘ANNEX IV

ANIMAL FEEDING

CHAPTER I

Extensions of the prohibition provided for in Article 7(1)

In accordance with Article 7(2), the prohibition provided for in Article 7(1) shall be extended to the feeding:

- (a) to ruminants of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing these products;

(b) to non-ruminant farmed animals, other than fur animals, of:

- (i) processed animal protein;
- (ii) collagen and gelatine of ruminant origin;
- (iii) blood products;
- (iv) hydrolysed protein of animal origin;
- (v) dicalcium phosphate and tricalcium phosphate of animal origin;
- (vi) feed containing the products listed in (i) to (v).

CHAPTER II

Derogations from the prohibitions provided for in Article 7(1) and in Chapter I

In accordance with the first subparagraph of Article 7(3), the prohibitions provided for in Article 7(1) and in Chapter I shall not apply to the feeding to:

(a) ruminants of:

- (i) milk, milk-based products, milk-derived products, colostrum and colostrum products;
- (ii) eggs and egg products;
- (iii) collagen and gelatine derived from non-ruminants;
- (iv) hydrolysed proteins derived from:
 - parts of non-ruminants, or
 - ruminant hides and skins;

(v) compound feed containing the products listed in points (i) to (iv) above;

(b) non-ruminant farmed animals of the following feed materials and compound feed:

- (i) hydrolysed proteins derived from parts of non-ruminants or from ruminant hides and skins;
- (ii) fishmeal and compound feed containing fishmeal which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section A of Chapter IV;
- (iii) dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section B of Chapter IV;
- (iv) blood products derived from non-ruminants and compound feed containing such blood products which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section C of Chapter IV;

(c) aquaculture animals of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such processed animal protein which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section D of Chapter IV;

(d) unweaned ruminants of milk replacers containing fishmeal and which are produced, placed on the market and used in accordance with specific conditions laid down in Section E of Chapter IV;

(e) farmed animals of feed materials of plant origin and compound feed containing such feed materials contaminated with insignificant amount of bone spicules derived from unauthorised animal species. Member States may only use this derogation if they have carried out a risk assessment beforehand which has confirmed there is a negligible risk for animal health. That risk assessment must take into account at least the following:

- (i) the level of the contamination;
- (ii) the nature and the source of the contamination;
- (iii) the intended use of the contaminated feed.

CHAPTER III

General conditions for the application of certain derogations provided for in Chapter II

SECTION A

Transport of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals

1. The following products intended to be used for feeding non-ruminant farmed animals, shall be transported in vehicles and containers which are not used for the transport of feed intended for ruminants:
 - (a) bulk processed animal protein, including fishmeal, derived from non-ruminants;
 - (b) bulk dicalcium and tricalcium phosphate of animal origin;
 - (c) bulk blood products derived from non-ruminants;
 - (d) bulk compound feed containing the feed materials listed in (a), (b) and (c).

Records detailing the type of products that were transported shall be kept available to the competent authority for a period of at least two years.

2. By way of derogation from point 1, vehicles and containers which have been previously used for the transport of the products listed in that point, may be subsequently used for the transport of feed intended for ruminants provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

3. Bulk processed animal protein derived from non-ruminants and bulk compound feed containing processed animal protein derived from such animals shall be transported in vehicles and containers which are not used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals.
4. By way of derogation from point 3, vehicles and containers which have been previously used for the transport of the products referred to in that point may be subsequently used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

SECTION B

Production of compound feed intended to be used for feeding non-ruminant farmed animals

1. Compound feed intended to be used for feeding non-ruminant farmed animals and which contain the following feed materials, shall be produced in establishments which do not produce compound feed for ruminants, and which are authorised by the competent authority:
 - (a) fishmeal;
 - (b) dicalcium and tricalcium phosphate of animal origin;
 - (c) blood products derived from non-ruminants.
2. By way of derogation from point 1, the production of compound feed for ruminants, in establishments which also produce compound feed for non-ruminant farmed animals which contains the products listed in that point, may be authorised by the competent authority, following an on-site inspection by it, subject to compliance with the following conditions:
 - (a) compound feed intended for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminants are manufactured and kept;

- (b) records detailing the purchases and uses of the products listed in point 1 and the sales of compound feed containing those products must be kept available to the competent authority for a period of at least five years;
 - (c) regular sampling and analysis of the compound feed intended for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Commission Regulation (EC) No 152/2009 (*); the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.
3. By way of derogation from point 1, a specific authorisation for the production of complete feed from compound feed containing the products listed in that point shall not be required for home compounders subject to their compliance with the following conditions:
- (a) they must be registered by the competent authority;
 - (b) they must keep only non-ruminant animals;
 - (c) they must produce complete feed for use only in the same holding;
 - (d) any compound feed containing fishmeal used in the production of the complete feed must contain less than 50 % crude protein;
 - (e) any compound feed containing dicalcium and tricalcium phosphate of animal origin used in the production of the complete feed must contain less than 10 % total phosphorus;
 - (f) any compound feed containing blood products derived from non- ruminants used in the production of the complete feed must contain less than 50 % total protein.

SECTION C

Import of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals other than fur animals

Before release for free circulation in the Union, importers shall ensure that each of the consignment of the following feed materials and compound feed, which are intended to be used for the feeding of non-ruminant farmed animals, other than fur animals, in accordance with Chapter II of this Annex, is analysed in accordance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin:

- (a) processed animal protein, including fishmeal, derived from non-ruminants;
- (b) blood products derived from non-ruminants;
- (c) compound feed containing the feed materials listed in (a) and (b).

SECTION D

Use and storage on farms of feed intended to be used for feeding non-ruminant farmed animals

1. The use and storage of the following feed shall be prohibited on farms keeping farmed animal species for which such feed is not intended:
- (a) processed animal protein, including fishmeal, derived from non-ruminants;
 - (b) dicalcium and tricalcium phosphate of animal origin;
 - (c) blood products derived from non-ruminants;
 - (d) compound feed containing the feed materials listed in (a) to (c).
2. By way of derogation from point 1, the competent authority may authorise the use and storage of compound feed referred to in point 1(d) in farms keeping farmed animal species for which the compound feed is not intended provided that on-farm measures are implemented to prevent such compound feed being fed to an animal species for which it is not intended.

CHAPTER IV

Specific conditions for the application of derogations provided for in Chapter II

SECTION A

Specific conditions applicable to the production and the use of fishmeal and compound feed containing fishmeal intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of fishmeal and compound feed containing fishmeal intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

- (a) the fishmeal must be produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals;
- (b) the accompanying commercial document or health certificate, as appropriate, of fishmeal and compound feed containing fishmeal and any packaging containing such products must be clearly marked with the words “contains fishmeal — shall not be fed to ruminants”.

SECTION B

Specific conditions applicable to the use of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates intended to be used for feeding non-ruminant farmed animals other than fur animals

The accompanying commercial document or health certificate, as appropriate, of dicalcium phosphate or tricalcium phosphate of animal origin, compound feed containing such phosphates and any packaging of such products shall be clearly marked with the words “contains dicalcium/tricalcium phosphate of animal origin — shall not be fed to ruminants”.

SECTION C

Specific conditions applicable to the production and use of blood products derived from non-ruminants and compound feed containing those products intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of blood products derived from non-ruminants and to compound feed containing such blood products, intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

- (a) The blood intended to be used for the production of blood products shall be derived from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant blood intended for the production of blood products for use in feed for non-ruminant farmed animals.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant blood.

Those measures shall include the following minimum requirements:

- (i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from lines used for the slaughtering of ruminants;
 - (ii) the collection, storage, transport and packaging facilities for blood of non-ruminant origin must be kept separate from those used for blood of ruminant origin;
 - (iii) a regular sampling and analysis of blood of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis must be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.
- (b) The blood intended to be used for the production of blood products for non-ruminants shall be transported to a processing plant in vehicles and containers dedicated exclusively for the transport of non-ruminant blood.

By way of derogation from that specific condition, vehicles and containers which have been previously used for the transport of blood derived from ruminants may be used for the transport of non-ruminant blood provided that they have been thoroughly cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

- (c) The blood products shall be produced in processing plants exclusively processing non-ruminant blood.

By way of derogation from that specific condition, the competent authority may authorise the production of blood products for use in feed for non-ruminant farmed animals in processing plants processing ruminant blood.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination.

Those measures shall include the following minimum requirements:

- (i) the production of non-ruminant blood products must be carried out in a closed system that is kept physically separated from that used for the production of ruminant blood products;
 - (ii) the collection, storage, transport and packaging facilities for bulk raw material and bulk finished products of non-ruminant origin must be kept separate from those for bulk raw material and bulk finished of ruminant origin;
 - (iii) an ongoing reconciliation process between the incoming blood respectively derived from ruminants and non-ruminants and the corresponding blood products must be applied;
 - (iv) a regular sampling and analysis of blood products of non ruminant origin must be carried out to verify the absence of cross-contamination with blood products of ruminant origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.
- (d) The accompanying commercial document or health certificate, as appropriate, of the blood products, compound feed containing blood products and any packaging of these products must be clearly marked with the words "contains blood products — shall not be fed to ruminants".

SECTION D

Specific conditions applicable to the production and use of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such processed animal protein intended to be used for feeding aquaculture animals

The following specific conditions shall apply to the production and use of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such protein intended to be used for feeding aquaculture animals:

- (a) The animal by-products intended to be used for the production of processed animal protein referred to in this Section shall be derived either from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants or from cutting plants which do not bone or cut up ruminant meat.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant animal by-products intended for the production of processed animal protein referred to in this Section.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant by-products.

Those measures shall include the following minimum requirements:

- (i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from those used for the slaughtering of ruminants;
- (ii) the collection, storage, transport and packaging facilities for animal by-products of non-ruminant origin must be kept separate from those for animal by-products of ruminant origin;
- (iii) a regular sampling and analysis of animal by-products of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.

- (b) The animal by-products of non-ruminant origin intended to be used for the production of processed animal protein referred to in this Section shall be transported to a processing plant in vehicles and containers which are not used for the transport of animal by-products of ruminant origin.

By way of derogation from that specific condition, they may be transported in vehicles and containers which have been previously used for the transport of animal by-products derived from ruminants, provided that those vehicles and containers have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

- (c) The processed animal protein referred to in this Section shall be produced in processing plants that are dedicated exclusively to processing non-ruminant animal by-products sourced from slaughterhouses and cutting plants referred to in point (a).

By way of derogation from that specific condition, the competent authority may authorise the production of processed animal protein referred to in this Section in processing plants processing ruminant animal by-products.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of the measures aimed to prevent cross-contamination between processed animal protein of ruminant origin and processed animal protein of non-ruminant origin.

Those preventive measures shall include the following minimum requirements:

- (i) the production of processed animal protein derived from ruminants must be carried out in a closed system that is physically separated from that used for the production of the processed animal protein referred to in this Section;
 - (ii) the keeping of animal by-products derived from ruminants during storage and transport in facilities that are physically separated from those for animal by-products derived from non-ruminants;
 - (iii) the keeping of processed animal protein derived from ruminants during storage and packaging in facilities that are physically separated from those used for finished products derived from non-ruminants;
 - (iv) regular sampling and analysis of the processed animal protein referred to in this Section must be carried out to verify the absence of cross-contamination with ruminant processed animal protein using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.
- (d) Compound feed containing processed animal protein referred to in this Section shall be produced in establishments authorised for that purpose by the competent authority and which are dedicated exclusively to the production of feed for aquaculture animals.

By way of derogation from that specific condition:

- (i) the production of compound feed for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, except fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:
 - compound feed destined for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminant animals are manufactured and kept;
 - compound feed destined for aquaculture animals must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for other non-ruminant animals are manufactured and kept;
 - records detailing the purchases and uses of processed animal protein referred to in this Section and the sales of compound feed containing such protein must be kept available to the competent authority for a period of at least five years;
 - regular sampling and analysis of the compound feed destined for farmed animals other than aquaculture animals in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;

- (ii) a specific authorisation for the production of complete feed from compound feed containing processed animal protein referred to in this Section shall not be required for home compounders that comply with the following conditions:
 - they are registered by the competent authority,
 - they keep only aquaculture animals,
 - they produce complete feed for aquaculture animals for use only in the same holding, and
 - the compound feed containing processed animal protein referred to in this Section used in their production contains less than 50 % total protein.
- (e) The accompanying commercial document or health certificate, as appropriate, of processed animal protein referred to in this Section and any packaging shall be clearly marked with the following words: “processed animal protein derived from non ruminants — shall not be used for the production of feed for farmed animals except aquaculture animals and fur animals”.

The accompanying commercial document or health certificate, as appropriate, of the compound feed for aquaculture animals containing processed animal protein referred to in this Section and any packaging shall be clearly marked the following words: “contains processed animal protein derived from non ruminants — shall not be fed to farmed animals except aquaculture animals and fur animals”.

SECTION E

Specific conditions applicable to the production, placing on the market and use of milk replacers containing fishmeal for the feeding of unweaned ruminants

The following specific conditions shall apply to the production, placing on the market and use of milk replacers containing fishmeal in the feeding of unweaned farmed animals of the ruminant species:

- (a) The fishmeal used in milk replacers shall be produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals, and shall comply with general conditions laid set out in Chapter III.
- (b) The use of fishmeal for unweaned farmed animals of the ruminant species shall only be authorised for the production of milk replacers, distributed in dry form and administered after dilution in a given quantity of liquid, intended for the feeding of unweaned ruminants as a supplement to, or substitute for, post-colostral milk before weaning is complete.
- (c) Milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be produced in establishments which do not produce other compound feed for ruminants and which are authorised for this purpose by the competent authority.

By way of derogation from that special condition, the production of other compound feed for ruminants in establishments which also produce milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

- (i) other compound feed destined for ruminants must be kept in facilities that are physically separate from those used for bulk fishmeal and bulk milk replacers containing fishmeal during storage, transport and packaging;
- (ii) other compound feed destined for ruminants must be manufactured in facilities that are physically separate from facilities where milk replacers containing fishmeal are manufactured;
- (iii) records detailing the purchases and uses of fishmeal and the sales of milk replacers containing fishmeal must be kept available to the competent authority for a period of at least five years;
- (iv) regular sampling and analysis of the other compound feed destined for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years.

- (d) Before release for free circulation in the Union, importers shall ensure that each consignment of imported milk replacers containing fishmeal is analysed in accordance with methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin.
- (e) The accompanying commercial document or health certificate, as appropriate, of milk replacers containing fishmeal, intended for unweaned farmed animals of the ruminant species, and any packaging containing such milk replacers, must be clearly marked with the words "*contains fishmeal — shall not be fed to ruminants except unweaned ruminants*".
- (f) Bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be transported by means of vehicles and containers which are not used for the transport of other feed intended for ruminants.

By way of derogation from that special condition, vehicles and containers which will be subsequently used for the transport of other bulk feed intended for ruminants may be used for the transport of bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species provided that such vehicles and containers have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

- (g) On farms where ruminants are kept, on-farm measures shall be in place to prevent milk replacers containing fishmeal being fed to other ruminants than unweaned ruminants. The competent authority shall establish a list of farms where milk replacers containing fishmeal are used through a system of prior notification by the farm or another system thereby ensuring compliance with this specific condition.

CHAPTER V

General requirements

SECTION A

Listing

Member States shall keep up-to-date and make publicly available lists of:

- (a) slaughterhouses from which blood produced in accordance with point (a) of Section C of Chapter IV can be sourced;
- (b) authorised processing plants producing blood products in accordance with point (c) of Section C of Chapter IV;
- (c) slaughterhouses and cutting plants from which animal by-products intended to be used for the production of processed animal protein in accordance with point (a) of Section D of Chapter IV can be sourced;
- (d) authorised processing plants producing processed animal protein derived from non-ruminants which operate in accordance with point (c) of Section D of Chapter IV;
- (e) authorised establishments referred to in Section B of Chapter III, in point (d) of Section D of Chapter IV and in point (c) of Section E of Chapter IV;
- (f) home compounders which have been registered and operate in accordance with the conditions laid down in Section B of Chapter III and point (d) of Section D of Chapter IV.

SECTION B

Transport of feed materials and compound feed containing products derived from ruminants

1. Bulk feed materials and bulk compound feed containing products derived from ruminants other than those listed in the following points (a), (b) and (c) shall be transported in vehicles and containers which are not used for the transport of feed intended for farmed animals other than fur animals:
 - (a) milk, milk-based products, milk-derived products, colostrum and colostrum products;
 - (b) dicalcium and tricalcium phosphate of animal origin;
 - (c) hydrolysed proteins derived from ruminant hides and skins.

2. By way of derogation from point 1, vehicles and containers which have been previously used for the transport of bulk feed materials and bulk compound feed listed in that point, may be used for the transport of feedingstuffs intended for farmed animals other than fur animals provided that they have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of this use shall be kept available to the competent authority for a period of at least two years.

SECTION C

Production of compound feed containing products derived from ruminants

Compound feed which contains products derived from ruminants other than those listed in points (a), (b) and (c) shall not be produced in establishments which produce feed for farmed animals other than fur animals:

- (a) milk, milk-based products, milk-derived products, colostrum and colostrum products;
- (b) dicalcium and tricalcium phosphate of animal origin;
- (c) hydrolysed proteins derived from ruminant hides and skins.

SECTION D

Use and storage on farms of feed materials and compound feed for farmed animals containing products derived from ruminants

The use and storage of feed materials and compound feed for farmed animals containing products derived from ruminants other than those listed in points (a), (b) and (c) shall be prohibited in farms keeping farmed animals other than fur animals:

- (a) milk, milk-based products, milk-derived products, colostrum and colostrum products;
- (b) dicalcium and tricalcium phosphate of animal origin;
- (c) hydrolysed proteins derived from ruminant hides and skins.

SECTION E

Export of processed animal protein and products containing such protein

1. The export of processed animal protein derived from ruminants, and of products containing such protein shall be prohibited.

By way of derogation, that prohibition shall not apply to processed petfood including canned petfood which contains processed animal protein derived from ruminants and which has undergone treatment and which is labelled in accordance with Union legislation.

2. The export of processed animal protein derived from non-ruminants, and of products containing such protein, shall only be authorised subject to compliance with the following conditions:
 - (a) they are destined for uses not prohibited by Article 7 and this Annex;
 - (b) a written agreement is concluded prior the exportation between the competent authority of the exporting Member State, or the Commission, and the competent authority of the importing third country which includes an undertaking from the importing third country to respect the intended use and not to re-export the processed animal protein or the products containing such protein for uses prohibited by Article 7 and this Annex.
3. Written agreements concluded in accordance with point 2(b) above shall be presented in the framework of the Standing Committee on the Food Chain and Animal Health.
4. Points 2 and 3 shall not apply to the export of the following:
 - (a) fishmeal and compound feed containing fishmeal;
 - (b) compound feed intended for aquaculture animals;
 - (c) petfood.

SECTION F

Official controls

1. Official controls carried out by the competent authority in order to verify compliance with the rules laid down set out in this Annex shall include inspections and sampling for analysis on processed animal protein and feed in compliance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009.
2. The competent authority shall verify on a regular basis the competence of laboratories carrying out analyses for such official controls, in particular by evaluating the results of inter-proficiency tests.

If the competence is considered unsatisfactory, a retraining of the laboratory staff shall be undertaken by the laboratory as the minimal corrective measure, prior to carrying out further analyses.

(*) OJ L 54, 26.2.2009, p. 1.

COMMISSION REGULATION (EU) No 57/2013**of 23 January 2013****amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries****(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 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste ⁽¹⁾, and in particular the third subparagraph of Article 37(2) thereof,

Whereas:

- (1) The Annex to Commission Regulation (EC) No 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of wastes does not apply ⁽²⁾ was amended by Regulation (EU) No 674/2012 ⁽³⁾.
- (2) Pursuant to Article 37(1) and (2) of Regulation (EC) No 1013/2006, the Commission took into account the reply received from Malaysia to its written request. Malaysia subsequently stated in writing that the information

provided in its reply regarding the sub-entry B1100 — hard zinc spelter and the entries B3010 and GH013 did not reflect the existing legislation and procedures, which did not prohibit imports of those wastes. It requested, therefore, that the procedure for the sub-entry B1100 — hard zinc spelter is changed from option (a) to option (c) and for the entries B3010 and GH013 from option (a) to option (d).

- (3) In order to rectify this mistake and considering the impact on economic operators, the Annex to Regulation (EC) No 1418/2007 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1418/2007 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the fourteenth 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, 23 January 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 190, 12.7.2006, p. 1.

⁽²⁾ OJ L 316, 4.12.2007, p. 6.

⁽³⁾ OJ L 196, 24.7.2012, p. 12.

ANNEX

The Annex to Regulation (EC) No 1418/2007 is amended as follows:

1. The following entry for Malaysia:

'B1020-B1100'			
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is replaced by the following entries:

'B1020-B1100, except for hard zinc spelter from B1100		from B1100: — Hard zinc spelter'	
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2. The following entry for Malaysia:

'B3010'			
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is replaced by the following entry:

			'B3010'
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3. The following entry for Malaysia:

'GG030-GH013'			
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is replaced by the following entries:

'GG030-GG040			
			GH013'

COMMISSION IMPLEMENTING REGULATION (EU) No 58/2013**of 23 January 2013****amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾, and in particular Article 247 thereof,

Whereas:

- (1) Commission Regulation (EC) No 1875/2006 of 18 December 2006 amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽²⁾ introduced the concept of authorised economic operators (AEO). Economic operators who fulfil the conditions for obtaining the full AEO or AEO Security and safety status should be considered as reliable partners in the supply chain and therefore benefit from facilitations with regard to customs controls relating to security and safety.
- (2) The Union recognises the trade partnership programmes of certain third countries that have been developed in accordance with the World Customs Organization Framework of Standards to Secure and Facilitate Global Trade. Consequently, the Union grants facilitations to those economic operators of a third country who hold a membership status under the customs authority's

programme of that third country. It is therefore necessary to introduce means to identify in entry summary declarations the economic operators holding a membership status under trade partnership programmes of third countries. The relevant facilitations will not be provided without proper identification of those economic operators in the entry summary declarations.

- (3) It is therefore appropriate to adapt Annex 30a to Commission Regulation (EEC) No 2454/93 ⁽³⁾ in order to allow indication of economic operators' third country unique identification number.
- (4) Regulation (EEC) No 2454/93 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Annex 30a to Regulation (EEC) No 2454/93 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 31 January 2013.

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

Done at Brussels, 23 January 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 360, 19.12.2006, p. 64.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

ANNEX

In Annex 30a of Regulation (EEC) No 2454/93, in Section 4, 'Data elements explanatory notes', the third paragraph of the data element explanatory note 'Consignor' 'Entry summary declarations' is replaced by the following:

'Entry summary declarations':

This information takes the form of the consignor EORI number whenever this number is available to the person lodging the summary declaration.

Where facilitations are granted in the framework of a third country traders' partnership programme which is recognised by the Union, this information may take the form of a third country unique identification number which has been made available to the Union by the third country concerned. That number may be used whenever available to the person lodging the summary declaration.

The structure of the number is as follows:

Field	Content	Field type	Format	Examples
1	Identifier of the third country (ISO alpha 2 country code)	Alphabetic 2	a2	US JP
2	Unique identification number in a third country	Alphanumeric up to 15	an..15	1234567890ABCDE AbCd9875F pt20130101aa

Examples: "US1234567890ABCDE" for a consignor in the US (country code: US) whose unique identification number is 1234567890ABCDE. "JPAbCd9875F" for a consignor in Japan (country code: JP) whose unique identification number is AbCd9875F. "USpt20130101aa" for a consignor in the US (country code: US) whose unique identification number is pt20130101aa.

Identifier of the third country: the Union's alphabetical codes for countries and territories are based on the current ISO alpha 2 codes (a2) insofar as they are compatible with the country codes laid down in accordance with Article 5(2) of Regulation (EC) No 471/2009 of the European Parliament and of the Council of 6 May 2009 on Community statistics relating to external trade with non-member countries and repealing Council Regulation (EC) No 1172/95 (*).

(*) OJ L 152, 16.6.2009, p. 23.'

COMMISSION IMPLEMENTING REGULATION (EU) No 59/2013

of 23 January 2013

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance monensin

(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 of 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 ('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 should 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 of 22 December 2009 on pharmacologically active substances and their classification regarding MRL in foodstuffs of animal origin⁽²⁾.
- (3) Monensin 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, fat, liver, kidney and milk.

- (4) An application for the modification of the existing entry for monensin has been submitted to the European Medicines Agency.
- (5) Additional data was provided by the applicant and assessed by the Committee for Medicinal Products for Veterinary Use. As a result that Committee recommends the modification of the current MRLs for monensin.
- (6) The entry for monensin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (7) 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.
- (8) 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 25 March 2013.

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

Done at Brussels, 23 January 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ OJ L 15, 20.1.2010, p. 1.

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance monensin 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
Monensin	Monensin A	Bovine	2 µg/kg 10 µg/kg 50 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Anti-infectious agents/Antibiotics'

COMMISSION IMPLEMENTING REGULATION (EU) No 60/2013**of 23 January 2013****amending for the 185th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al Qaida network**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network,⁽¹⁾ and in particular Article 7(1)(a) and 7a(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 14 January 2013 the Sanctions Committee of the United Nations Security Council decided to remove one natural person from its list of persons, groups and

entities to whom the freezing of funds and economic resources should apply after considering the de-listing request submitted by this person and the Comprehensive Report of the Ombudsperson established pursuant to United Nations Security Council Resolution 1904(2009).

(3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 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*.

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

Done at Brussels, 23 January 2013.

*For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments*

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

The following entry the heading 'Natural persons' is deleted:

'Adel Abdul Jalil Ibrahim Batterjee (*alias* (a) 'Adil Al-Battarjee, (b) Adel Batterjee, (c) 'Adil 'Abd al Jalil Batarji, (d) Adel AbdulJaleel I. Batterjee). Address: 2 Helmi Kutbi Street, Jeddah, Saudi Arabia. Date of birth: (a) 1.7.1946, (b) 1.6.1946. Place of birth: Jeddah, Saudi Arabia. Nationality: Saudi Arabian. Passport No: F 572010 (issued on 22.12.2004, expiring on 28.10.2009.)'

COMMISSION IMPLEMENTING REGULATION (EU) No 61/2013**of 23 January 2013****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 multi-lateral 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, 23 January 2013.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
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	MA	65,3
	TN	84,9
	TR	103,3
	ZZ	84,5
0707 00 05	EG	200,0
	JO	182,1
	MA	158,2
	TR	166,4
	ZZ	176,7
0709 91 00	EG	128,6
	ZZ	128,6
0709 93 10	EG	105,4
	MA	92,6
	TR	138,3
	ZZ	112,1
0805 10 20	EG	54,1
	MA	56,8
	TN	54,0
	TR	63,8
	ZA	46,1
	ZZ	55,0
0805 20 10	MA	89,0
	ZZ	89,0
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	180,3
	KR	138,2
	MA	158,2
	TR	84,6
	ZZ	140,3
0805 50 10	EG	56,9
	TR	74,0
	ZZ	65,5
0808 10 80	CN	100,8
	MK	35,9
	US	176,0
	ZZ	104,2
0808 30 90	CN	51,8
	US	132,9
	ZZ	92,4

⁽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'.

COMMISSION IMPLEMENTING REGULATION (EU) No 62/2013**of 23 January 2013****fixing an acceptance percentage for the issuing of export licences, rejecting export-l licence applications and suspending the lodging of export-l licence applications for out-of-quota sugar**

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 Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ⁽²⁾, and in particular Article 7e in conjunction with Article 9(1) thereof,

Whereas:

- (1) According to Article 61, first subparagraph, point (d) of Regulation (EC) No 1234/2007 the sugar produced during the marketing year in excess of the quota referred to in Article 56 of that Regulation may be exported only within the quantitative limit fixed by the Commission.
- (2) Commission Implementing Regulation (EU) No 394/2012 of 8 May 2012 fixing the quantitative limit for the exports of out-of-quota sugar and isoglucose until the end of the 2012/2013 marketing year ⁽³⁾ sets the abovementioned limits.

- (3) The quantities of sugar covered by applications for export licences exceed the quantitative limit fixed by Implementing Regulation (EU) No 394/2012. An acceptance percentage should therefore be set for quantities applied for from 14 to 18 January 2013. All export-l licence applications for sugar lodged after 18 January 2013 should accordingly be rejected and the lodging of export-l licence applications should be suspended,

HAS ADOPTED THIS REGULATION:

Article 1

1. Export licences for out-of-quota sugar for which applications were lodged from 14 to 18 January 2013 shall be issued for the quantities applied for, multiplied by an acceptance percentage of 40,367343 %.
2. Applications for out-of-quota sugar export licences submitted on 21, 22, 23, 24 and 25 January 2013 are hereby rejected.
3. The lodging of applications for out-of-quota sugar export licences shall be suspended for the period 28 January 2013 to 30 September 2013.

Article 2

This Regulation shall enter into force on the day following 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, 23 January 2013.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 123, 9.5.2012, p. 30.

COMMISSION IMPLEMENTING REGULATION (EU) No 63/2013**of 23 January 2013****amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 892/2012 for the 2012/13 marketing year**

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 Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ⁽²⁾, and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

- (1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2012/13 marketing year are fixed by Commission Implementing Regulation (EU) No 892/2012 ⁽³⁾. Those prices and duties were last amended by Commission Implementing Regulation (EU) No 48/2013 ⁽⁴⁾.

- (2) The data currently available to the Commission indicate that those amounts should be amended in accordance with Article 36 of Regulation (EC) No 951/2006.

- (3) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Implementing Regulation (EU) No 892/2012 for the 2012/13 marketing year, are hereby amended as set out in the Annex hereto.

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, 23 January 2013.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 263, 28.9.2012, p. 37.

⁽⁴⁾ OJ L 18, 22.1.2013, p. 15.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 24 January 2013

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 12 10 ⁽¹⁾	31,88	1,59
1701 12 90 ⁽¹⁾	31,88	5,16
1701 13 10 ⁽¹⁾	31,88	1,72
1701 13 90 ⁽¹⁾	31,88	5,59
1701 14 10 ⁽¹⁾	31,88	1,72
1701 14 90 ⁽¹⁾	31,88	5,59
1701 91 00 ⁽²⁾	36,96	6,75
1701 99 10 ⁽²⁾	36,96	3,25
1701 99 90 ⁽²⁾	36,96	3,25
1702 90 95 ⁽³⁾	0,37	0,30

⁽¹⁾ For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.⁽²⁾ For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.⁽³⁾ Per 1 % sucrose content.

DECISIONS

COUNCIL IMPLEMENTING DECISION

of 22 January 2013

amending Implementing Decision 2011/77/EU on granting Union financial assistance to Ireland

(2013/48/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) No 407/2010 of 11 May 2010 establishing a European financial stabilisation mechanism ⁽¹⁾, and in particular Article 3(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Upon a request by Ireland, the Council granted financial assistance to it by means of Implementing Decision 2011/77/EU ⁽²⁾ in support of a strong economic and financial reform programme aiming at restoring confidence, enabling the economy to return to sustainable growth, and safeguarding financial stability in Ireland, the euro area and the Union.

(2) In line with Article 3(9) of Implementing Decision 2011/77/EU, the European Commission, together with the International Monetary Fund (IMF) and in liaison with the European Central Bank (ECB), has conducted the eighth review of the Irish authorities' progress on the implementation of the agreed measures as well as of the effectiveness and economic and social impact of those measures.

(3) Significant progress has been made towards the programme's bank deleveraging objectives. Specifically, two domestic banks have either already met or are well on their way towards meeting the 122,5 % loan-to-deposit ratio (LDR) target, originally envisaged to be met by the end of 2013. The remaining domestic bank has completed some non-core asset disposals and its programme deleveraging requirements will be reassessed following a decision on its restructuring plan by the European Commission.

(4) In view of that significant progress, a modification of the programme's monitoring framework for banks'

deleveraging towards nominal non-core asset disposal targets and advanced monitoring designed to ensure that banks improve their net stable funding ratios (NSFRs) and their liquidity coverage ratios (LCRs) would contribute to avoiding any undue distortion in banks' deposit pricing and prepare banks for compliance with Basel III liquidity requirements.

(5) In light of those developments and considerations, Implementing Decision 2011/77/EU should be amended,

HAS ADOPTED THIS DECISION:

Article 1

Article 3 of Implementing Decision 2011/77/EU is amended as follows:

(1) in paragraph 8, point (c) is replaced by the following:

'(c) the deleveraging of the domestic banks towards the nominal targets for non-core asset disposals and amortisation established under the 2011 PLAR, unless otherwise agreed with the European Commission in the context of ongoing assessments of banks' restructuring plans, and the monitoring of banks' progress towards the relevant Basel III liquidity and net-stable-funding ratio requirements in line with the advanced monitoring framework agreed under the programme;'

(2) paragraph 10 is replaced by the following:

'10. Ireland shall during 2013, in line with specifications in the Memorandum of Understanding:

(a) complete bank stress tests, aligned to the European Banking Authority (EBA) exercise, building on the outcomes from PCAR 2011 and the Financial Measures Programme 2012. The stress test shall be rigorous and continue to be based on robust loan-loss forecasts and a high level of transparency. The publication of the results shall be aligned with the timing of the next EBA exercise.

⁽¹⁾ OJ L 118, 12.5.2010, p. 1.

⁽²⁾ OJ L 30, 4.2.2011, p. 34.

- (b) deleverage the domestic banks towards the end-2013 nominal targets for non-core asset disposals and amortisation established under the 2011 PLAR, unless otherwise agreed with the European Commission in the context of ongoing assessments of banks' restructuring plans, and monitor banks' progress towards the relevant Basel III liquidity and net-stable-funding ratio requirements in line with the advanced monitoring framework agreed under the programme.'

Article 2

This Decision is addressed to Ireland.

Done at Brussels, 22 January 2013.

For the Council
The President
M. NOONAN

COMMISSION IMPLEMENTING DECISION

of 22 January 2013

authorising the placing on the market of synthetic zeaxanthin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council*(notified under document C(2013) 110)***(Only the Dutch text is authentic)**

(2013/49/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 1 June 2004, the company DSM Nutritional Products VML made a request to the competent authorities of the Netherlands to place synthetic zeaxanthin on the market as a novel food ingredient.
- (2) On 16 June 2005 the competent food assessment body of the Netherlands issued its initial assessment report. In that report it came to the conclusion that synthetic zeaxanthin with a maximum intake for not more than 20 mg per person per day, would not present a significant risk for human health. However, it concluded that the data presented were not sufficient to complete the safety assessment.
- (3) Therefore an additional assessment was required.
- (4) The Commission forwarded the initial assessment report to all Member States on 1 August 2005 for additional comments.
- (5) On 2 February 2007 the applicant informed the Commission that the use of zeaxanthin should be limited to be used only as an ingredient in food supplements.
- (6) The Commission consulted the European Food Safety Authority (EFSA) on 20 March 2007.
- (7) On 24 April 2008 the EFSA adopted a Scientific Opinion on the safety of 'synthetic zeaxanthin as an ingredient in food supplements'⁽²⁾ concluding that based on the existing data, the safety of synthetic zeaxanthin as an ingredient in food supplements at the proposed level of 20 mg per person per day has not been established.

- (8) On 25 January 2012 the applicant provided additional information and proposed an intake of synthetic zeaxanthin as an ingredient in food supplements of up to 2 mg per person per day.
- (9) Following a request from the Commission, EFSA was asked to update its opinion on the safety of synthetic zeaxanthin as a novel food ingredient in food supplements in the light of the additional information. On 13 September 2012, EFSA adopted a 'Statement on the safety of synthetic zeaxanthin as an ingredient in food supplements'⁽³⁾ concluding that the use level proposed by the applicant does not raise safety concerns.
- (10) On the basis of the scientific assessment, it is established that synthetic zeaxanthin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (11) The intentional addition of synthetic zeaxanthin to food for colouring purposes falls within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽⁴⁾ and should be authorised in accordance with that Regulation.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Synthetic zeaxanthin as specified in the Annex may be placed on the market in the Union as a novel food ingredient in food supplements at the maximum intake recommended by the manufacturer of up to 2 mg per day.

Article 2

The designation of synthetic zeaxanthin authorised by this Decision on the labelling of the foodstuffs containing it shall be 'synthetic zeaxanthin'.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal (2008) 728, 1-27.⁽³⁾ EFSA Journal 2012: 10(10):2891.⁽⁴⁾ OJ L 354, 31.12.2008, p. 16.

Article 3

This Decision is addressed to DSM Nutritional Products, Alexander Fleminglaan 1, 2613 AX Delft, The Netherlands.

Done at Brussels, 22 January 2013.

For the Commission
Tonio BORG
Member of the Commission

ANNEX

SPECIFICATIONS OF SYNTHETIC ZEAXANTHIN

Definition

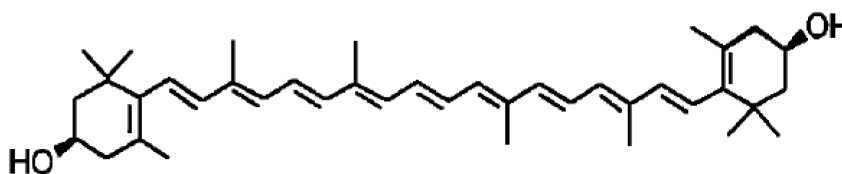
Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules.

Synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added α -tocopherol and ascorbyl palmitate or as a corn oil suspension with added α -tocopherol

Description: Orange-red crystalline powder with little or no odour

Chemical formula: $C_{40}H_{56}O_2$

Structural formula:



CAS No: 144-68-3

Molecular weight: 568,9 daltons

Physical-chemical properties of synthetic zeaxanthin

Loss on drying	less than 0,2 %
All-trans zeaxanthin	more than 96 %
Cis-zeaxanthin	less than 2 %
Other carotenoids	less than 1,5 %
Triphenylphosphine oxid (CAS No 791-28-6)	less than 50 mg/kg

COMMISSION IMPLEMENTING DECISION

of 22 January 2013

authorising an extension of use of Chia (*Salvia hispanica*) seed as a novel food ingredient under
Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2013) 123)

(Only the English text is authentic)

(2013/50/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) Commission Decision 2009/827/EC ⁽²⁾ authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of Chia (*Salvia hispanica*) seed as a novel food ingredient to be used in bread products with a maximum content of 5 % Chia (*Salvia hispanica*) seeds.
- (2) On 14 April 2011 The Chia Company made a request to the competent authorities of the United Kingdom for an extension of use of Chia seed on the market as a novel food ingredient. In particular, they asked to use up to 10 % Chia seed in certain food categories and to sell pre-packed Chia seed with a recommended daily intake of up to 15 g.
- (3) On 16 March 2012, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that extending the use of Chia seeds for the proposed food categories meets the criteria set out in Article 3(1) of Regulation (EC) No 258/97.
- (4) On 26 March 2012, the Commission forwarded the initial assessment report to all Member States.
- (5) Reasoned objections were raised within the 60-day period laid down in the second subparagraph of Article 6(4) of Regulation (EC) No 258/97, in particular concerning the possible lack of toxicological data. Additional explanations by the applicant alleviated these concerns to the satisfaction of the Member States and the

Commission. Therefore it was confirmed that the criteria set out in Article 3(1) of Regulation (EC) No 258/97 are fulfilled.

- (6) Pursuant to Article 7(1) of Regulation (EC) No 258/97 an Implementing Decision should be adopted to authorise an extension of use of Chia seed as a novel food ingredient.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the food chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Chia (*Salvia hispanica*) seed as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses listed in Annex II.

Chia (*Salvia hispanica*) seed as such may be sold to the final consumer in a pre-packaged form only.

Article 2

The designation of Chia (*Salvia hispanica*) seed authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Chia (*Salvia hispanica*) seeds'.

Additional labelling of pre-packaged Chia (*Salvia hispanica*) seed is required to inform the consumer that the daily intake is no more than 15 g.

Article 3

This Decision is addressed to The Chia Company, 262-276 Lorimer Street, Port Melbourne, VIC 3207 Australia.

Done at Brussels, 22 January 2013.

For the Commission

Tonio BORG

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ OJ L 294, 11.11.2009, p. 14.

ANNEX I

SPECIFICATIONS OF CHIA (*SALVIA HISPANICA*) SEED**Description**

Chia (*Salvia hispanica*) is a summer annual herbaceous plant belonging to the *Labiatae* family.

Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed.

Typical Composition of Chia Seed

Dry matter	91-96 %
Protein	20-22 %
Fat	30-35 %
Carbohydrate	25-41 %
Dietary fibre (Crude Fibre (*))	18-30 %
Ash	4-6 %

(*) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin.

ANNEX II

USES OF CHIA (*SALVIA HISPANICA*) SEED

Baked products	not more than 10 %
Breakfast cereals	not more than 10 %
Fruit, nut and seed mixes	not more than 10 %
Pre-packaged Chia seed as such	not more than 15 g per day

COMMISSION IMPLEMENTING DECISION

of 23 January 2013

on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC of the European Parliament and of the Council

(Text with EEA relevance)

(2013/51/EU)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular Article 111b(2) thereof,

Whereas:

- (1) Article 111b(1) of Directive 2001/83/EC specifies the aspects of which the Commission must take particular account when assessing whether a third country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.
- (2) It should be set out in more detail which aspects and respective EU documents are taken into account when conducting the equivalence assessment in accordance with Article 111b(1) of Directive 2001/83/EC.
- (3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

This Decision specifies how the aspects referred to in points (a) to (d) of Article 111b(1) of Directive 2001/83/EC are to be assessed for the purposes of determining whether a third country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.

Article 2

For the purposes of assessing the equivalence of the level of protection of public health ensured by a third country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities

pursuant to Article 111b of Directive 2001/83/EC, the requirements set out in points (a) to (d) of Article 111b(1) shall be applied as follows:

- (a) in applying point (a) of Article 111b(1), the Commission shall take into account the applicable guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC;
- (b) in applying point (b) of Article 111b(1), the Commission shall take into account the applicable guidelines referred to in Article 3(1) of 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 ⁽²⁾;
- (c) in applying point (c) of Article 111b(1), the Commission shall assess inspection resources, the qualification and training of inspectors, inspection procedures, inspection strategies and mechanisms to address conflicts of interest, inspection performance standards, enforcement powers, alert and crisis mechanisms, and analytical capacity taking into account the applicable guidelines referred to in Article 3(1) of Directive 2003/94/EC;
- (d) in applying point (d) of Article 111b(1), the Commission shall assess the third country's arrangements in order to ensure regular and rapid provision of information by the third country to the EU in relation to non-compliant producers of active substances.

Article 3

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

Done at Brussels, 23 January 2013.

For the Commission
The President

José Manuel BARROSO

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 262, 14.10.2003, p. 22.

III

(Other acts)

EUROPEAN ECONOMIC AREA

DECISION OF THE EEA JOINT COMMITTEE

No 191/2012

of 26 October 2012

amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement

THE EEA JOINT COMMITTEE,

HAS ADOPTED THIS DECISION:

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Article 1

Chapter I of Annex I to the EEA Agreement shall be amended as follows:

Whereas:

(1) Commission Implementing Regulation (EU) No 176/2012 of 1 March 2012 amending Annexes B, C and D to Council Directive 90/429/EEC as regards animal health requirements for brucellosis and Aujeszky's disease ⁽¹⁾ is to be incorporated into the EEA Agreement.

(1) the following indent shall be added in point 8 (Council Directive 90/429/EEC) in Part 4.1 and point 7 (Council Directive 90/429/EEC) in Part 8.1:

— **32012 R 0176**: Commission Implementing Regulation (EU) No 176/2012 of 1 March 2012 (OJ L 61, 2.3.2012, p. 1).;

(2) Commission Implementing Decision 2011/396/EU of 4 July 2011 authorising a laboratory in Japan to carry out serological tests to monitor the effectiveness of rabies vaccines ⁽²⁾ is to be incorporated into the EEA Agreement.

(2) the following point shall be inserted after point 96 (Commission Decision 2011/91/EU) in Part 4.2:

‘97. **32011 D 0396**: Commission Implementing Decision 2011/396/EU of 4 July 2011 authorising a laboratory in Japan to carry out serological tests to monitor the effectiveness of rabies vaccines (OJ L 176, 5.7.2011, p. 51).

(3) This Decision concerns legislation regarding live animals other than fish and aquaculture animals. Legislation concerning these matters shall not apply to Iceland, as specified in paragraph 2 of the Introductory Part of Chapter I of Annex I to the EEA Agreement. This Decision is therefore not to apply to Iceland.

This act shall not apply to Iceland.’

(4) This Decision concerns legislation regarding veterinary matters. Legislation regarding veterinary matters shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the sectoral adaptations to Annex I to the EEA Agreement. This Decision is therefore not to apply to Liechtenstein.

Article 2

The texts of Implementing Regulation (EU) No 176/2012 and Implementing Decision 2011/396/EU in the Norwegian language, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

(5) Annex I to the EEA Agreement should therefore be amended accordingly,

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

⁽¹⁾ OJ L 61, 2.3.2012, p. 1.

⁽²⁾ OJ L 176, 5.7.2011, p. 51.

(*) No constitutional requirements indicated.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

DECISION OF THE EEA JOINT COMMITTEE

No 192/2012

of 26 October 2012

amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Implementing Regulation (EU) No 233/2012 of 16 March 2012 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the approval of the amended national scrapie control programme for Denmark ⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) Commission Implementing Decision 2011/825/EU of 8 December 2011 amending Decision 2010/221/EU as regards national measures for preventing the introduction of certain aquatic animal diseases into parts of Ireland, Finland and Sweden ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Commission Implementing Decision 2012/111/EU of 10 February 2012 amending Decision 2007/453/EC as regards the BSE status of Denmark and Panama ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (5) Regulation (EU) No 200/2012 repeals Commission Regulation (EC) No 646/2007 ⁽⁵⁾ which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (6) This Decision concerns legislation regarding veterinary matters. Legislation regarding veterinary matters shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the sectoral adaptations to Annex I to the EEA Agreement. This Decision is therefore not to apply to Liechtenstein.
- (7) Annex I to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter I of Annex I to the EEA Agreement shall be amended as follows:

- (1) the following indent shall be added in point 94 (Commission Decision 2010/221/EU) in Part 4.2:

‘— **32011 D 0825**: Commission Implementing Decision 2011/825/EU of 8 December 2011 (OJ L 328, 10.12.2011, p. 53).’;
- (2) the text of point 47 (Commission Regulation (EC) No 646/2007) in Part 7.2 shall be deleted;
- (3) the following indent shall be added in point 49 (Commission Decision 2007/453/EC) in Part 7.2:

‘— **32012 D 0111**: Commission Implementing Decision 2012/111/EU of 10 February 2012 (OJ L 50, 23.2.2012, p. 49).’;
- (4) the following points shall be inserted after point 56 (Commission Implementing Regulation (EU) No 931/2011) in Part 7.2:

‘57. **32012 R 0200**: Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council (OJ L 71, 9.3.2012, p. 31).

58. **32012 R 0233**: Commission Implementing Regulation (EU) No 233/2012 of 16 March 2012 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the approval of the amended national scrapie control programme for Denmark (OJ L 78, 17.3.2012, p. 13).’

Article 2

The texts of Regulation (EU) No 200/2012 and Implementing Regulation (EU) No 233/2012 and Implementing Decisions 2011/825/EU and 2012/111/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

⁽¹⁾ OJ L 71, 9.3.2012, p. 31.

⁽²⁾ OJ L 78, 17.3.2012, p. 13.

⁽³⁾ OJ L 328, 10.12.2011, p. 53.

⁽⁴⁾ OJ L 50, 23.2.2012, p. 49.

⁽⁵⁾ OJ L 151, 13.6.2007, p. 21.

(*) No constitutional requirements indicated.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

DECISION OF THE EEA JOINT COMMITTEE

No 193/2012

of 26 October 2012

amending Annex I (Veterinary and phytosanitary matters) and Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Regulation (EU) No 277/2012 of 28 March 2012 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Recommendation 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) This Decision concerns legislation regarding feedingstuffs and foodstuffs. Legislation regarding feedingstuffs and foodstuffs shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the sectoral adaptations to Annex I and the introduction to Chapter XII of Annex II to the EEA Agreement. This Decision is therefore not to apply to Liechtenstein.
- (4) Annexes I and II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter II of Annex I to the EEA Agreement shall be amended as follows:

- (1) the following indent shall be added in point 33 (Directive 2002/32/EC of the European Parliament and of the Council):

— **32012 R 0277:** Commission Regulation (EU) No 277/2012 of 28 March 2012 (OJ L 91, 29.3.2012, p. 1).';

- (2) the following point shall be inserted after point 40 (Regulation (EC) No 396/2005 of the European Parliament and of the Council):

'40a. **32012 H 0154:** Commission Recommendation 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food (OJ L 77, 16.3.2012, p. 20).'

Article 2

Under the heading 'ACTS OF WHICH THE CONTRACTING PARTIES SHALL TAKE NOTE' the following point shall be inserted after point 13 (Commission Recommendation 2010/161/EU) of Chapter XII of Annex II to the EEA Agreement:

'14. **32012 H 0154:** Commission Recommendation 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food (OJ L 77, 16.3.2012, p. 20).'

Article 3

The texts of Regulation (EU) No 277/2012 and Recommendation 2012/154/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 4

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 5

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 91, 29.3.2012, p. 1.

⁽²⁾ OJ L 77, 16.3.2012, p. 20.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 194/2012

of 26 October 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Regulation (EU) No 347/2012 of 16 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council with respect to type-approval requirements for certain categories of motor vehicles with regard to advanced emergency braking systems ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Regulation (EU) No 351/2012 of 23 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council as regards type-approval requirements for the installation of lane departure warning systems in motor vehicles ⁽²⁾, as corrected by OJ L 121, 8.5.2012, p. 44, is to be incorporated into the EEA Agreement.
- (3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following points shall be inserted after point 45zzo (Commission Regulation (EU) No 65/2012) of Chapter I of Annex II to the EEA Agreement:

'45zpz. **32012 R 0347**: Commission Regulation (EU) No 347/2012 of 16 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council with respect to type-approval

requirements for certain categories of motor vehicles with regard to advanced emergency braking systems (OJ L 109, 21.4.2012, p. 1).

45zzq. **32012 R 0351**: Commission Regulation (EU) No 351/2012 of 23 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council as regards type-approval requirements for the installation of lane departure warning systems in motor vehicles (OJ L 110, 24.4.2012, p. 18), as corrected by OJ L 121, 8.5.2012, p. 44.'

Article 2

The texts of Regulations (EU) No 347/2012 and (EU) No 351/2012, as corrected by OJ L 121, 8.5.2012, p. 44, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 109, 21.4.2012, p. 1.

⁽²⁾ OJ L 110, 24.4.2012, p. 18.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 195/2012

of 26 October 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ⁽¹⁾ is to be incorporated into the EEA Agreement.

(2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following indent shall be added in point 12zc (Regulation (EC) No 1907/2006 of the European Parliament and of the Council) of Chapter XV of Annex II to the EEA Agreement:

‘— **32012 R 0412**: Commission Regulation (EU) No 412/2012 of 15 May 2012 (OJ L 128, 16.5.2012, p. 1).’

Article 2

The text of Regulation (EU) No 412/2012 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 128, 16.5.2012, p. 1.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 196/2012

of 26 October 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Decision 2010/11/EU of 7 January 2010 on the safety requirements to be met by European standards for consumer-mounted childproof locking devices for windows and balcony doors pursuant to Directive 2001/95/EC of the European Parliament and of the Council ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Decision 2010/376/EU of 2 July 2010 on the safety requirements to be met by European standards for certain products in the sleep environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council ⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) Commission Implementing Decision 2012/48/EU of 26 January 2012 extending the validity of Decision 2009/251/EC requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XIX of Annex II to the EEA Agreement shall be amended as follows:

- (1) the following indent shall be added in point 3n (Commission Decision 2009/251/EC):

— **32012 D 0048:** Commission Implementing Decision 2012/48/EU of 26 January 2012 (OJ L 26, 28.1.2012, p. 35).;

- (2) the following points shall be inserted after point 3n (Commission Decision 2009/251/EC):

‘3o. **32010 D 0011:** Commission Decision 2010/11/EU of 7 January 2010 on the safety requirements to be met by European standards for consumer-mounted childproof locking devices for windows and balcony doors pursuant to Directive 2001/95/EC of the European Parliament and of the Council (OJ L 4, 8.1.2010, p. 91).

3p. **32010 D 0376:** Commission Decision 2010/376/EU of 2 July 2010 on the safety requirements to be met by European standards for certain products in the sleep environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council (OJ L 170, 6.7.2010, p. 39).’.

Article 2

The texts of Decisions 2010/11/EU and 2010/376/EU and Implementing Decision 2012/48/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee
The President
Atle LEIKVOLL

⁽¹⁾ OJ L 4, 8.1.2010, p. 91.

⁽²⁾ OJ L 170, 6.7.2010, p. 39.

⁽³⁾ OJ L 26, 28.1.2012, p. 35.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 197/2012

of 26 October 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

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 ⁽⁶⁾ is to be incorporated into the EEA Agreement.

Whereas:

- (1) 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 ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) 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 ⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) 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 ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) 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 ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (5) 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 ⁽⁵⁾ is to be incorporated into the EEA Agreement.
- (6) 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 ⁽⁶⁾ is to be incorporated into the EEA Agreement.
- (7) 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 ⁽⁷⁾ is to be incorporated into the EEA Agreement.
- (8) 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 ⁽⁸⁾ is to be incorporated into the EEA Agreement.
- (9) 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) ⁽⁹⁾ is to be incorporated into the EEA Agreement.
- (10) 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 ⁽¹⁰⁾ is to be incorporated into the EEA Agreement.
- (11) 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 ⁽¹¹⁾ is to be incorporated into the EEA Agreement.

⁽¹⁾ OJ L 38, 11.2.2010, p. 9.⁽²⁾ OJ L 38, 11.2.2010, p. 11.⁽³⁾ OJ L 38, 11.2.2010, p. 13.⁽⁴⁾ OJ L 38, 11.2.2010, p. 17.⁽⁵⁾ OJ L 292, 10.11.2010, p. 55.⁽⁶⁾ OJ L 293, 11.11.2010, p. 60.⁽⁷⁾ OJ L 317, 3.12.2010, p. 39.⁽⁸⁾ OJ L 317, 3.12.2010, p. 42.⁽⁹⁾ OJ L 10, 14.1.2011, p. 5.⁽¹⁰⁾ OJ L 11, 15.1.2011, p. 49.⁽¹¹⁾ OJ L 97, 12.4.2011, p. 49.

- (12) 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 ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (13) 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 ⁽²⁾ is to be incorporated into the EEA Agreement.
- (14) 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 ⁽³⁾ is to be incorporated into the EEA Agreement.
- (15) 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 ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (16) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XXI of Annex II to the EEA Agreement shall be amended as follows:

- (1) the following shall be added in the 10th indent (Commission Decision 95/467/EC) of point 1 (Council Directive 89/106/EEC):
- ‘, as amended by:
- **32010 D 0679**: Commission Decision 2010/679/EU of 8 November 2010 (OJ L 292, 10.11.2010, p. 55).’;
- (2) the following shall be added in the 18th indent (Commission Decision 97/555/EC) of point 1 (Council Directive 89/106/EEC):

⁽¹⁾ OJ L 103, 19.4.2011, p. 114.

⁽²⁾ OJ L 131, 18.5.2011, p. 22.

⁽³⁾ OJ L 109, 21.4.2012, p. 20.

⁽⁴⁾ OJ L 109, 21.4.2012, p. 22.

‘, as amended by:

— **32010 D 0683**: Commission Decision 2010/683/EU of 9 November 2010 (OJ L 293, 11.11.2010, p. 60).’;

- (3) the following shall be added in the 19th indent (Commission Decision 97/556/EC) of point 1 (Council Directive 89/106/EEC):

‘, as amended by:

— **32011 D 0014**: Commission Decision 2011/14/EU of 13 January 2011 (OJ L 10, 14.1.2011, p. 5).’;

- (4) the following shall be added in the 25th indent (Commission Decision 98/213/EC) of point 1 (Council Directive 89/106/EEC):

‘, as amended by:

— **32012 D 0201**: Commission Implementing Decision 2012/201/EU of 26 March 2012 (OJ L 109, 21.4.2012, p. 20).’;

- (5) the following shall be added in the 40th indent (Commission Decision 1999/93/EC) of point 1 (Council Directive 89/106/EEC):

‘, as amended by:

— **32011 D 0246**: Commission Decision 2011/246/EU of 18 April 2011 (OJ L 103, 19.4.2011, p. 114).’;

- (6) the following shall be added in the 41st indent (Commission Decision 1999/94/EC) of point 1 (Council Directive 89/106/EEC):

‘, as amended by:

— **32012 D 0202**: Commission Implementing Decision 2012/202/EU of 29 March 2012 (OJ L 109, 21.4.2012, p. 22).’;

- (7) the following shall be added in the 49th indent (Commission Decision 2000/367/EC) of point 1 (Council Directive 89/106/EEC):

‘, as amended by:

— **32011 D 0232**: Commission Decision 2011/232/EU of 11 April 2011 (OJ L 97, 12.4.2011, p. 49).’;

(8) the following points shall be inserted after point 2g (Commission Decision 2006/600/EC):

- 2h. **32010 D 0081**: 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).
- 2i. **32010 D 0082**: 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).
- 2j. **32010 D 0083**: 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).
- 2k. **32010 D 0085**: 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).
- 2l. **32010 D 0737**: 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).
- 2m. **32010 D 0738**: 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).
- 2n. **32011 D 0019**: 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).

- 2o. **32011 D 0284**: 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).'

Article 2

The texts of Decisions 2010/81/EU, 2010/82/EU, 2010/83/EU, 2010/85/EU, 2010/679/EU, 2010/683/EU, 2010/737/EU, 2010/738/EU, 2011/14/EU, 2011/19/EU, 2011/232/EU, 2011/246/EU and 2011/284/EU and Implementing Decisions 2012/201/EU and 2012/202/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 198/2012

of 26 October 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices ⁽¹⁾ is to be incorporated into the EEA Agreement.

(2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following point shall be inserted after point 8 (Commission Decision 2010/227/EU) of Chapter XXX of Annex II to the EEA Agreement:

'9. **32012 R 0207**: 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).'

Article 2

The text of Regulation (EU) No 207/2012 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

*For the EEA Joint Committee**The President*

Atle LEIKVOLL

⁽¹⁾ OJ L 72, 10.3.2012, p. 28.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 199/2012

of 26 October 2012

amending Annex XIII (Transport) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

- (1) Annex XIII to the Agreement was amended by Decision of the EEA Joint Committee No 180/2012 of 28 September 2012 ⁽¹⁾.
- (2) Commission Regulation (EU) No 1286/2011 of 9 December 2011 adopting a common methodology for investigating marine casualties and incidents developed pursuant to Article 5(4) of Directive 2009/18/EC of the European Parliament and of the Council ⁽²⁾ is to be incorporated into the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The following point shall be inserted after point 55ca (Commission Implementing Regulation (EU) No 651/2011) of Annex XIII to the Agreement:

'55cb. **32011 R 1286**: Commission Regulation (EU) No 1286/2011 of 9 December 2011 adopting a common methodology for investigating marine

casualties and incidents developed pursuant to Article 5(4) of Directive 2009/18/EC of the European Parliament and of the Council (OJ L 328, 10.12.2011, p. 36).'

Article 2

The text of Regulation (EU) No 1286/2011 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee ^(*), or on the day of the entry into force of Decision of the EEA Joint Committee No 62/2012 of 30 March 2012 ⁽³⁾, whichever is the later.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 341, 13.12.2012, p. 34.

⁽²⁾ OJ L 328, 10.12.2011, p. 36.

^(*) No constitutional requirements indicated.

⁽³⁾ OJ L 207, 2.8.2012, p. 42.

DECISION OF THE EEA JOINT COMMITTEE

No 200/2012

of 26 October 2012

amending Annex XX (Environment) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ⁽¹⁾, as corrected by OJ L 108, 29.4.2010, p. 355, is to be incorporated into the EEA Agreement.
- (2) Regulation (EC) No 66/2010 repeals Regulation (EC) No 1980/2000 of the European Parliament and of the Council ⁽²⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (3) Annex XX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The text of point 2a (Regulation (EC) No 1980/2000 of the European Parliament and of the Council) of Annex XX to the EEA Agreement shall be replaced by the following:

'32010 R 0066: Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27, 30.1.2010, p. 1), as corrected by OJ L 108, 29.4.2010, p. 355.'

Article 2

The text of Regulation (EC) No 66/2010, as corrected by OJ L 108, 29.4.2010, p. 355, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

⁽¹⁾ OJ L 27, 30.1.2010, p. 1.

⁽²⁾ OJ L 237, 21.9.2000, p. 1.

(*) Constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 201/2012

of 26 October 2012

amending Annex XX (Environment) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Decision 2010/709/EU of 22 November 2010 establishing the European Union Ecolabelling Board ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Decision 2011/263/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers ⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) Commission Decision 2011/264/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Commission Decision 2011/330/EU of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for notebook computers ⁽⁴⁾ is to be incorporated into the EEA Agreement.
- (5) Commission Decision 2011/331/EU of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for light sources ⁽⁵⁾ is to be incorporated into the EEA Agreement.
- (6) Commission Decision 2011/333/EU of 7 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for copying and graphic paper ⁽⁶⁾, as corrected by OJ L 161, 21.6.2011, p. 34, is to be incorporated into the EEA Agreement.
- (7) Commission Decision 2011/337/EU of 9 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for personal computers ⁽⁷⁾ is to be incorporated into the EEA Agreement.
- (8) Commission Decision 2011/381/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants ⁽⁸⁾ is to be incorporated into the EEA Agreement.
- (9) Commission Decision 2011/382/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents ⁽⁹⁾ is to be incorporated into the EEA Agreement.
- (10) Commission Decision 2011/383/EU of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners ⁽¹⁰⁾, as corrected by OJ L 110, 24.4.2012, p. 44, is to be incorporated into the EEA Agreement.
- (11) Decision 2010/709/EU repeals Commission Decision 2000/730/EC ⁽¹¹⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (12) Decision 2011/263/EU repeals Commission Decision 2003/31/EC ⁽¹²⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (13) Decision 2011/264/EU repeals Commission Decision 2003/200/EC ⁽¹³⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (14) Decision 2011/330/EU repeals Commission Decision 2005/343/EC ⁽¹⁴⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (15) Decision 2011/331/EU repeals Commission Decision 2002/747/EC ⁽¹⁵⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (16) Decision 2011/333/EU repeals Commission Decision 2002/741/EC ⁽¹⁶⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.

⁽¹⁾ OJ L 308, 24.11.2010, p. 53.

⁽²⁾ OJ L 111, 30.4.2011, p. 22.

⁽³⁾ OJ L 111, 30.4.2011, p. 34.

⁽⁴⁾ OJ L 148, 7.6.2011, p. 5.

⁽⁵⁾ OJ L 148, 7.6.2011, p. 13.

⁽⁶⁾ OJ L 149, 8.6.2011, p. 12.

⁽⁷⁾ OJ L 151, 10.6.2011, p. 5.

⁽⁸⁾ OJ L 169, 29.6.2011, p. 28.

⁽⁹⁾ OJ L 169, 29.6.2011, p. 40.

⁽¹⁰⁾ OJ L 169, 29.6.2011, p. 52.

⁽¹¹⁾ OJ L 293, 22.11.2000, p. 24.

⁽¹²⁾ OJ L 9, 15.1.2003, p. 11.

⁽¹³⁾ OJ L 76, 22.3.2003, p. 25.

⁽¹⁴⁾ OJ L 115, 4.5.2005, p. 35.

⁽¹⁵⁾ OJ L 242, 10.9.2002, p. 44.

⁽¹⁶⁾ OJ L 237, 5.9.2002, p. 6.

- (17) Decision 2011/337/EU repeals Commission Decision 2005/341/EC ⁽¹⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (18) Decision 2011/381/EU repeals Commission Decision 2005/360/EC ⁽²⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (19) Decision 2011/382/EU repeals Commission Decision 2005/342/EC ⁽³⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (20) Decision 2011/383/EU repeals Commission Decision 2005/344/EC ⁽⁴⁾ which is incorporated into the EEA Agreement and is therefore to be repealed from the EEA Agreement.
- (21) Annex XX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex XX to the EEA Agreement shall be amended as follows:

- (1) the text of point 2ad (Commission Decision 2000/730/EC) shall be replaced by the following:

'32010 D 0709: Commission Decision 2010/709/EU of 22 November 2010 establishing the European Union Ecolabelling Board (OJ L 308, 24.11.2010, p. 53).';

- (2) the text of point 2e (Commission Decision 2003/200/EC) shall be replaced by the following:

'32011 D 0264: Commission Decision 2011/264/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents (OJ L 111, 30.4.2011, p. 34).';

- (3) the text of point 2h (Commission Decision 2003/31/EC) shall be replaced by the following:

'32011 D 0263: Commission Decision 2011/263/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers (OJ L 111, 30.4.2011, p. 22).';

- (4) the text of point 2o (Commission Decision 2002/747/EC) shall be replaced by the following:

'32011 D 0331: Commission Decision 2011/331/EU of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for light sources (OJ L 148, 7.6.2011, p. 13).';

- (5) the text of point 2q (Commission Decision 2005/341/EC) shall be replaced by the following:

'32011 D 0337: Commission Decision 2011/337/EU of 9 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for personal computers (OJ L 151, 10.6.2011, p. 5).';

- (6) the text of point 2r (Commission Decision 2005/342/EC) shall be replaced by the following:

'32011 D 0382: Commission Decision 2011/382/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents (OJ L 169, 29.6.2011, p. 40).';

- (7) the text of point 2s (Commission Decision 2005/343/EC) shall be replaced by the following:

'32011 D 0330: Commission Decision 2011/330/EU of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for notebook computers (OJ L 148, 7.6.2011, p. 5).';

- (8) the text of point 2t (Commission Decision 2005/344/EC) shall be replaced by the following:

'32011 D 0383: Commission Decision 2011/383/EU of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners (OJ L 169, 29.6.2011, p. 52), as corrected by OJ L 110, 24.4.2012, p. 44.');

- (9) the text of point 2u (Commission Decision 2005/360/EC) shall be replaced by the following:

'32011 D 0381: Commission Decision 2011/381/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants (OJ L 169, 29.6.2011, p. 28).';

- (10) the text of point 2x (Commission Decision 2002/741/EC) shall be replaced by the following:

'32011 D 0333: Commission Decision 2011/333/EU of 7 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for copying and graphic paper (OJ L 149, 8.6.2011, p. 12), as corrected by OJ L 161, 21.6.2011, p. 34.');

Article 2

The texts of Decisions 2010/709/EU, 2011/263/EU, 2011/264/EU, 2011/330/EU, 2011/331/EU, 2011/333/EU, as corrected by OJ L 161, 21.6.2011, p. 34, 2011/337/EU, 2011/381/EU, 2011/382/EU and 2011/383/EU, as corrected by OJ L 110, 24.4.2012, p. 44, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

⁽¹⁾ OJ L 115, 4.5.2005, p. 1.

⁽²⁾ OJ L 118, 5.5.2005, p. 26.

⁽³⁾ OJ L 115, 4.5.2005, p. 9.

⁽⁴⁾ OJ L 115, 4.5.2005, p. 42.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*), or on the day of the entry into force of the Decision of the EEA Joint Committee No 200/2012 of 26 October 2012 ⁽¹⁾, whichever is the later.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

(*) No constitutional requirements indicated.

⁽¹⁾ See page 50 of this Official Journal.

DECISION OF THE EEA JOINT COMMITTEE

No 202/2012

of 26 October 2012

amending Annex XX (Environment) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Commission Regulation (EU) No 744/2010 of 18 August 2010 amending Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, with regard to the critical uses of halons⁽²⁾ is to be incorporated into the EEA Agreement.
- (3) Commission Regulation (EU) No 291/2011 of 24 March 2011 on essential uses of controlled substances other than hydrochlorofluorocarbons for laboratory and analytical purposes in the Union under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Regulation (EC) No 1005/2009 repeals Regulation (EC) No 2037/2000 of the European Parliament and of the Council⁽⁴⁾ which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (5) Without prejudice to future development by the EEA Joint Committee, it should be noted that Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code)⁽⁵⁾ is not incorporated into the EEA Agreement. The references to this Regulation should therefore not apply.
- (6) Annex XX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex XX of the EEA Agreement shall be amended as follows:

⁽¹⁾ OJ L 286, 31.10.2009, p. 1.

⁽²⁾ OJ L 218, 19.8.2010, p. 2.

⁽³⁾ OJ L 79, 25.3.2011, p. 4.

⁽⁴⁾ OJ L 244, 29.9.2000, p. 1.

⁽⁵⁾ OJ L 145, 4.6.2008, p. 1.

- (1) the text of point 21aa (Regulation (EC) No 2037/2000 of the European Parliament and of the Council) shall be replaced by the following:

'32009 R 1005: Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1), as amended by:

— **32010 R 0744:** Commission Regulation (EU) No 744/2010 of 18 August 2010 (OJ L 218, 19.8.2010, p. 2).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

- (a) The references to Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code) shall not apply.
- (b) Article 8(4) and (5)(b) shall not apply.
- (c) With regard to the EFTA States, the words “, the respective quantities, the period for which the exemption shall be valid and those users which may take advantage of those essential laboratory and analytical uses” in Article 10(2) shall not apply.
- (d) Article 10(6) shall not apply.
- (e) In Article 11(2) the words “, except for 10(6),” shall be inserted after the words “Article 10(3) to (7)”.
- (f) Article 11(5) shall not apply.
- (g) Article 14(1), (3) and (4) shall not apply.
- (h) Chapter IV shall not apply.
- (i) The provisions concerning import and export in Article 24 shall not apply.
- (j) Articles 27 and 28 shall not apply.

The EFTA States shall, at national level, put into effect the measures necessary to comply with the corresponding provisions of the Montreal Protocol and with the corresponding measures in Regulation (EC) No 1005/2009 of the European Parliament and of the Council;

(2) the following point shall be inserted after point 21aa (Regulation (EC) No 1005/2009 of the European Parliament and of the Council):

‘21aaa. **32011 R 0291**: Commission Regulation (EU) No 291/2011 of 24 March 2011 on essential uses of controlled substances other than hydrochlorofluorocarbons for laboratory and analytical purposes in the Union under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone (OJ L 79, 25.3.2011, p. 4).’

Article 2

The texts of Regulations (EC) No 1005/2009, (EU) No 744/2010 and (EU) No 291/2011 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 203/2012

of 26 October 2012

amending Annex XX (Environment) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Decision 2009/10/EC of 2 December 2008 establishing a major accident report form pursuant to Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Annex XX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following point shall be inserted after point 23aa (Commission Decision 2002/605/EC) of Annex XX to the EEA Agreement:

- '23ab. **32009 D 0010:** Commission Decision 2009/10/EC of 2 December 2008 establishing a major accident report form pursuant to Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (OJ L 6, 10.1.2009, p. 64).'

Article 2

The text of Decision 2009/10/EC in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee
The President
Atle LEIKVOLL

⁽¹⁾ OJ L 6, 10.1.2009, p. 64.

(*) No constitutional requirements indicated.

DECISION OF THE EEA JOINT COMMITTEE

No 204/2012

of 26 October 2012

amending Protocol 10 on simplification of inspections and formalities in respect of carriage of goods to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Paragraph 1 of Article 9b of Chapter IIa of Protocol 10 to the EEA Agreement provides that the Contracting Parties shall introduce and apply to goods entering or leaving their customs territories the customs security measures defined in Chapter IIa, thus ensuring an equivalent level of security at their external borders.
- (2) Article 9h of Chapter IIa of Protocol 10 to the EEA Agreement provides for a procedure to introduce the necessary amendments in order to take into account the development of the legislation of the European Union on matters covered by Chapter IIa.
- (3) The legislation of the European Union on customs security measures has been amended, in particular by Commission Regulation (EC) No 312/2009 ⁽¹⁾, Commission Regulation (EU) No 169/2010 ⁽²⁾ and Commission Regulation (EU) No 430/2010 ⁽³⁾.
- (4) The provisions of Protocol 10 to the EEA Agreement shall be aligned with the amendments to the legislation of the European Union, in order to guarantee an equivalent level of security.
- (5) This Decision shall not apply to Iceland and Liechtenstein. However, subject to a new Decision, it could be opened to these countries.
- (6) Protocol 10 to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Protocol 10 to the EEA Agreement shall be amended as follows:

- (1) the text of point (e) of paragraph 1 of Article 2 shall be replaced by the following:

‘(e) goods for which an oral customs declaration or a declaration by simple crossing the border is permitted in accordance with the legislation of the Contracting Parties, with the exception of, if carried under a

transport contract, household effects, pallets, containers and means of road, rail, air, sea or inland waterway transport;’;

- (2) the text of point (j) of paragraph 1 of Article 2 shall be replaced by the following:

‘(j) the following goods brought into or out from the customs territory of a Contracting Party directly to or from drilling or production platforms or wind turbines operated by a person established in the customs territory of the Contracting Parties:

(i) goods which were incorporated in such platforms or wind turbines, for the purposes of their construction, repair, maintenance or conversion;

(ii) goods which were used to fit to or to equip the said platforms or wind turbines;

(iii) other provisions used or consumed on the said platforms or wind turbines; and

(iv) non-hazardous waste products from the said platforms or wind turbines;’;

- (3) the following points shall be added after point (l) in paragraph 1 of Article 2:

‘(m) goods brought from Heligoland, the Republic of San Marino and the Vatican City State to one of the Contracting Parties or sent from one of the Contracting Parties to these territories;

(n) goods carried on board vessels of regular shipping services, duly certified following the same procedures as laid out in Article 313b of Regulation (EEC) No 2454/93;’;

- (4) the text of paragraph 3 of Article 2 shall be replaced by the following:

‘3. An exit summary declaration shall not be required in the following cases:

(a) for goods which are supplied for incorporation as parts of or accessories in vessels and aircraft, motor fuels, lubricants and gas necessary for the operation of the vessels or aircraft, foodstuffs, and other items to be consumed or sold on board;

(b) for goods that are placed under a transit procedure, when the data required for the exit summary declaration are given in the electronic transit declaration and provided the office of destination is also the customs office of exit;

⁽¹⁾ OJ L 98, 17.4.2009, p. 3.

⁽²⁾ OJ L 51, 2.3.2010, p. 2.

⁽³⁾ OJ L 125, 21.5.2010, p. 10.

- (c) for goods that are loaded at a port or airport in the respective customs territory of the Contracting Parties for discharge at another port or airport in that territory, when during an intermediate call at a port or airport outside that customs territory, those goods are to remain loaded on board the vessel or aircraft that transports them;
- (d) for goods that in a port or airport are not unloaded from the means of transport which carried them into the respective customs territory of the Contracting Parties and which will carry them out of that territory;
- (e) for goods that were loaded at a previous port or airport in the respective customs territory of the Contracting Parties and remain on the means of transport that will carry them out of that territory;
- (f) where goods in temporary storage or in a control type I free zone are transhipped from the means of transport that brought them to that temporary storage facility or free zone under the supervision of the same customs office onto a vessel, airplane or railway that will carry them from that temporary storage facility or free zone out of the respective customs territory of the Contracting Parties, provided that:
 - (i) the transhipment is undertaken within 14 calendar days from when the goods were presented for temporary storage or at a control type I free

zone; in exceptional circumstances, the customs authorities may extend this period of time in order to deal with those circumstances;

- (ii) information about the goods is available to the customs authorities; and
- (iii) the destination of the goods and the consignee do not change, to the knowledge of the carrier.'.

Article 2

This Decision shall enter into force on 1 November 2012, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (*).

Article 3

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

For the EEA Joint Committee

The President

Atle LEIKVOLL

(*) No constitutional requirements indicated.

Joint declaration by the Contracting Parties to the Decision of the EEA Joint Committee No 204/2012 of 26 October 2012 amending Protocol 10, concerning paragraph 2 of Article 1 of Annex I to Protocol 10

With regard to the data required for the entry or exit summary declaration, the Contracting Parties confirm that:

- the provisions concerning EORI numbers,
 - the provisions concerning requirements for diversion requests in point 2.6 — Table 6 of Annex 30a,
- introduced by Commission Regulation (EC) No 312/2009 of 16 April 2009 do not apply to declarations lodged in an EFTA State.
-

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