# 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)

## 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

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

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 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[(6)]. 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)[(7)]. 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[(8)], 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[9] 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[10]. 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 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.

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(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* U.K.

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

*Article 2* U.K.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

## ANNEX U.K.

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[(11)], Commission Regulation (EU) No 142/2011[(12)], Regulation (EC) No 178/2002 of the European Parliament and of the Council[(13)], Regulation (EC) No 767/2009 of the European Parliament and of the Council[(14)] and Council Directive 2006/88/EC[(15)] 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).;

(2) Annex IV is replaced by the following:

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

‘ANNEX IV U.K.

# ANIMAL FEEDING

## CHAPTER I U.K.

### 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 U.K.

### 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

(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.

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# CHAPTER III U.K.

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

### *SECTION A* U.K.

#### *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: U.K.

(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. U.K.

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. U.K.

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.

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## *SECTION B* U.K.

### *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: U.K.

(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: U.K.

(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[(16)]; 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: U.K.

(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;

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(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* U.K.

### *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* U.K.

### *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: U.K.

(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.

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## CHAPTER IV U.K.

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

### *SECTION A* U.K.

***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* U.K.

***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* U.K.

***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.

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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;

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(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* U.K.

### ***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:

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(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

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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* U.K.

### ***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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

(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

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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 U.K.

## General requirements

### *SECTION A* U.K.

#### *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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

## *SECTION B* U.K.

### *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: U.K.

(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. U.K.

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* U.K.

### *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* U.K.

### *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:

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

(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* U.K.

### *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. U.K.

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: U.K.

(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: U.K.

(a) fishmeal and compound feed containing fishmeal;

(b) compound feed intended for aquaculture animals;

(c) petfood.

## *SECTION F* U.K.

### *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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

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. U.K.

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.

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013. (See end of Document for details)*

(**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.

(**6**) http://register.consilium.europa.eu/pdf/en/10/st13/st13889-ad01re01.en10.pdf

(**7**) 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.

(**8**) Text adopted, P7_TA(2011)0084.

(**9**) Text adopted, P7_TA(2011)0328.

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

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

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

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

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

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

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

**Changes to legislation:**
There are currently no known outstanding effects for the Commission Regulation (EU) No 56/2013.