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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein
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Delegations will find attached document D048174/04 ANNEX 1.

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ANNEX 1

**ANNEX**

**to the**

**COMMISSION REGULATION (EU) .../...**

**amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein**

## ANNEX I

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

(1) Annex I is amended as follows:

(a) in point 1(d), the following point iv) is added:

'iv) 'label' in Article 3(2)(t);'

(b) the following points are added to point 2:

'(m) 'farmed insects' means farmed animals, as defined in Article 3(6)(a) of Regulation (EC) No 1069/2009, of those insect species which are authorised for the production of processed animal protein in accordance with point 2 of Part A of Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011.

(n) 'home compounders' means livestock farmers who mix compound feed for the exclusive use on their own holding.'

(2) Annex IV is amended as follows:

(a) in Chapter II, point (c) is replaced by the following:

'(c) aquaculture animals of the following feed materials and compound feed:

(i) processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects, 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;

(ii) processed animal protein derived from farmed insects, 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 F of Chapter IV;'

(b) Chapter III is amended as follows:

(i) Section A is replaced by the following:

### 'SECTION A

#### ***Transport and storage 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 and stored in storage facilities which are not used,

respectively, for the transport or storage of feed intended for ruminants:

- (a) bulk processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;
- (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 or stored in a storage plant 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, containers and storage facilities which have been previously used for the transport or storage of the products listed in that point, may be subsequently used for the transport or storage 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 record of such use shall be kept available to the competent authority for a period of at least two years.

3. Storage plants storing in accordance with point 2 feed materials and compound feed listed in point 1 shall be authorised by the competent authority based on verification of their compliance with the requirements listed in point 2.
4. Bulk processed animal protein derived from non-ruminants, including processed animal protein derived from farmed insects but excluding fishmeal, and bulk compound feed containing such processed animal protein, shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals.
5. By way of derogation from point 4, vehicles, containers and storage facilities which have been previously used for the transport or storage of the products referred to in that point may be subsequently used for the transport or storage 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 record of such use shall be kept available to the competent authority for a period of at least two years.'

(ii) In Section B, point 3 is replaced by the following:

'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 as producing complete feed from compound feed containing the products listed in point 1;
- (b) they must keep only non-ruminant animals;
- (c) any compound feed containing fishmeal used in the production of the complete feed must contain less than 50 % crude protein;
- (d) 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;
- (e) any compound feed containing blood products derived from non- ruminants used in the production of the complete feed must contain less than 50 % crude protein.'

(iii) in Section C, point (a) is replaced by the following:

'(a) processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;'

(iv) in Section D, in point 1, (a) is replaced by the following:

'(a) processed animal protein derived from non-ruminants, including fishmeal and processed animal protein derived from farmed insects;'

(c) Chapter IV is amended as follows:

(i) in Section A, point (b) is replaced by the following:

'(b) The words "fishmeal — shall not be used in feed for ruminants except unweaned ruminants" shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of fishmeal;

The words "contains fishmeal — shall not be fed to ruminants" shall be clearly indicated on the label of compound feed containing fishmeal intended for non-ruminant farmed animals other than fur animals.'

- (ii) Section B is replaced by the following:

**'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***

- (a) The words "di-/tricalcium phosphate of animal origin — shall not be used in feed for ruminants" shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of dicalcium/tricalcium phosphate of animal origin;
- (b) The words "contains dicalcium/tricalcium phosphate of animal origin — shall not be fed to ruminants" shall be clearly indicated on the label of compound feed containing dicalcium/tricalcium phosphate of animal origin.'
- (iii) in Section C, the first paragraph of point (c) is replaced by the following:
- '(c) The blood products shall be produced in processing plants exclusively processing non-ruminant blood, and registered by the competent authority as processing exclusively non-ruminant blood.'
- (iv) in Section C, point (d) is replaced by the following:
- '(d) The words "non-ruminant blood products — shall not be used in feed for ruminants" shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as on the label of blood products derived from non-ruminants;
- The words "contains non-ruminant blood products — shall not be fed to ruminants" shall be clearly indicated on the label of compound feed containing blood products derived from non-ruminants.'
- (v) in Section D, the title of that Section, the introductory phrase of the first paragraph and point (a) are replaced by the following:

**'SECTION D**

***Specific conditions applicable to the production and use of processed animal protein derived from non-ruminants, other than fishmeal and***

***other than processed animal protein derived from farmed insects, and compound feed containing such protein, intended to be used for feeding aquaculture animals***

The following specific conditions shall apply to the production and use of processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects, 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 come from:
  - (i) slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants, or
  - (ii) cutting plants which do not bone or cut up ruminant meat and which are registered by the competent authority as not boning or cutting up ruminant meat, or
  - (iii) other establishments than those referred to in (i) or (ii) which do not handle ruminant products and which are registered by the competent authority as not handling ruminant products.

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, and the handling of ruminant products in a cutting plant or another establishment 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 on-site inspection, of 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) non-ruminant products must be handled on production lines that are physically separate from those used for the handling of ruminant products;

- (iii) 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;
  - (iv) 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.'
- (vi) in Section D, the first paragraph of point (c) is replaced by the following:
- '(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, cutting plants or other establishments referred to in point (a). Those processing plants shall be registered by the competent authority as processing exclusively non-ruminant animal by-products.'
- (vii) in Section D, in the second paragraph of point (d), the introductory phrase of (i) is replaced by the following:
- (i) the production of compound feed, containing processed animal protein referred to in this Section, for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, other than fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:'
- (viii) in Section D, point d(ii) and point (e) are replaced by the following:
- (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 as producing complete feed from compound feed containing processed animal protein derived from non-ruminants, other than fishmeal and other than processed animal protein derived from farmed insects,
    - they keep only aquaculture animals, and
    - the compound feed containing processed animal protein referred to in this Section used in their production contains less than 50 % crude protein.



- (e) The accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, of processed animal protein referred to in this Section and the label thereof shall be clearly marked with the following words: "non-ruminant processed animal protein – shall not be used in feed for farmed animals except aquaculture and fur animals".

The following words shall be clearly indicated on the label of compound feed containing processed animal protein referred to in this Section:

"contains non-ruminant processed animal protein – shall not be fed to farmed animals except aquaculture and fur animals".'

- (ix) in Section E, points (b) to (g) are replaced by the following:

- (b) The words "fishmeal — shall not be used in feed for ruminants except unweaned ruminants" shall be clearly indicated on the accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, as well as the label of fishmeal intended to be used in milk replacers.
- (c) 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.
- (d) 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;
- (e) 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.
- (f) The label of milk replacers containing fishmeal, intended for unweaned farmed animals of the ruminant species, must be clearly marked with the words "contains fishmeal – shall not be fed to ruminants except unweaned ruminants".
- (g) bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively for the transport or storage of other feed intended for ruminants.

By way of derogation from that special condition, vehicles, containers and storage facilities which will be subsequently used for the transport or storage of other bulk feed intended for ruminants may be used for the transport or storage of bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species 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 record of such use shall be kept available to the competent authority for a period of at least two years.

- (h) 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.'

- (x) the following Section F is added:

*'SECTION F*

***Specific conditions applicable to the production and use of processed animal protein derived from farmed insects and compound feed containing such protein intended to be used for feeding aquaculture animals***

The following specific conditions shall apply to the production and use of processed animal protein derived from farmed insects and compound feed containing such processed animal protein intended to be used for feeding aquaculture animals:

- (a) Processed animal protein derived from farmed insects must:
- (i) be produced in processing plants approved in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009 and dedicated exclusively to the production of products derived from farmed insects; and
  - (ii) be produced in accordance with the requirements laid down in Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011;
- (b) Compound feed containing processed animal protein derived from farmed insects must 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, containing processed animal protein derived from farmed insects, 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 derived from farmed insects 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 derived from farmed insects shall not be required for home compounders that comply with the following conditions:

- they are registered by the competent authority as producing complete feed from compound feed containing processed animal protein derived from farmed insects,
- they keep only aquaculture animals, and
- the compound feed containing processed animal protein derived from farmed insects used in their production contains less than 50 % crude protein.

(c) The accompanying commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009, as appropriate, of processed animal protein derived from farmed insects and the label thereof shall be clearly marked with the following words: "processed insect protein – shall not be used in feed for farmed animals except aquaculture and fur animals".

The following words shall be clearly indicated on the label of compound feed containing processed animal protein derived from insects:

"contains non-ruminant processed animal protein – shall not be fed to farmed animals except aquaculture and fur animals".'

(d) Chapter V is amended as follows:

(i) Section A, B and C are replaced by the following:

*'SECTION A*

*Listing*

1. Member States shall keep up-to-date and make publicly available lists of:
  - (a) slaughterhouses registered as not slaughtering ruminants in accordance with the first paragraph of point (a) of Section C of Chapter IV, as well as authorised slaughterhouses from which blood produced in accordance with the second, third and fourth paragraphs of point (a) of Section C of Chapter IV can be sourced;
  - (b) processing plants registered as processing exclusively non-ruminant blood in accordance with the first paragraph of point (c) of Section C of Chapter IV, as well as authorised processing plants producing blood products in accordance with the second, third and fourth paragraph of point (c) of Section C of Chapter IV;
  - (c) slaughterhouses, cutting plants and other establishments registered as, respectively, not slaughtering ruminants, boning or cutting up ruminant meat, and not handling ruminant products, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with the first paragraph of point (a) of Section D of Chapter IV can be sourced, as well as authorised slaughterhouses, cutting plants and other establishments, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with the second, third and fourth paragraphs of point (a) of Section D of Chapter IV can be sourced;
  - (d) processing plants registered as not processing ruminant animal by-products in accordance with the first paragraph of point (c) of Section D of Chapter IV, as well as authorised processing plants producing processed animal protein derived from non-ruminants which operate in accordance with the second, third and fourth paragraphs of point (c) of Section D of Chapter IV;
  - (e) authorised compound feed establishments producing, in accordance with Section B of Chapter III, compound feed containing fishmeal, dicalcium and tricalcium phosphate of animal origin, or blood products derived from non-ruminants;

- (f) authorised compound feed establishments producing, in accordance with point (d) of Section D of Chapter IV, compound feed containing processed animal protein derived from non-ruminants; as well as authorised compound feed establishments producing, in accordance with point 3(b)(ii) of Section E of Chapter V, exclusively compound feed for export from the Union or compound feed for export from the Union and compound feed for aquaculture animals to be placed on the market;
  - (g) authorised compound feed establishments producing, in accordance with point (d) of Section E of Chapter IV, milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species;
  - (h) authorised compound feed establishments producing, in accordance with point (b) of Section F of Chapter IV, compound feed containing processed animal protein derived from farmed insects;
  - (i) storage plants authorised in accordance with point 3 of Section A of Chapter III or in accordance with the third paragraph of point 3(d) of Section E of Chapter V.
2. Member States shall keep up-to-date lists of home compounders registered in accordance with point 3 of Section B of Chapter III, point (d)(ii) of Section D of Chapter IV, and point (b)(ii) of Section F of Chapter IV.

#### *SECTION B*

##### ***Transport and storage 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) to (d) shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage 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;
  - (d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15% in weight and derivatives made from such fat.

2. By way of derogation from point 1, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk feed materials and bulk compound feed listed in that point, may be used for the transport or storage 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 record 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 intended for fur animals or for pet animals containing products derived from ruminants or from non-ruminants***

1. Compound feed intended for fur animals or for pet animals which contains products derived from ruminants other than those listed in the following points (a) to (d) 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;
    - (d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15% in weight and derivatives made from such fat.
  2. Compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from non-ruminants, other than fishmeal, shall not be produced in establishments which produce feed for farmed animals other than fur animals or aquaculture animals.'
- (ii) Section D is replaced by the following:

### *'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) to (d) 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;
- (d) rendered fat from ruminants with a maximum level of insoluble impurities of 0,15% in weight and derivatives made from such fat.'

(iii) Section E is replaced by the following:

*'SECTION E*

***Export of processed animal protein and products containing such protein***

1. The export of processed animal protein derived from ruminants, or of processed animal protein derived from both ruminants and non-ruminants, shall be subject to compliance with the following conditions:
  - (a) The processed animal protein shall be transported in sealed containers, directly from the processing plant of production to the point of exit from the Union territory, which shall be a border inspection post listed in Annex I to Commission Decision 2009/821/EC<sup>1</sup>. Before leaving the Union territory, the operator responsible for arranging the transport of the processed animal protein shall inform the competent authority at that border inspection post of the arrival of the consignment at the point of exit.
  - (b) The consignment shall be accompanied by a duly completed commercial document produced according to the model set out in point 6 of Chapter III of Annex VIII to Regulation (EU) No 142/2011 and issued from the integrated computerised veterinary system (TRACES) introduced by Commission Decision 2004/292/EC<sup>2</sup>. On that commercial document, the border inspection post of exit must be indicated as exit point in box I.28.
  - (c) When the consignment arrives at the point of exit, the competent authority at the border inspection post shall verify

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<sup>1</sup> Commission Decision of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by the Commission veterinary experts and laying down the veterinary units in Traces (OJ L 296, 12.11.2009, p. 1).

<sup>2</sup> Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).



the seal of each of the containers presented at the border inspection post.

By way of derogation, based on an analysis of the risk, the competent authority at the border inspection post may decide to verify the seal of the container on a random basis.

If the seal verification is not satisfactory, the consignment must either be destroyed or must be re-dispatched to the establishment of origin.

The competent authority at the border inspection post shall inform, via TRACES, the competent authority responsible for the establishment of origin of the arrival of the consignment at the point of exit and, where applicable, of the outcome of the verification of the seal and of any corrective action taken.

- (d) The competent authority responsible for the establishment of origin shall carry out regular official controls to verify the correct implementation of points (a) and (b) and to verify that, for each consignment of processed animal protein of ruminant origin intended for export, the confirmation of the control carried out at the exit point was received from the competent authority of the border inspection post, through TRACES.

- 2. Without prejudice to point 1, the export of products containing processed animal protein derived from ruminants shall be prohibited.

By way of derogation, that prohibition shall not apply to processed petfood containing processed animal protein derived from ruminants which:

- (a) has been processed in approved petfood establishments in accordance with Article 24 of Regulation (EC) No 1069/2009; and
- (b) is packaged and labelled in accordance with Union legislation.

- 3. The export of processed animal protein derived from non-ruminants, or compound feed containing such protein, shall be subject to compliance with the following conditions:

- (a) The processed animal protein derived from non-ruminants shall be produced in processing plants which fulfil the requirements of point (c) of Section D of Chapter IV;
- (b) The compound feed containing processed animal protein derived from non-ruminants shall be produced in compound feed establishments which:

- (i) produce in accordance with point (d) of Section D of Chapter IV; or
  - (ii) source the processed animal protein used in compound feed destined for export in processing plants that comply with point (a) and, either:
    - are dedicated exclusively to the production of compound feed for export from the Union and are authorised for that purpose by the competent authority, or
    - are dedicated exclusively to the production of compound feed for export from the Union and to the production of compound feed for aquaculture animals to be placed on the market in the Union, and authorised for that purpose by the competent authority.
- (c) The compound feed containing processed animal protein derived from non-ruminants shall be packaged and labelled in accordance with Union legislation or with the legal requirements of the importing country. Where the compound feed containing processed animal protein derived from non-ruminants is not labelled in accordance with Union legislation, the following words shall be indicated on the labelling: "contains non-ruminant processed animal protein".
- (d) Bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein, and intended for export from the Union, shall be transported in vehicles and containers and stored in storage facilities which are not used, respectively, for the transport or storage of feed for placing on market and intended for feeding to ruminants or non-ruminant farmed animals other than aquaculture animals. Records detailing the type of products that were transported or stored shall be kept available to the competent authority for a period of at least two years.

By way of derogation from the first paragraph, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein, and intended for export from the Union, may be subsequently used for the transport or storage of feed for placing on the market and intended for feeding to ruminants or 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 record of such use shall be kept available to the competent authority for a period of at least two years.

Storage plants storing bulk processed animal protein derived from non-ruminants and bulk compound feed containing such protein under the conditions set out in the second paragraph of point (d) shall be authorised by the competent authority based on verification of their compliance with the requirements listed in that paragraph.

4. By way of derogation from point 3, the conditions laid down in that point shall not apply to:
  - (a) petfood which contains processed animal protein derived from non-ruminants and which has been processed in petfood establishments approved in accordance with Article 24 of Regulation (EC) No 1069/2009 and which is packaged and labelled in accordance with Union legislation;
  - (b) fishmeal, provided that it is produced in accordance with this Annex;
  - (c) processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;
  - (d) compound feed containing no other processed animal protein than fishmeal and processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;
  - (e) processed animal protein derived from non-ruminants destined for the manufacturing of petfood or of organic fertilisers and soil improvers in the third country of destination, provided that, before export, the exporter ensures that each consignment of processed animal protein is analysed in accordance with the method of analysis set out in point 2.2 of Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of constituents of ruminant origin.'

## ANNEX II

Annexes X, XIV and XV of Regulation (EU) No 142/2011 are amended as follows:

(1) In Annex X, Chapter II, Section 1, Part A is replaced by the following:

'A. Raw materials

1. Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than the Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of processed animal protein.
2. Processed animal protein derived from farmed insects, intended for the production of feed for farmed animals other than fur animals, may only be obtained from the following insect species:
  - (i) Black Soldier Fly (*Hermetia illucens*) and Common Housefly (*Musca domestica*),
  - (ii) Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphitobius diaperinus*),
  - (iii) House cricket (*Acheta domesticus*), Banded cricket (*Gryllobates sigillatus*) and Field Cricket (*Gryllus assimilis*).'

(2) In Annex XIV, Chapter I is amended as follows:

(a) In Section 1, Table 1, the first row is replaced by the following:

1	processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such proteins as defined in Article 3(2)(h) of Regulation (EC) No 767/2009	Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (h), (i), (j), (k), (l) and (m).	(a) The processed animal protein must have been produced in accordance with Section 1 of Chapter II of Annex X; and  (b) the processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter.	(a) In the case of processed animal proteins excluding fishmeal:  Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.  (b) In the case of fishmeal:  Third countries listed in Annex II to Decision 2006/766/EC.	(a) In the case of processed animal protein other than those derived from farmed insects:  Annex XV, Chapter 1.  (b) In the case of processed animal protein derived from farmed insects:  Annex XV, Chapter 1a.
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(b) In Section 2, the following point 5 is added:

- '5. Processed animal protein obtained from farmed insects may be imported into the Union provided that it has been produced in compliance with the following conditions:
  - (a) the insects belong to one of the following species:

- Black Soldier Fly (*Hermetia illucens*) and Common Housefly (*Musca domestica*),
  - Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphitobius diaperinus*),
  - House cricket (*Acheta domesticus*), Banded cricket (*Gryllodes sigillatus*) and Field Cricket (*Gryllus assimilis*).
- (b) the substrate for the feeding of insects may only contain products of non-animal origin or the following products of animal origin of Category 3 material:
- fishmeal;
  - blood products from non-ruminants;
  - di and tricalcium phosphate of animal origin;
  - hydrolysed proteins from non-ruminants;
  - hydrolysed proteins from hides and skins of ruminants ;
  - gelatine and collagen from non-ruminants;
  - eggs and egg products;
  - milk, milk based-products, milk-derived products and colostrum;
  - honey;
  - rendered fats;
- (c) The substrate for the feeding of insects and the insects or their larvae have not been in contact with any other materials of animal origin than those mentioned in point (b) and the substrate did not contain manure, catering waste or other waste.'

(3) Annex XV is amended as follows:

- (a) in Chapter 1, the title of the model Health Certificate is replaced by the following:

**'Health certificate**

*For processed animal protein, other than those derived from farmed insects, not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through<sup>2</sup> the European Union'*

- (b) the following Chapter 1a is added:

'CHAPTER 1a

**Health certificate**

*For processed animal protein derived from farmed insects not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through<sup>2</sup> the European Union*

**COUNTRY:**

**Veterinary certificate to EU**

<b>Part I : Details of dispatched consignment</b>	I.1. Consignor Name Address  Tel.		I.2. Certificate reference No	I.2.a.					
			I.3. Central competent authority						
			I.4. Local competent authority						
	I.5. Consignee Name Address  Postcode Tel.		I.6. Person responsible for the load in EU Name Address  Postcode Tel.						
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code	
	I.11. Place of origin  Name Address Name Address Name Address		Approval number	I.12. Place of destination  Name Address Postcode				Custom warehouse <input type="checkbox"/>	Approval number
	I.13. Place of loading		I.14. Date of departure						
	I.15. Means of transport  Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification Documentation references		I.16. Entry BIP in EU						
			I.17.						
	I.18. Description of commodity				I.19. Commodity code (HS code)				
						I.20. Quantity			
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>						I.22. Number of packages			
I.23. Seal/Container No						I.24. Type of packaging			
I.25. Commodities certified for:  Animal feedingstuff <input type="checkbox"/> Technical use <input type="checkbox"/> Production of petfood <input type="checkbox"/>									
I.26. For transit through EU to third country <input type="checkbox"/>  Third country				I.27. For import or admission into EU <input type="checkbox"/>  ISO code					
I.28. Identification of the commodities  Species (Scientific name) Nature of commodity Approval number of establishments Manufacturing plant Net weight Batch number									

**COUNTRY**

**Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein**

<b>Part II: Certification</b>	<b>II. Health information</b>	II.a. Certificate reference No	II.b.
	<p>I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>(1a)</sup> and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011<sup>(1b)</sup>, and in particular Section 1 of Chapter II of Annex X, and Chapter I of Annex XIV thereto and certify that:</p> <p>II.1. the processed animal protein derived from farmed insects or product described above contains exclusively processed animal protein not intended for human consumption that:</p> <p>(a) has been prepared and stored in an establishment or plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, and</p> <p>(b) has been prepared exclusively from farmed insects of the following species:  <sup>(2)</sup>either [- Black Soldier Fly (<i>Hermetia illucens</i>);]  <sup>(2)</sup>and/or [- Common Housefly (<i>Musca domestica</i>);]  <sup>(2)</sup>and/or [- Yellow Mealworm (<i>Tenebrio molitor</i>);]  <sup>(2)</sup>and/or [- Lesser Mealworm (<i>Alphitobius diaperinus</i>);]  <sup>(2)</sup>and/or [- House cricket (<i>Acheta domesticus</i>);]  <sup>(2)</sup>and/or [- Banded cricket (<i>Gryllodes sigillatus</i>);]  <sup>(2)</sup>and/or [- Field Cricket (<i>Gryllus assimilis</i>).]</p> <p>and</p> <p>(c) has been processed by method [1]-[2]-[3]-[4]-[5]-[7]<sup>(2)</sup> as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;</p> <p>and</p> <p>(d) the substrate for the feeding of farmed insects may only contain products of non-animal origin or the following products of animal origin of Category 3 material:</p> <ul style="list-style-type: none"> <li>- fishmeal;</li> <li>- blood products from non-ruminants;</li> <li>- di and tricalcium phosphate of animal origin;</li> <li>- hydrolysed proteins from non-ruminants;</li> <li>- hydrolysed proteins from hides and skins of ruminants;</li> <li>- gelatine and collagen from non-ruminants;</li> <li>- eggs and egg products;</li> <li>- milk, milk based-products, milk-derived products, and colostrum;</li> <li>- honey;</li> <li>- rendered fats;</li> </ul> <p>and</p> <p>(e) the substrate for the feeding of insects and the insects or their larvae have not been in contact with any other materials of animal origin than those mentioned in point (d) and the substrate did not contain manure, catering waste or other waste.</p> <p>II.2. the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards<sup>(3)</sup>:</p> <p style="padding-left: 40px;">Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0</p> <p style="padding-left: 40px;">Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1g;</p> <p>II.3. the product has undergone all precautions to avoid recontamination with pathogenic agents</p>		

- after treatment;
- II.4. the end product:
- <sup>(2)</sup>*either* [was packed in new or sterilised bags,]
- <sup>(2)</sup>*or* [was transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected before use,]
- which bear labels indicating ‘NOT FOR HUMAN CONSUMPTION/ PROCESSED INSECT PROTEIN – SHALL NOT BE USED IN FEED FOR FARMED ANIMALS EXCEPT AQUACULTURE AND FUR ANIMALS’;
- II.5. the end product was stored in enclosed storage;
- II.6. the processed animal protein derived from farmed insects, or product described above, does not contain and is not derived from
- <sup>(2)</sup>*either* [(a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council<sup>(4)</sup>;
- (b) mechanically separated meat obtained from bones of bovine, ovine or caprine animals except if the animals from which the animal-by products or derived product have been obtained, were born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Commission Decision 2007/453/EC<sup>(5)</sup>, in which there has been no BSE indigenous cases,
- (c) animal by-product or derived product obtained from animals which have been killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]
- <sup>(2)</sup>*or* [bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]
- II.7. the processed animal protein or product described above:
- <sup>(2)</sup>*either* [does not contain milk or milk products of ovine or caprine animal origin.]
- <sup>(2)</sup>*or* [contains milk or milk products of ovine or caprine animal origin which:
- (a) derive from ovine and caprine animals which have been kept continuously since birth in a country where the following conditions are fulfilled:
- (i) classical scrapie is compulsorily notifiable;
- (ii) an awareness, surveillance and monitoring system is in place;
- (iii) official restrictions apply to holdings of ovine or caprine animals in the case of a suspicion of TSE or a confirmation of classical scrapie;
- (iv) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;
- (v) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin, as defined in the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code, has been banned and effectively enforced in the whole country for a period of at least the preceding seven years;
- (b) originate from holdings where no official restriction is imposed due to a suspicion of TSE;
- (c) originate from holdings where no case of classical scrapie has been diagnosed during the preceding seven years or, following the confirmation of a case of classical scrapie:
- <sup>(2)</sup>*either* [all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR



genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele;]

<sup>(2)</sup>or [all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for two years at least since the confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in point 3.2 of Chapter C of Annex X to Regulation (EC) No 999/2001, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

- animals which have been slaughtered for human consumption; and
- animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.]]

## Notes

### Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for a transit commodity; it may be filled in if the certificate is for an import commodity.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.
- Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07; 05.11 or 23.01.
- Box reference I.25: technical use: any use other than for animal consumption.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28: Species: insects, specify its scientific name.

### Part II:

<sup>(1a)</sup> OJ L 300, 14.11.2009, p. 1.

<sup>(1b)</sup> OJ L 54, 26.2.2011, p. 1.

<sup>(2)</sup> Delete as appropriate.

<sup>(3)</sup> Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

<sup>(4)</sup> OJ L 147, 31.5.2001, p. 1.

<sup>(5)</sup> Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (notified under document number C(2007) 3114) (OJ L 172 30.6.2007, p. 84).

- The signature and the stamp must be in a different colour to that of the printing.
- Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian/Official inspector

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp: