

Commission Regulation (EU) 2017/893 of 24 May 2017 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 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/893

of 24 May 2017

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

(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<sup>(1)</sup>, and in particular the first paragraph of Article 23 thereof,

Having regard to 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)<sup>(2)</sup>, and in particular the second subparagraph of Article 31(2), the third subparagraph of Article 41(3) and the second subparagraph of Article 42(2) thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine 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 prohibits the feeding to ruminants of protein derived from animals. 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. However, by way of derogation and under specific conditions, point (c) of Chapter II of Annex IV authorises the feeding of non-ruminant processed animal protein to aquaculture animals only, provided that the processed animal protein and compound

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feed containing such protein have been produced in compliance with Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001. This Section currently requires that the animal by-products used for the production of such processed animal protein be derived from slaughterhouses or cutting plants. Given the production process of processed animal protein derived from insects, this requirement cannot be met in the case of insects. As a result, the use of processed animal protein derived from insects in feed for aquaculture animals is currently not allowed.

- (4) In several Member States, the rearing of insects for the production of processed animal protein derived from them and other insect derivatives destined for petfood has started. This production is carried out under the national control schemes of the competent authorities of the Member States. Studies have shown that farmed insects could represent an alternative and sustainable solution to conventional sources of animal proteins destined for feed for non-ruminant farmed animals.
- (5) On 8 October 2015, the EFSA (European Food Safety Authority) published a scientific opinion on a risk profile related to the production and consumption of insects as food and feed<sup>(3)</sup>. As regards the risks related to the presence of prions, EFSA concludes that, compared to the occurrence of hazards in currently authorised protein sources of animal origin, the occurrence of hazards in non-processed insects is expected to be equal or lower, as long as the insects are fed on substrates that do not harbour material of ruminant or human (manure) origin. As the processing of insects may further reduce the occurrence of biological hazards, that statement is also valid when it comes to processed animal proteins derived from insects.
- (6) As per the definition of ‘farmed animals’ laid down in Article 3(6) of Regulation (EC) No 1069/2009, insects bred for the production of processed animal protein derived from insects are to be considered as farmed animals, and are therefore subject to the feed ban rules laid down in Article 7 and Annex IV to Regulation (EC) No 999/2001 as well as to the rules of animal feeding laid down in Regulation (EC) No 1069/2009. Thus, the use of ruminant proteins, catering waste, meat-and-bone meal and manure as a feed for insects is prohibited. Furthermore, in accordance with Annex III to Regulation (EC) No 767/2009 of the European Parliament and of the Council<sup>(4)</sup>, the use of faeces for animal nutritional purposes is prohibited.
- (7) Processed animal protein derived from insects and compound feed containing such processed animal protein should therefore be authorised for feeding aquaculture animals. Point (c) of Chapter II of Annex IV to Regulation (EC) No 999/2001 should therefore be modified accordingly and a Section laying down TSE related conditions for the production of processed animal protein derived from farmed insects and compound feed containing such protein should be added in Chapter IV of Annex IV to that Regulation.
- (8) By analogy with what is already applicable for processed animal protein derived from non-ruminant animals and compound feed containing such protein destined for feeding aquaculture animals, specific conditions for the production and use of processed animal protein derived from insects should be laid down in order to avoid any risk of cross-contamination with other proteins which could pose a TSE risk to ruminant animals.

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In particular, by analogy with the conditions laid down in Section A of Chapter IV of Annex IV to Regulation (EC) No 999/2001, processed animal protein derived from insects should be produced in plants dedicated exclusively to the production of products derived from farmed insects.

- (9) In addition, in the interest of legal certainty, it is appropriate to insert a definition of farmed insects in Annex I to Regulation (EC) No 999/2001.
- (10) Annexes I and IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (11) Annex X to Commission Regulation (EU) No 142/2011<sup>(6)</sup> lays down rules for implementing Regulation (EC) No 1069/2009, including parameters for the production of safe feed of animal origin intended for feeding farmed animals. Only animal by-products and derived products complying with the requirements of Annex X to Regulation (EU) No 142/2011 may be fed to farmed animals, other than fur animals. While the provisions set out in Annex X to that Regulation do not cover live insects and dried insects in feed for farmed animals, the use of dried insects in or as pet food is subject to the provisions set out in Annex XIII to the aforementioned Regulation.
- (12) The amendment to Regulation (EC) No 999/2001 with a view to authorise processed animal protein derived from insects for feeding aquaculture animals is likely to open the opportunity for bigger production of processed animal protein derived from insects in the Union. Whereas the current small scale rearing of insects for petfood can adequately be addressed by existing national control schemes, Union provisions addressing animal health, public health, plant health or environmental risks are appropriate to ensure that insect rearing within the Union on a larger scale is safe. With respect to the insect species reared in the Union, these should not be pathogenic or have other adverse effects on plant, animal or human health; they should not be recognised as vectors of human, animal or plant pathogens and they should not be protected or defined as invasive alien species. Taking into account these national risk assessments, as well as the EFSA opinion of 8 October 2015, the following insect species can be identified as those insect species currently reared in the Union which fulfil the abovementioned safety conditions for insect production for feed use: Black Soldier Fly (*Hermetia illucens*), Common Housefly (*Musca domestica*), Yellow Mealworm (*Tenebrio molitor*), Lesser Mealworm (*Alphitobius diaperinus*), House cricket (*Acheta domesticus*), Banded cricket (*Grylloides sigillatus*) and Field Cricket (*Gryllus assimilis*).
- (13) Annex X to Regulation (EU) No 142/2011 should therefore be amended to add, in Section 1 of its Chapter II, a list of insect species which may be used for the production of processed animal protein obtained from farmed insects. This list should include the abovementioned insect species and may be amended in the future based on an assessment of the risks posed by the insect species concerned to animal health, public health, plant health or the environment.
- (14) Annex XIV to Regulation (EU) No 142/2011 sets out requirements for the import of animal by-products and derived products from third countries. Safety requirements applicable for growing insects intended to be used in feed for aquaculture animals and for the placing on the market of processed animal proteins derived from those insects,

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in particular as regards the insect species which may be used and the feed which may be given to the insects, should apply also in the case of imports from third countries. Sections 1 and 2 of Chapter I of Annex XIV to Regulation (EU) No 142/2011 should therefore be amended to lay down those requirements for imports into the Union.

- (15) Annex XV to Regulation (EU) No 142/2011 lays down model health certificates for the import into the Union of animal by-products. The model health certificate set out in Chapter 1 of Annex XV to that Regulation applies to imports into the Union of processed animal protein. For the purpose of imports of processed animal protein derived from farmed insects, a new model health certificate should be laid down and should include the specific requirements for breeding of farmed insects for the production of processed animal protein mentioned in Annex XIV to Regulation (EU) No 142/2011, as well as the other relevant requirements for imports of processed animal protein. Therefore new model of health certificate for the import of processed animal protein derived from farmed insects should be inserted into Chapter 1 of Annex XV.
- (16) Furthermore, the new model health certificate inserted in Chapter 1 of Annex XV to Regulation (EU) No 142/2011 should also take into account the amendment by Commission Regulation (EU) 2016/1396<sup>(6)</sup> of the requirements related to TSE applicable to imports of animal by-products and derived products of bovine, ovine or caprine origin, as set out in Chapter D of Annex IX to Regulation (EC) No 999/2001.
- (17) Annexes X, XIV and XV to Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (18) Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001 lays down requirements to prevent cross-contamination during transport in bulk between, on the one hand, fishmeal, dicalcium and tricalcium phosphate of animal origin, blood products derived from non-ruminants as well as compound feed containing these products, which are intended for feeding non-ruminant farmed animals, and, on the other hand, feed intended for ruminants. Considering that a similar risk of cross-contamination exists when those materials are stored in bulk, the requirements of Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001 should be extended to cover the storage in bulk of fishmeal, dicalcium and tricalcium phosphate of animal origin, blood products derived from non-ruminants and compound feed containing these materials.
- (19) Section B of Chapter V of Annex IV to Regulation (EC) No 999/2001 lays down requirements to prevent cross-contamination during transport between, on the one hand, bulk feed materials and bulk compound feed containing products derived from ruminants other than milk and milk based products, dicalcium and tricalcium phosphate of animal origin and hydrolysed proteins derived from ruminant hides and skins, and, on the other hand, feed intended for farmed animals other than fur animals. Considering that a similar risk of cross contamination exists when those materials are stored in bulk, the requirements of Section B of Chapter V of Annex IV to Regulation (EC) No 999/2001, should be extended to cover the storage in bulk of feed materials and compound feed containing products derived from ruminants other than milk and milk

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based products, dicalcium and tricalcium phosphate of animal origin and hydrolysed proteins derived from ruminant hides and skins.

- (20) Point (a) of Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 requires that animal by-products used for the production of processed animal protein, other than fishmeal, derived from non-ruminants and intended to be used in feed for aquaculture animals, are sourced in slaughterhouses which do not slaughter ruminants and cutting plants which do not bone or cut up ruminant meat. Point (a) provides for a derogation from that requirement for slaughterhouses which carry out effective measures in order to prevent cross-contamination between ruminant and non-ruminants by-products and which are inspected and authorised on that basis by the competent authority.
- (21) In order to allow for more possibilities in the types of raw materials used for the production of non-ruminant processed animal protein destined for use in feed for aquaculture animals or destined for export, it is appropriate to amend point (a) of Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 in order to allow the use of animal by-products originating from establishments other than slaughterhouses or cutting plants, provided that those other establishments are dedicated exclusively to the handling of non-ruminant materials, or are authorised by the competent authority, following an on-site inspection, based on the same channelling requirements as those provided for in the existing derogation for slaughterhouses, given that those channelling requirements provide the necessary guarantees that cross-contamination is prevented and controlled. It is also appropriate to extend to cutting plants the derogation existing for slaughterhouses, provided that the same channelling requirements are applied. Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (22) Point (b) of section A of Chapter IV of Annex IV to Regulation (EC) No 999/2001 requires that the accompanying commercial document or health certificate and any packaging of fishmeal and of compound feed containing fishmeal be marked with the words ‘contains fishmeal — shall not be fed to ruminants’. However, the commercial document or health certificate referred to in Article 21(2) of Regulation (EC) No 1069/2009 is not required for compound feed. It is therefore appropriate to amend point (b) of Section A of Chapter IV of Annex IV to Regulation (EC) No 999/2001 to clarify that, for compound feed containing fishmeal, the words ‘contains fishmeal — shall not be fed to ruminants’ should only be added on the label of the compound feed. Section B, point (d) of Section C and point (e) of Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 should also be amended in this respect.
- (23) Section C of Chapter V of Annex IV to Regulation (EC) No 999/2001 prohibits the production of feed for farmed animals other than fur animals in establishments producing petfood or feed for fur animals containing ruminant products which are prohibited for use in feed for farmed animals, other than fur animals. A similar prohibition should be laid down for establishments producing petfood or feed for fur animals containing non-ruminant processed animal protein, other than fishmeal, in order to ensure the absence of cross-contamination of feed for farmed animals other than

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fur animals or aquaculture animals with products prohibited in such feed. Section C of Chapter V of Annex IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.

- (24) Point 1 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 prohibits the export of processed animal protein derived from ruminants. That requirement was originally intended to control the spread of Bovine Spongiform Encephalopathy (BSE) at a time when BSE was epidemic in the Union and when the Europe was the main part of the world affected by the epidemic. However, the BSE situation in the Union has improved significantly. In 2015, five cases of BSE were reported in the Union compared to 2 166 reported cases in 2001. This improvement of the BSE situation in the Union is reflected in the fact that 23 Member States are now recognised as having a negligible BSE risk status in accordance with Commission Decision 2007/453/EC<sup>(7)</sup>, based on the BSE risk status recognised at international level by the World Animal Health Organisation (OIE).
- (25) The prohibition on the export of processed animal protein derived from ruminants should therefore be abolished and replaced by specific conditions to be complied with, in order to reduce the burden for trade and bring more proportionality compared to the current BSE epidemiological situation. Those conditions should notably be aimed at ensuring that the exported products do not contain meat-and-bone meal, the export of which is not authorised by Article 43(3) of Regulation (EC) No 1069/2009. As meat-and-bone meal may contain specified risk materials or may be derived from animals which have died or have been killed for reasons other than slaughter for human consumption, meat-and-bone meal represents a higher BSE risk and should therefore not be exported.
- (26) In order to ensure that the exported processed animal protein of ruminant origin do not contain meat-and-bone meal and are not used for other purposes than those authorised by Union legislation, the processed animal protein derived from ruminants should be transported in sealed containers directly from the processing plant to the point of exit from the Union, which should be a border inspection post listed in Annex I to Commission Decision 2009/821/EC<sup>(8)</sup>, in order to permit official controls. Such official controls should be carried out using the existing official control procedures, in particular the commercial document in accordance with the model established in point 6 of Chapter III of Annex VIII to Regulation (EU) No 142/2011 and the communication between competent authorities via the integrated computerised veterinary system (TRACES) introduced by Commission Decision 2004/292/EC<sup>(9)</sup>.
- (27) In accordance with Article 24 of Regulation (EC) No 1069/2009, the processing plant must be approved for the processing of Category 3 material and in accordance with Article 45 of that Regulation, it must be subject to regular official controls, including, where the processing plant is also approved for the processing of Category 1 and/or 2 material, as regards the permanent marking of Category 1 and 2 material required by that Regulation.
- (28) Point 2 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 requires that compound feed containing processed animal proteins derived from non-ruminants

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and intended for export are produced in accordance with certain requirements, referring notably to point (e) of Section A of Chapter V of Annex IV to that Regulation, which, in turn, refers to Section D of Chapter IV of that Annex. As those cross-references have led to diverging interpretations, it is appropriate to reformulate point 2 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 in order to clarify the requirements applicable for the production of processed animal proteins derived from non-ruminants, or compound feed containing such proteins, intended for export from the Union.

- (29) In particular, the reference, in point 2(b) of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001, which concerns exports of compound feed containing processed animal protein derived from non-ruminants, to point (d) of Section D of Chapter IV of that Annex, which concerns the production of compound feed containing processed animal protein derived from non-ruminants for feeding aquaculture animals, is not adapted to all cases. While point (d) of Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 requires that the compound feed establishment be dedicated exclusively to the production of feed for aquaculture animals or be authorised based on measures taken to avoid cross-contamination between feed intended for aquaculture animals and feed intended for other farmed animals, in the case of exports, Annex IV to Regulation (EC) No 999/2001 does not limit the species to which the exported compound feed may be fed to in the third country. The cross-contamination to be targeted in this case is therefore between the exported compound feed containing non-ruminant processed animal protein and feed destined for other farmed animals than aquaculture animals to be placed on the Union market. Point 2 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (30) The amendments described in previous recitals concerning (1) the storage of certain feed materials and compound feed; (2) the production of processed animal protein derived from farmed insects and of compound feed containing such protein; (3) the export of compound feed containing processed animal protein derived from non-ruminants; and (4) the use of raw materials from other establishments than slaughterhouses and cutting plants for the manufacturing of non-ruminant processed animal protein, include requirements for Member States competent authority to register or authorise certain establishments based on the fulfilment of those requirements. Section A of Chapter V of Annex IV to Regulation (EC) No 999/2001 should therefore be amended in order to include the obligation for Member States to keep up-to-date and make publicly available lists of those establishments.
- (31) To limit the burden for competent authorities, the publication of lists of operators should be limited only to those cases where such publication is necessary in order for operators to identify which potential suppliers comply with the requirements of Annex IV to Regulation (EC) No 999/2001, and for competent authorities to control the respect of those requirements along the production chain. Section A of Chapter V of Annex IV should therefore be amended to exclude lists of home compounders from the obligation to be made publicly available.

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- (32) As Member States and operators need sufficient time to adapt to the amendments made by this Regulation in Section A of Chapter III, as regards the storage of certain bulk feed materials and compound feed, and in Sections A, B and C of Chapter V of Annex IV to Regulation (EC) No 999/2001, as regards the lists of establishments producing in accordance with certain requirements of Annex IV to Regulation (EC) No 999/2001, as regards the storage of feed containing products derived from ruminants, and as regards the production of petfood containing processed animal protein derived from non-ruminants, those changes should apply from 1 January 2018.
- (33) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

Annexes X, XIV and XV to Regulation (EU) No 142/2011 are amended in accordance with Annex II to this Regulation.

*Article 3*

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

It shall apply from 1 July 2017.

However, the following amendments made to Annex IV to Regulation (EC) No 999/2001 by this Regulation shall apply from 1 January 2018:

- (a) the amendments made to Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001 by point 2(b)(i) of Annex I to this Regulation; and
- (b) the amendments made to Sections A, B and C of Chapter V of Annex IV to Regulation (EC) No 999/2001 by point 2(d)(i) of Annex I to this Regulation.

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

Done at Brussels, 24 May 2017.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## 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:

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- (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

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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;

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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;

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- (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

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- 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

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- 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

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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:

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- (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;

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(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;

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- (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

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- 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.

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### 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;

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- (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>(10)</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>(11)</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 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

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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

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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.

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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*);

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- (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 the processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter. | (a) processed animal protein must have been produced in accordance with Section 1 of Chapter II of Annex X; and 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. In the case of fishmeal: Third countries listed in Annex II to Decision 2006/766/EC. | In the case of processed animal protein other than those derived from farmed insects: Annex XV, Chapter 1. In the case of processed animal protein derived from farmed insects: Annex XV, Chapter 1a. |
|---|--|---|--|--|--|---|

- (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:

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- 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 (*Grylloides 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*

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| COUNTRY:   |   | Veterinary certificate to EU |   |                 |        |
|--|---|------------------------------|---|-----------------|--------|
| Part I: Details of dispatched consignment  | I.1. Consignor<br>Name<br>Address<br><br>Tel.             |                              | I.2. Certificate reference No   |                 | I.2.a. |
|  |   |                              | I.3. Central competent authority  |                 |        |
|  |   |                              | I.4. Local competent authority  |                 |        |
|  | I.5. Consignee<br>Name<br>Address<br><br>Postcode<br>Tel. |                              | I.6. Person responsible for the load in EU<br>Name<br>Address<br><br>Postcode<br>Tel. |                 |        |
|  | I.7. Country of origin                                    | ISO code                     | I.8. Region of origin   | Code            |        |
|  |   |                              |   |                 |        |
|  |   |                              |   |                 |        |
| I.11. Place of origin<br><br>Name<br>Address<br>Name<br>Address<br>Name<br>Address   |   | Approval number              | I.12. Place of destination<br><br>Name<br>Address<br><br>Postcode                     |                 |        |
|  |   | Approval number              | Custom warehouse <input type="checkbox"/>   | Approval number |        |
|  |   | Approval number              |   |                 |        |
| I.13. Place of loading   |   | I.14. Date of departure      |   |                 |        |
| I.15. Means of transport<br><br><input type="checkbox"/> Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon<br><input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/><br>Identification<br>Documentation references |   | I.16. Entry BIP in EU        |   |                 | I.17.  |
|  |   |                              |   |                 |        |

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|  |                     |  |  |
|--|---------------------|--|--|
| I.18. Description of commodity   |                     | I.19. Commodity code (HS code)                                 |  |
|  |                     | I.20. Quantity   |  |
| I.21. Temperature of product<br>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:<br><br>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"/><br><br>Third country                      ISO code  |                     | I.27. For import or admission into EU <input type="checkbox"/> |  |
| I.28. Identification of the commodities<br><br>Approval number of establishments   |                     |  |  |
| Species<br>(Scientific name)   | Nature of commodity | Manufacturing plant  | Net weight                      Batch number |

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| COUNTRY                       | Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein  |       |
|-------------------------------|---|-------|
| <b>II. Health information</b> | II.a. Certificate reference No  | II.b. |
| Part II: Certification        | 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>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:</p> <p><sup>(2)</sup> either <input type="checkbox"/> Black Soldier Fly (<i>Hermetia illucens</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> Common Housefly (<i>Musca domestica</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> Yellow Mealworm (<i>Tenebrio molitor</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> Lesser Mealworm (<i>Alphitobius diaperinus</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> House cricket (<i>Acheta domestica</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> Banded cricket (<i>Gryllodes sigillatus</i>);</p> <p><sup>(2)</sup> and/or <input type="checkbox"/> 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><input type="checkbox"/> fishmeal;</li> <li><input type="checkbox"/> blood products from non-ruminants;</li> <li><input type="checkbox"/> di and tricalcium phosphate of animal origin;</li> <li><input type="checkbox"/> hydrolysed proteins from non-ruminants;</li> <li><input type="checkbox"/> hydrolysed proteins from hides and skins of ruminants;</li> <li><input type="checkbox"/> gelatine and collagen from non-ruminants;</li> <li><input type="checkbox"/> eggs and egg products;</li> <li><input type="checkbox"/> milk, milk based-products, milk-derived products, and colostrum;</li> <li><input type="checkbox"/> honey;</li> <li><input type="checkbox"/> 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> |       |

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| COUNTRY                | Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein  |       |
|------------------------|---|-------|
| II. Health information | II.a. Certificate reference No  | II.b. |
| 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> :   |       |
|                        | Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0   |       |
|                        | Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g;   |       |
| II.3.                  | the product has undergone all precautions to avoid recontamination with pathogenic agents 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;  |       |

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## COUNTRY

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

| II. Health information  | II.a. Certificate reference No | II.b. |
|---|--------------------------------|-------|
| <p>(b) originate from holdings where no official restriction is imposed due to a suspicion of TSE;</p> <p>(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:</p> <p>(<sup>2</sup>) <i>either</i> [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;]</p> <p>(<sup>2</sup>) <i>or</i> [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:</p> <ul style="list-style-type: none"> <li>— animals which have been slaughtered for human consumption; and</li> <li>— animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.]]</li> </ul> |                                |       |
| <p>Notes</p>  |                                |       |
| <p><b>Part I:</b></p>   |                                |       |
| <p>— 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.</p>   |                                |       |
| <p>— 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.</p>  |                                |       |
| <p>— 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.</p>   |                                |       |
| <p>— Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07; 05.11 or 23.01.</p>  |                                |       |
| <p>— Box reference I.25: technical use: any use other than for animal consumption.</p>  |                                |       |
| <p>— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.</p>  |                                |       |
| <p>— Box reference I.28: Species: insects, specify its scientific name.</p>   |                                |       |
| <p><b>Part II:</b></p>  |                                |       |
| <p>(<sup>1a</sup>) OJ L 300, 14.11.2009, p. 1.</p>  |                                |       |
| <p>(<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1.</p>  |                                |       |
| <p>(<sup>2</sup>) Delete as appropriate.</p>  |                                |       |
| <p>(<sup>3</sup>) Where:</p>  |                                |       |
| <p>n = number of samples to be tested;</p>  |                                |       |
| <p>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;</p>  |                                |       |

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COUNTRY

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

| II. Health information  | II.a. Certificate reference No | II.b. |
|---|--------------------------------|-------|
| <p>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</p> <p>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.</p> <p>(<sup>4</sup>) OJ L 147, 31.5.2001, p. 1.</p> <p>(<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 (OJ L 172, 30.6.2007, p. 84).</p> <p>— The signature and the stamp must be in a different colour to that of the printing.</p> <p>— 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.</p> |                                |       |
| <p>Official veterinarian/Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>  |                                |       |

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- (1) [OJ L 147, 31.5.2001, p. 1.](#)
- (2) [OJ L 300, 14.11.2009, p. 1.](#)
- (3) Scientific Opinion on a Risk profile related to production and consumption of insects as food and feed, *The EFSA Journal* (2015);13(10):4257.
- (4) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC ([OJ L 229, 1.9.2009, p. 1.](#))
- (5) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive ([OJ L 54, 26.2.2011, p. 1.](#))
- (6) Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (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 ([OJ L 225, 19.8.2016, p. 76.](#))
- (7) 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 ([OJ L 172, 30.6.2007, p. 84.](#))
- (8) Commission Decision 2009/821/EC 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.](#))
- (9) 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.](#))
- (10) Commission Decision 2009/821/EC 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.](#))
- (11) 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.](#))

**Changes to legislation:**

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