

Official Journal of the European Union

L 295



English edition

Legislation

Volume 64

18 August 2021

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⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/1372

of 17 August 2021

amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs). 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, as laid down in Annex IV, Chapter I, while Chapters II to V set out and detail certain derogations to the prohibitions provided for in Chapter I under specific conditions.
- (3) The Communication from the Commission to the European Parliament and the Council of a Strategy paper on TSEs for 2010-2015 ('the TSE Road Map 2') ⁽²⁾ outlines possible amendments to Union legislation to align the TSE's prevention, control and eradication measures with the evolution of the epidemiological situation on Bovine Spongiform Encephalopathy (BSE). It also emphasises that any review of the TSE rules should be primarily driven by scientific advice. The TSE Road Map 2 addresses the revision of the current feed ban provisions for non-ruminant animals laid down in Union legislation.
- (4) Based on the contents of two scientific opinions issued by the Panel on Biological Hazards (BIOHAZ) of the European Food Safety Authority ('the Authority') on 24 January 2007 and on 17 November 2007 respectively, the TSE Road Map 2 acknowledges that no TSE have been identified as occurring in non-ruminant farmed animals under natural conditions.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ COM(2010) 384 final, 16.7.2010.

- (5) On 7 June 2018, the Authority adopted a scientific opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins ⁽³⁾. The QRA estimated a total BSE infectivity four times lower than that estimated in 2011, with less than one new case of BSE expected to arise each year.
- (6) On 22 September 2020, the Authority adopted a scientific opinion on the potential cattle BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminant farmed animals ⁽⁴⁾. The Authority concludes that the probability that no new case of BSE in the cattle population would be generated through any of the three risk pathways identified in that opinion is larger than 99 % (almost certain).
- (7) At the same time, an estimated 100 000 tonnes of former foodstuffs containing ruminant collagen and/or gelatine go yearly for disposal in the Union, since they cannot be used in the feed of farmed animals under the current feed ban rules.
- (8) The prohibition to feed non-ruminant farmed animals with collagen and gelatine of ruminant origin should therefore be repealed.
- (9) Article 11 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁵⁾, prohibits the feeding of terrestrial animals of a given species other than fur animals with processed animal protein from the bodies or parts of bodies of animals of the same species (intra-species recycling).
- (10) The TSE Road Map 2 also acknowledges that the transmission risk of BSE from non-ruminants to non-ruminants is negligible as long as intra-species recycling is avoided. Consequently, it concludes that a lifting of the ban on the use of processed animal protein from non-ruminants in non-ruminant feed, respecting the existing prohibition on intra-species recycling, could be considered.
- (11) On 29 November 2010, the Council adopted conclusions on the TSE Road Map 2 ⁽⁶⁾. Those conclusions consider that it should be a prerequisite of any possible reintroduction of the use of non-ruminant processed animal protein to feed for other non-ruminant species that effective and validated analytical techniques are available to distinguish between processed animal protein originating from different species and also that there has been an analysis of the risks of such reintroduction, regarding animal and public health.
- (12) The European Union Reference Laboratory for Animal Proteins in feeding stuffs (EURL- AP) validated in 2012 a new diagnostic DNA-based method (PCR) which is able to detect ruminant material that may be present in feed. The validation of this method permitted the re-authorisation in 2013 of the use of non-ruminant processed animal protein in feed for aquaculture animals as set out in Commission Regulation (EU) No 56/2013 ⁽⁷⁾.
- (13) Subsequently, in 2015 and 2018 respectively, PCR methods able to detect the presence of porcine or poultry material in feed were also validated by the EURL-AP. Therefore, they enable the control of the correct implementation of the prohibition on intra-species recycling in porcine animals and poultry.
- (14) The Report from the Commission to the Council and the European Parliament on the development of plant proteins in the European Union ⁽⁸⁾, published on 22 November 2018, highlights the need to reduce the Union dependence on third countries for its protein supply. From the nutritional point of view, processed animal proteins are an excellent

⁽³⁾ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5314>

⁽⁴⁾ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6267>

⁽⁵⁾ 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 (OJ L 300, 14.11.2009, p. 1).

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

⁽⁷⁾ Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 21, 24.1.2013, p. 3).

⁽⁸⁾ https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/plants_and_plant_products/documents/report-plant-proteins-com2018-757-final_en.pdf

feed material, with high concentration of highly digestible nutrients such as amino acids and phosphorous, and a high content in vitamins. Re-authorisation of processed animal proteins from non-ruminant origin in the feed of non-ruminant animals would reduce this dependence on third countries' protein.

- (15) The use of processed animal protein of porcine origin in poultry feed and of processed animal protein of poultry origin in the feed of porcine animals should be re-authorised. Strict requirements during the collection, transport and processing of those products should apply, and regular sampling and analysis be performed, in order to avoid any risk and contribute to the verification of the absence of cross-contamination with prohibited ruminant protein and intra-species recycling.
- (16) Commission Regulation (EU) 2017/893 ⁽⁹⁾ authorised the use of processed animal protein derived from insects and compound feed containing such processed animal protein for feeding aquaculture animals. Poultry are insectivorous animals, porcine animals are omnivorous, and there are no concerns with this feed material. As a consequence, processed animal protein derived from insects should be authorised to feed poultry and porcine animals, under the same conditions as required for feeding aquaculture animals.
- (17) Annex IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (18) 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

Annex IV to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 17 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁹⁾ 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 (OJ L 138, 25.5.2017, p. 92).

ANNEX

Annex IV to Regulation (EC) No 999/2001 is amended as follows:

(1) in Chapter I, point (b) is replaced by the following:

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

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

(2) in Chapter II, the following points are added:

‘(f) poultry of the following feed materials and compound feed:

- (i) processed animal protein derived from porcine animals 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 Chapter IV, Section G;
- (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 Chapter IV, Section F;

(g) porcine animals of the following feed materials and compound feed:

- (i) processed animal protein derived from poultry 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 Chapter IV, Section H;
- (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 Chapter IV, Section F.’;

(3) Chapter III is amended as follows:

(a) Section A is amended as follows:

(i) point 1(a) is replaced by the following:

‘(a) bulk processed animal protein derived from non-ruminants, including fishmeal, processed animal protein derived from farmed insects, processed animal protein derived from porcine animals and processed animal protein derived from poultry.’;

(ii) points 4 and 5 are replaced by the following:

‘4. Bulk processed animal protein derived from porcine animals, 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 and poultry.

5. By way of derogation from point 4, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from porcine animals and bulk compound feed containing such processed animal protein may be subsequently used for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals and poultry 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.’;

(iii) the following points are added:

- ‘6. Bulk processed animal protein derived from poultry, 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 and porcine animals.
7. By way of derogation from point 6, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from poultry and bulk compound feed containing such processed animal protein may be subsequently used for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals and porcine 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.

8. Bulk processed animal protein derived from farmed insects, 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, poultry and porcine animals.
9. By way of derogation from point 8, vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from farmed insects and bulk compound feed containing such processed animal protein may be subsequently used for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals, poultry and porcine 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.

10. Bulk processed animal protein derived from non-ruminants, excluding fishmeal and processed animal protein derived from poultry, porcine animals and farmed insects, 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.
11. By way of derogation from point 10, 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.’;

(b) Section B is amended as follows:

(i) in point 1, the following points are added:

- ‘(d) processed animal protein derived from farmed insects;
- (e) processed animal protein derived from porcine animals;
- (f) processed animal protein derived from poultry.’;

(ii) in point 3, point (b) is replaced by the following:

‘(b) they must keep only non-ruminant animals and:

- (i) where they keep poultry, they shall not produce complete feed from compound feed containing processed animal protein derived from poultry;

(ii) where they keep porcine animals, they shall not produce complete feed from compound feed containing processed animal protein derived from porcine animals;;

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

‘(a) processed animal protein derived from non-ruminants, including fishmeal, processed animal protein derived from farmed insects, processed animal protein derived from porcine animals and processed animal protein derived from poultry;’;

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

‘(a) processed animal protein derived from non-ruminants, including fishmeal, processed animal protein derived from farmed insects, processed animal protein derived from porcine animals and processed animal protein derived from poultry;’;

(4) Chapter IV is amended as follows:

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

‘(a) The animal by-products intended to be used for the production of processed animal protein referred to in this Section shall come from one or more of the following:

- (i) slaughterhouses approved in accordance with Article 4 of Regulation (EC) No 853/2004 which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants;
- (ii) cutting plants approved in accordance with Article 4 of Regulation (EC) No 853/2004 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;
- (iii) other establishments than those referred to in point (i) or (ii), registered or approved in accordance with Article 4 of Regulation (EC) No 853/2004, which do not handle ruminant products and which are registered by the competent authority as not handling ruminant products;
- (iv) approved establishments referred to in Article 24(1), points (h) and (i) of Regulation (EC) No 1069/2009 which are registered by the competent authority as handling or storing only non-ruminant animal by-products coming from establishments referred to in points (i), (ii) and (iii).

By way of derogation from points (i), (ii) and (iii) of the first paragraph, the competent authority may authorise the slaughter of ruminants and the handling of ruminant products in the establishments referred to in points (i), (ii) and (iii) of the first paragraph 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:

- (1) the slaughtering of non-ruminants must be carried out in lines that are physically separate from those used for the slaughtering of ruminants;
- (2) non-ruminant products must be handled on production lines that are physically separate from those used for the handling of ruminant products;
- (3) 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;
- (4) a regular sampling and analysis of animal by-products of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.’;

- (b) Section F is replaced by the following:

‘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, poultry and porcine 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, poultry and porcine animals:

- (a) Processed animal protein derived from farmed insects must be produced:
- (i) in processing plants approved in accordance with Article 24(1), point (a) of Regulation (EC) No 1069/2009 and dedicated exclusively to the production of products derived from farmed insects;
 - (ii) in accordance with the requirements laid down in Annex X, Chapter II, Section 1 to Regulation (EU) No 142/2011.

By way of derogation from the condition provided for in point (i) of the first paragraph, the competent authority may authorise the production of processed animal protein derived from farmed insects in processing plants processing by-products from other species.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of the measures aimed to prevent cross-contamination of processed animal protein derived from farmed insects with processed animal protein derived from other farmed animals.

Those preventive measures shall include the following minimum requirements:

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

By way of derogation from point (i) of the first paragraph, 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 do not keep farmed animals as defined in Article 3, point 6(a) of Regulation (EC) No 1069/2009, other than aquaculture animals, poultry, porcine animals or fur animals,
- the compound feed containing processed animal protein derived from farmed insects used in their production contains less than 50 % crude protein.

By way of derogation from point (ii) of the first paragraph, the production of compound feed containing processed animal protein derived from farmed insects, intended for aquaculture animals, poultry or porcine 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, poultry or porcine 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, poultry and porcine 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.

- (c) The commercial document or, as appropriate, the health certificate accompanying the processed animal protein derived from farmed insects in accordance with Article 21(2) of Regulation (EC) No 1069/2009, the label of that processed animal protein derived from farmed insects, and the label of compound feed containing processed animal protein derived from farmed insects shall be clearly marked in accordance with Chapter V, Section G of this Annex.'

- (c) the following sections are added:

'SECTION G

Specific conditions applicable to the production and use of processed animal protein derived from porcine animals and compound feed containing such protein, intended to be used for feeding poultry

The following specific conditions shall apply to the production and use of processed animal protein derived from porcine animals and compound feed containing such protein, intended to be used for feeding poultry ("processed animal protein derived from porcine animals"):

- (a) The animal by-products intended to be used for the production of processed animal protein derived from porcine animals shall come from one or more of the following:

- (i) slaughterhouses approved in accordance with Article 4 of Regulation (EC) No 853/2004 which do not slaughter ruminants and poultry and which are registered by the competent authority as not slaughtering ruminants and poultry;
- (ii) cutting plants approved in accordance with Article 4 of Regulation (EC) No 853/2004 which do not bone or cut up ruminant and poultry meat and which are registered by the competent authority as not boning or cutting up ruminant and poultry meat;
- (iii) other establishments than those referred to in point (i) or (ii), registered or approved in accordance with Article 4 of Regulation (EC) No 853/2004, which do not handle ruminant and poultry products and which are registered by the competent authority as not handling ruminant and poultry products;
- (iv) approved establishments referred to in Article 24(1), points (h) and (i) of Regulation (EC) No 1069/2009 which are registered by the competent authority as handling or storing only non-ruminant animal by-products coming from establishments referred to in points (i), (ii) and (iii).

By way of derogation from points (i), (ii) and (iii) of the first paragraph, the competent authority may authorise the slaughter of ruminants or poultry and the handling of ruminant or poultry products in the establishments referred to in points (i), (ii) and (iii) of the first paragraph producing porcine animal by-products intended for the production of processed animal protein derived from porcine animals.

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 or poultry and porcine animal by-products.

Those measures shall include the following minimum requirements:

- (1) the slaughtering of porcine animals must be carried out in lines that are physically separate from those used for the slaughtering of ruminants or poultry;
 - (2) products of porcine origin must be handled on production lines that are physically separate from those used for the handling of ruminant or poultry products;
 - (3) the collection, storage, transport and packaging facilities for animal by-products of porcine origin must be kept separate from those for animal by-products of ruminant or poultry origin;
 - (4) a regular sampling and analysis of animal by-products of porcine origin must be carried out to detect the presence of ruminant or poultry proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.
- (b) The animal by-products of porcine origin intended to be used for the production of processed animal protein derived from porcine animals shall be transported to a processing plant in vehicles and containers which are not used for the transport of animal by-products of ruminant or poultry origin.

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

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

- (c) The processed animal protein derived from porcine animals shall be produced in processing plants:
- (i) dedicated to processing by-products sourced from slaughterhouses, cutting plants or other establishments referred to in point (a);
 - (ii) registered by the competent authority as not processing ruminant animal or poultry by-products.

By way of derogation from point (ii) of the first paragraph, the competent authority may authorise the production of processed animal protein derived from porcine animals in processing plants processing ruminant animal or poultry by-products.

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

Those preventive measures shall include the following minimum requirements:

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

By way of derogation from point (i) of the first paragraph, a specific authorisation for the production of complete feed from compound feed containing processed animal protein derived from porcine animals 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 porcine animals,
- they do not keep farmed animals as defined in Article 3, point 6(a) of Regulation (EC) No 1069/2009, other than poultry, aquaculture animals or fur animals,
- the compound feed containing processed animal protein derived from porcine animals used in their production contains less than 50 % crude protein.

By way of derogation from point (ii) of the first paragraph, the production of compound feed for poultry, containing processed animal protein derived from porcine animals, in establishments which also produce compound feed intended for farmed animals other than aquaculture and 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 porcine 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 porcine animals 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 poultry, aquaculture and fur 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.
- (e) The commercial document or, as appropriate, the health certificate accompanying the processed animal protein derived from porcine animals in accordance with Article 21(2) of Regulation (EC) No 1069/2009, the label of that processed animal protein derived from porcine animals, and the label of compound feed containing processed animal protein derived from porcine animals shall be clearly marked in accordance with Chapter V, Section G of this Annex.

SECTION H

Specific conditions applicable to the production and use of processed animal protein derived from poultry and compound feed containing such protein, intended to be used for feeding porcine animals

The following specific conditions shall apply to the production and use of processed animal protein derived from poultry and compound feed containing such protein, intended to be used for feeding porcine animals (“processed animal protein derived from poultry”):

- (a) The animal by-products intended to be used for the production of processed animal protein derived from poultry shall come from one or several of the following:
- (i) slaughterhouses approved in accordance with Article 4 of Regulation (EC) No 853/2004 which do not slaughter ruminants and porcine animals and which are registered by the competent authority as not slaughtering ruminants and porcine animals;
 - (ii) cutting plants approved in accordance with Article 4 of Regulation (EC) No 853/2004 which do not bone or cut up ruminant meat and pork and which are registered by the competent authority as not boning or cutting up ruminant meat and pork;
 - (iii) other establishments than those referred to in point (i) or (ii), registered or approved in accordance with Article 4 of Regulation (EC) No 853/2004, which do not handle ruminant and porcine products and which are registered by the competent authority as not handling ruminant and porcine products;
 - (iv) approved establishments referred to in Article 24(1), points (h) and (i) of Regulation (EC) No 1069/2009 which are registered by the competent authority as handling or storing only non-ruminant animal by-products coming from establishments referred to in points (i), (ii) and (iii).

By way of derogation from points (i), (ii) and (iii) of the first paragraph, the competent authority may authorise the slaughter of ruminants or porcine animals and the handling of ruminant or porcine products in the establishments referred to in points (i), (ii) and (iii) of the first paragraph producing poultry animal by-products intended for the production of processed animal protein derived from poultry.

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 or porcine and poultry animal by-products.

Those measures shall include the following minimum requirements:

- (1) the slaughtering of poultry must be carried out in lines that are physically separate from those used for the slaughtering of ruminants or porcine animals;
 - (2) poultry products must be handled on production lines that are physically separate from those used for the handling of ruminant or porcine products;
 - (3) the collection, storage, transport and packaging facilities for animal by-products of poultry origin must be kept separate from those for animal by-products of ruminant or porcine origin;
 - (4) a regular sampling and analysis of animal by-products of poultry origin must be carried out to detect the presence of ruminant or porcine proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.
- (b) The animal by-products of poultry origin intended to be used for the production of processed animal protein derived from poultry shall be transported to a processing plant in vehicles and containers which are not used for the transport of animal by-products of ruminant or porcine origin.

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

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

- (c) The processed animal protein derived from poultry shall be produced in processing plants:
- (i) dedicated to processing animal by-products sourced from slaughterhouses, cutting plants or other establishments referred to in point (a);
 - (ii) registered by the competent authority as not processing ruminant or porcine animal by-products.

By way of derogation from point (ii) of the first paragraph, the competent authority may authorise the production of processed animal protein derived from poultry in processing plants processing ruminant or porcine animal by-products.

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

Those preventive measures shall include the following minimum requirements:

- (1) the production of processed animal protein derived from ruminants or porcine animals must be carried out in a closed system that is physically separated from that used for the production of the processed animal protein derived from poultry;
- (2) the keeping of animal by-products derived from ruminants or porcine animals during storage and transport in facilities that are physically separated from those for animal by-products derived from poultry;
- (3) the keeping of processed animal protein derived from ruminants or porcine animals during storage and packaging in facilities that are physically separated from those used for finished products derived from poultry;
- (4) regular sampling and analysis of the processed animal protein derived from poultry must be carried out to verify the absence of cross-contamination with ruminant or porcine processed animal protein using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined

on the basis of a risk assessment carried out by the operator as part of its procedures based on HACCP principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

- (d) Compound feed containing processed animal protein derived from poultry shall be produced in establishments:
- (i) authorised for that purpose by the competent authority;
 - (ii) dedicated exclusively to the production of feed for porcine, aquaculture or fur animals.

By way of derogation from point (i) of the first paragraph, a specific authorisation for the production of complete feed from compound feed containing processed animal protein derived from poultry 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 poultry,
- they do not keep farmed animals as defined in of Article 3, point 6(a) of Regulation (EC) No 1069/2009, other than porcine animals, aquaculture animals or fur animals,
- the compound feed containing processed animal protein derived from poultry used in their production contains less than 50 % crude protein.

By way of derogation from point (ii) of the first paragraph, the production of compound feed for porcine animals, containing processed animal protein derived from poultry, in establishments which also produce compound feed intended for farmed animals other than aquaculture and 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 poultry 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 poultry 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 poultry, aquaculture and fur 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;
- (e) The commercial document or, as appropriate, the health certificate accompanying the processed animal protein derived from poultry in accordance with Article 21(2) of Regulation (EC) No 1069/2009, the label of that processed animal protein derived from poultry, and the label of compound feed containing processed animal protein derived from poultry shall be clearly marked in accordance with Chapter V, Section G of this Annex.;

(5) Chapter V is amended as follows:

(a) Section A is 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 Chapter IV, Section C, point (a), first paragraph, as well as authorised slaughterhouses from which blood produced in accordance with Chapter IV, Section C, point (a), second, third and fourth paragraphs can be sourced;
- (b) slaughterhouses, cutting plants, other food establishments and animal by-products establishments registered as, respectively, not slaughtering ruminants, not boning or cutting up ruminant meat, not handling ruminant products, and handling or storing only animal by-products coming from these food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with Chapter IV, Section D, point (a), first paragraph can be sourced, as well as authorised slaughterhouses, cutting plants and other food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from non-ruminants in accordance with Chapter IV, Section D, point (a), second, third and fourth paragraphs can be sourced;
- (c) slaughterhouses, cutting plants and other food establishments and animal by-products establishments registered as, respectively, not slaughtering ruminants and poultry, not boning or cutting up ruminant and poultry meat, not handling ruminant and poultry products, and handling or storing only animal by-products coming from these food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from porcine animals in accordance with Chapter IV, Section G, point (a), first paragraph can be sourced, as well as authorised slaughterhouses, cutting plants and other food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from porcine animals in accordance with Chapter IV, Section G, point (a), second, third and fourth paragraphs can be sourced;
- (d) slaughterhouses, cutting plants and other food establishments and animal by-products establishments registered as, respectively, not slaughtering ruminants and porcine animals, not boning or cutting up ruminant meat and pork, not handling ruminant and porcine products, and handling or storing only animal by-products coming from these food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from poultry in accordance with Chapter IV, Section H, point (a), first paragraph can be sourced, as well as authorised slaughterhouses, cutting plants and other food establishments, from which animal by-products intended to be used for the production of processed animal protein derived from poultry in accordance with Chapter IV, Section H, point (a), second, third and fourth paragraphs can be sourced;
- (e) processing plants registered as processing exclusively non-ruminant blood in accordance with Chapter IV, Section C, point (c), first paragraph, as well as authorised processing plants producing blood products in accordance with Chapter IV, Section C, point (c), second, third and fourth paragraphs;
- (f) processing plants registered as not processing ruminant animal by-products in accordance with Chapter IV, Section D, point (c), first paragraph, as well as authorised processing plants producing processed animal protein derived from non-ruminants which operate in accordance with Chapter IV, Section D, point (c), second, third and fourth paragraphs;

- (g) processing plants registered as not processing ruminant and poultry animal by-products in accordance with Chapter IV, Section G, point (c), first paragraph, as well as authorised processing plants producing processed animal protein derived from porcine animals which operate in accordance with Chapter IV, Section G, point (c), second, third and fourth paragraphs;
 - (h) processing plants registered as not processing ruminant and porcine animal by-products in accordance with Chapter IV, Section H, point (c), first paragraph, as well as authorised processing plants producing processed animal protein derived from poultry which operate in accordance with Chapter IV, Section H, point (c), second, third and fourth paragraphs;
 - (i) authorised compound feed establishments producing, in accordance with Chapter III, Section B, compound feed containing fishmeal, dicalcium and tricalcium phosphate of animal origin, blood products derived from non-ruminants, processed animal protein derived from farmed insects, processed animal protein derived from porcine animals, or processed animal protein derived from poultry;
 - (j) authorised compound feed establishments producing, in accordance with Chapter IV, Section D, point (d), compound feed containing processed animal protein derived from non-ruminants; as well as authorised compound feed establishments producing, in accordance with Chapter V, Section E, point 3(b)(ii) 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;
 - (k) authorised compound feed establishments producing, in accordance with Chapter IV, Section E, point (d), milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species;
 - (l) authorised compound feed establishments producing, in accordance with Chapter IV, Section F, point (b), compound feed containing processed animal protein derived from farmed insects;
 - (m) authorised compound feed establishments producing, in accordance with Chapter IV, Section G, point (b), compound feed containing processed animal protein derived from porcine animals intended for poultry;
 - (n) authorised compound feed establishments producing, in accordance with Chapter IV, Section H, point (b), compound feed containing processed animal protein derived from poultry intended for porcine animals;
 - (o) storage plants authorised in accordance with Chapter III, Section A, point 3, or in accordance with Chapter V, Section E, point 3(d), third paragraph.
2. Member States shall keep up-to-date lists of home compounders registered in accordance with Chapter III, Section B, point 3, and with Chapter IV, Section D, point (d)(ii), Section F, point (b)(ii), Section G, point (d)(ii), and Section H, point (d)(ii).;
- (b) Section C is amended as follows:
- (i) point 2 is replaced by the following:
 - ‘2. Compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from non-ruminants, shall not be produced in establishments which produce feed for farmed animals other than fur animals or aquaculture animals.’;
 - (ii) the following point is added:
 - ‘3. By way of derogation from point 2:
 - (i) compound feed intended for fur animals or for pet animals, which contains fishmeal may be produced in establishments which produce feed for non-ruminant farmed animals and milk replacers for the feeding of unweaned ruminants;
 - (ii) compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from farmed insects, may be produced in establishments which produce feed for poultry or porcine animals provided the processed animal protein derived from farmed insects comply with Chapter IV, Section F, point (a);

- (iii) compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from porcine animals, may be produced in establishments which produce feed for poultry, provided the processed animal protein derived from porcine animals comply with Chapter IV, Section G, points (a), (b) and (c);
 - (iv) compound feed intended for fur animals or for pet animals, which contains processed animal protein derived from poultry, may be produced in establishments which produce feed for porcine animals, provided the processed animal protein derived from poultry comply with Chapter IV, Section H, points (a), (b) and (c).;
- (c) in Section E, point 3 is replaced by the following:
- ‘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 Chapter IV, Section D, point (c), or of Chapter IV, Section F, point (a)(i), or of Chapter IV, Section G, point (c), or of Chapter IV, Section H, point (c).
 - (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 Chapter IV, Section D, point (d), or with Chapter IV, Section F, point (b), or with Chapter IV, Section G, point (d), or with Chapter IV, Section H, point (d); 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, poultry or porcine 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.’;

(d) the following section is added:

‘SECTION G

Accompanying document and labelling of processed animal protein derived from farmed insects, porcine animals or poultry, and compound feed containing such processed animal protein

1. The commercial document or, as appropriate, the health certificate accompanying the processed animal protein derived from farmed insects, porcine animals or poultry in accordance with Article 21(2) of Regulation (EC) No 1069/2009, and the label of that processed animal protein derived from farmed insects, porcine animals or poultry shall be clearly marked with the following words: “Processed animal protein derived from ... [please insert relevant farmed animals from which the processed animal protein is derived listed in the first column of Table 1] – shall not be used in feed for farmed animals except ... [please insert corresponding farmed animals to which the processed animal protein may be fed listed in the second column of Table 1]”;
2. The following words shall be clearly indicated on the label of compound feed containing processed animal protein derived from farmed insects, porcine animals or poultry: “contains processed animal protein derived from ... [please insert relevant farmed animals from which the processed animal protein is derived listed in the first column of Table 1] – shall not be fed to farmed animals except ... [please insert corresponding farmed animals to which the processed animal protein may be fed listed in the second column of Table 1]”;

Table 1

Farmed animals from which the processed animal protein is derived	Farmed animals to which the processed animal protein may be fed
Farmed insects	Aquaculture animals, fur animals, porcine animals, poultry
Porcine animals	Aquaculture animals, fur animals, poultry
Poultry	Aquaculture animals, fur animals, porcine animals
Farmed insects and porcine animals	Aquaculture animals, fur animals, poultry
Farmed insects and poultry	Aquaculture animals, fur animals, porcine animals
Porcine animals and poultry	Aquaculture animals, fur animals
Farmed insects, porcine animals and poultry	Aquaculture animals, fur animals’

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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