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

of XXX

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

(Text with EEA relevance)

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

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(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 encephalopathies¹, 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)², and in particular the second subparagraph of Article 31(2) 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 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

¹ OJ L 147, 31.5.2001, p. 1.

² OJ L 300, 14.11.2009, p.1.

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 feed³. 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 Council⁴, 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 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.
- (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. 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.

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).

- (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 142/2011⁵ 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.
- (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 bigger 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 above-mentioned safety conditions for insect production for feed use: Black Soldier Fly (*Hermetia illucens*), Yellow Mealworm (*Tenebrio molitor*), Lesser Mealworm (*Alphitobius diaperinus*), House cricket (*Acheta domesticus*), Banded cricket (*Gryllobates sigillatus*) and Field Cricket (*Gryllus assimilis*).
- (13) Annex X to Regulation (EU) No 142/2011 should therefore be amended to add a Section in its Chapter II in order to establish 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 above-mentioned insect species and may be amended in the future based on an assessment of the animal health, public health, plant health or environmental risks of the insect species concerned.
- (14) 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 applies to the import into the Union of processed animal protein, including processed animal protein derived from farmed insects.
- (15) 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, 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. The model health certificate set out in Chapter 1 of Annex XI to Regulation (EU) No 142/2011 should therefore be amended accordingly.

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).

- (16) Furthermore, following the amendment by Commission Regulation (EU) 2016/1396⁶ of the requirements related to transmissible spongiform encephalopathies (TSE) applicable to imports of animal by-products and derived products from bovine, ovine and caprine origin, and set out in Chapter D of Annex IX to Regulation (EC) No 999/2001, the corresponding provisions of the model health certificate set out in Chapter 1 of Annex XV to Regulation (EU) No 142/2011 should also be updated.
- (17) Annex X 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 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

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).

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 packaging 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 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/EC⁷, 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

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 (notified under document number C(2007) 3114) (OJ L 172, 30.6.2007, p. 84).

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/EC⁸, 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/EC⁹.
- (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 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

⁸ Commission Decision of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by the Commission veterinary experts and laying down the veterinary units in Traces (OJ L 296, 12.11.2009, p. 1).

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).

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.
- (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 and operators 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 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 [XXX].

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,

For the Commission
The President
Jean-Claude JUNCKER