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From: Secretary-General of the European Commission, signed by Ms Martine
DEPREZ, Director

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To: Ms Thérèse BLANCHET, Secretary-General of the Council of the
European Union

No. Cion doc.: D103880/01

Subject: COMMISSION REGULATION (EU) .../... of XXX amending and
correcting Regulation (EU) No 142/2011 as regards certain
requirements for the placing on the market and imports of animal by-
products and derived products not intended for human consumption

Delegations will find attached document D103880/01.

Encl.: D103880/01



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

of **XXX**

**amending and correcting Regulation (EU) No 142/2011 as regards certain requirements
for the placing on the market and imports of animal by-products and derived products
not intended for human consumption**

(Text with EEA relevance)

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

of **XXX**

amending and correcting Regulation (EU) No 142/2011 as regards certain requirements for the placing on the market and imports of animal by-products and derived products not intended for human consumption

(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 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)¹, and in particular Article 15(1), point (c), Article 18(3), point (a), Article 20(11), point (a), Article 21(6), points (c) and (d), Article 27, point (g), Article 41(3), first and third subparagraphs, and Article 42(2) thereof,

Whereas:

- (1) Commission Regulation (EU) No 142/2011² lays down implementing measures for the public and animal health rules for animal by-products and derived products laid down in Regulation (EC) No 1069/2009, including rules for the placing on the market and imports from third countries of such products.
- (2) In light of recent outbreaks of highly pathogenic avian influenza (HPAI) and the observed occurrence of the HPAI virus infection in certain categories of mammals in the Union territory, it is necessary to lay down additional risk mitigation measures to prevent the introduction and spread of the HPAI virus from poultry materials to other species. Therefore, the special feeding rules for Category 2 material laid down in Article 13 of Regulation (EU) No 142/2011 should be amended.
- (3) Category 2 material obtained from birds that were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals may be fed to fur animals in accordance with Article 13(1), point (b), of Regulation (EU) No 142/2011. The Avian Influenza overview, published by the European Food Safety Authority³, ('the Authority) suggests that the mutations with potential public health implications of the HPAI virus likely emerge upon transmission to mammals. Therefore, to prevent the risk of the introduction and spread of the HPAI virus to animals of mammalian species and the possible emergence of mutations with potential increased animal and public health implications in the Union, it is necessary to lay down additional

¹ OJ L 300, 14.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1069/oj>.

² 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, ELI: <http://data.europa.eu/eli/reg/2011/142/oj>).

³ Avian influenza overview December 2022 – March 2023 (EFSA Journal 2023;21(3):7917).

conditions where such Category 2 material is fed to animals without prior processing. In particular, before the authorisation for feeding of Category 2 material obtained from birds, in accordance with Article 13(1), point (b), of Regulation (EU) No 142/2011, there should be a risk assessment of the competent authority which concludes that the risk for the introduction and spread of the HPAI virus at regional, national and Union level is negligible. Article 13 of Regulation (EU) No 142/2011 should, therefore, be amended accordingly.

- (4) Regulation (EC) No 999/2001 of the European Parliament and of the Council⁴, as amended by Commission Regulation (EU) 2022/2246⁵, prohibits the entry into the Union of urine hunting lures derived from cervids. This prohibition should be reflected in Article 25 of Regulation (EU) No 142/2011, as well as in Chapter 17 of Annex XV to that Regulation.
- (5) In addition, Article 25 of Regulation (EU) No 142/2011 lays down rules for the import, transit, and export of animal by-products and of derived products. Processed beeswaxes under CN code 1521 90 99 intended for use as final technical products, other than for use in feed production, fertilisers, apiaries, cosmetics, or pharmaceuticals, do not come in contact with farmed animals and do not pose a risk to animal health. Therefore, such processed beeswaxes should be included in the products listed in Article 25(2) of Regulation (EU) No 142/2011, the importation into and the transit through the Union of which are not be subject to any animal health conditions. Article 25 of Commission Regulation (EU) No 142/2011 should, therefore, be amended accordingly.
- (6) Chapter IV, Section 2 of Annex IV to Regulation (EU) No 142/2011 provides for a list with a detailed description of alternative processing methods for the production of biodiesel and renewable fuels. Used cooking oil, referred to in Article 2 (2), point (g)(iii), of Regulation (EC) No 1069/2009 may be used as a starting material in the production of biodiesel and renewable fuels. The wording of alternative processing methods referred to in Chapter IV, Section 2, points D, J and L, of Annex IV to Regulation (EU) No 142/2011 should therefore be amended, so as to clarify the use of starting material in the new alternative processing methods.
- (7) Following an application for the authorisation of an alternative method submitted by Ireland, as provided for in Article 20 of Regulation (EC) No 1069/2009, the Authority published a Scientific Opinion on the “Evaluation of an alternative method for production of biodiesel from processed fats derived from Category 1, 2 and 3 animal by- products”⁶.
- (8) Following an application for the authorisation of an alternative method submitted by Austria, as provided for in Article 20 of Regulation (EC) No 1069/2009, the Authority published a Scientific Opinion on the “Evaluation of the application for new alternative biodiesel production process from rendered fat including Category 1 animal by-products”⁷.

⁴ 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 (OJ L 147, 31.5.2001, p. 1, ELI: <http://data.europa.eu/eli/reg/2001/999/oj>).

⁵ Commission Regulation (EU) 2022/2246 of 15 November 2022 amending Annexes VIII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards chronic wasting disease in live cervids (OJ L 295, 16.11.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/2246/oj>).

⁶ EFSA Journal 2020;18(4):6089.

⁷ EFSA Journal 2021;19(4):6511.

- (9) Both of those alternative methods have been considered by the Authority as safe alternative methods for the processing of processed and rendered fats into biodiesel. Therefore, those two new alternative processing methods should be included in Chapter IV, Section 2 of Annex IV to Regulation (EU) No 142/2011.
- (10) Annex IV to Regulation (EU) No 142/2011 lays down rules for the use and disposal of derived products obtained by alternative processing methods. Chapter IV, Section 3 of Annex IV to Regulation (EU) No 142/2011 should, therefore, be amended, so as to lay down rules for the use and disposal of products derived from those two new alternative processing methods.
- (11) Annex V to Regulation (EU) No 142/2011 lays down rules for composting and biogas transformation. Recently, “frass” as defined in Annex I, point 61, to Regulation (EU) No 142/2011 has been included in Chapter 1, Section 2 of Annex XI to that Regulation in order to introduce safe parameters for heat treatment of frass. It is necessary to also lay down standard transformation parameters for composting or biogas transformation of frass. Annex V to Regulation (EU) No 142/2011 should, therefore, be amended accordingly.
- (12) Regulation (EU) No 142/2011, as amended by Commission Regulation (EU) 2021/1925⁸, includes silkworms (*Bombyx mori*) in the list of authorised insect species for the manufacturing of processed animal protein in the Union, as set out in Annex X, Chapter II, Section 1, to Regulation (EU) No 142/2011. It is, therefore, appropriate to allow imports into the Union of processed animal protein derived from silkworms (*Bombyx mori*). Indonesia applied to the Commission to be listed in Annex XIV to Regulation (EU) No 142/2011 as a third country authorised for imports into and transit through the Union of processed animal protein of insect origin. The Commission carried out an in-depth assessment of the applicant third country’s veterinary legislation and the capacity of its competent authorities to perform official controls in relation to petfood imported into the Union. It was concluded that the competent authorities of Indonesia can comply with the relevant health conditions for the import of processed petfood containing processed animal protein of insect origin. It is therefore justified to add Indonesia to the list of third countries set out in Annex XIV to Regulation (EU) No 142/2011 from where processed petfood, containing processed animal protein of insect origin, may be imported into and transit through the Union.
- (13) Commission Regulation (EU) 2022/384⁹ amended Table 1 in Chapter I, Section 1, and Table 2 in Chapter II, Section 2 of Annex XIV to Regulation (EU) No 142/2011. That amendment concerned, among others, the alignment of the list of third countries authorised for imports into the Union of animal by-products and derived products with the list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of ungulates set out in Part 1 of Annex XIII to

⁸ Commission Regulation (EU) 2021/1925 of 5 November 2021 amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method (OJ L 393, 8.11.2021, p. 4, ELI: <http://data.europa.eu/eli/reg/2021/1925/oj>).

⁹ Commission Regulation (EU) 2022/384 of 4 March 2022 amending Annex XIV to Regulation (EU) No 142/2011 as regards adaptation of the lists of third countries, territories or zones thereof from which the entry into the Union of animal by-products and derived products is permitted (OJ L 78, 8.3.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/384/oj>).

Commission Implementing Regulation (EU) 2021/404¹⁰. However, it appears that during the alignment, the list for imports of animal by-products for the manufacture of pharmaceuticals was established incorrectly, as a result of which some third countries were erroneously listed as eligible for imports of animal by-products for the manufacturing of pharmaceutical products. That error should be corrected by a new wording in Chapter II, Table 2, row 14, of Annex XIV to Regulation (EU) No 142/2011.

- (14) Following the introduction, in accordance with the amendments made to Regulation (EU) No 142/2011 by this Regulation, of two new alternative methods for the use or disposal of animal by-products or derived products in Annex IV to Regulation (EU) No 142/2011, Table 2, row 17, column 'Raw material (reference to provisions of Regulation (EC) No 1069/2009)' in Annex XIV to Regulation (EU) No 142/2011 should be amended to include a reference to those two new alternative methods, in order to allow imports into the Union of raw materials for the manufacturing of renewable fuels.
- (15) The competent authorities of Japan provided the Commission with an updated list of their exporters of photogelatine. Table 3 in Chapter II, Section 11, of Annex XIV to Regulation (EU) No 142/2011 should be amended to take account of that updated list of exporters. That Annex should, therefore, be amended accordingly.
- (16) Regulation (EC) No 999/2001, as amended by Commission Regulation (EU) 2021/1372¹¹, authorises processed animal protein derived from insects to be used for feeding poultry and porcine animals, therefore the labelling requirements for imported consignment should be adapted. Following the introduction of silkworms (*Bombyx mori*) to the list of authorised insect species for the production of processed animal protein intended for the manufacturing of feed, the relevant health certificate should be adapted. The health certificate for processed animal protein derived from farmed insects for dispatch to or for transit through the Union set out in Chapter 1A of Annex XV to Regulation (EU) No 142/2011 should be amended as regards the required labelling and the list of authorised insect species.
- (17) Regulation (EU) No 142/2011, as amended by Commission Regulation (EU) 2021/1925¹², lays down rules for the placing on the market of processed frass. It is appropriate to introduce relevant animal health requirements for imports of frass from third countries which are at least as stringent as those applicable to the placing on the Union market of frass. The prohibition of imports of urine hunting lurs from cervids should be inserted in the certificate for imports of manure. The health certificate for imports of processed manure set out in Chapter 17 of Annex XV, to Regulation (EU) No 142/2011 should be amended to allow also the imports of processed frass into the Union and prohibit the imports of urine hunting lures. Annex XV to Regulation (EU) No 142/2011 should, therefore, be amended accordingly.

¹⁰ Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2021/404/oj).

¹¹ 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 (OJ L 295, 18.8.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/1372/oj>).

¹² Commission Regulation (EU) 2021/1925 of 5 November 2021 amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method (OJ L 393, 8.11.2021, p. 4, ELI: <http://data.europa.eu/eli/reg/2021/1925/oj>).

- (18) Regulation (EU) No 142/2011 should, therefore, be amended accordingly.
- (19) 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

Regulation (EU) No 142/2011 is amended and corrected as follows:

1. in Article 13(1), the following subparagraph is added:
‘The competent authority may only authorise the feeding of unprocessed Category 2 material obtained from birds to the animals referred to in the first subparagraph on their territory, if a risk assessment of the competent authority concludes that the risk for the introduction and spread of the HPAI virus at regional, national and Union level is negligible.’;
2. Article 25 is amended as follows:
 - (a) in paragraph 1, the following point (d) is added:
‘(d) urine hunting lures derived from cervids.’;
 - (b) in paragraph 2, the following point (f) is added:
‘(f) derived beeswaxes ready to sell products, not intended for uses as feed, petfood, fertilisers, apiaries, cosmetics or pharmaceuticals.’;
3. Annexes IV, V, XIV and XV are amended in accordance with Part 1 of the Annex to this Regulation;
4. Annex XIV is corrected in accordance with Part 2 of 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,

For the Commission
The President
Ursula VON DER LEYEN