



Council of the
European Union

Brussels, 7 November 2019
(OR. en)

13807/19

AGRILEG 188
VETER 93

COVER NOTE

From:	European Commission
date of receipt:	5 November 2019
To:	General Secretariat of the Council

No. Cion doc.:	D061269/04
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products

Delegations will find attached document D061269/04.

Encl.: D061269/04



Brussels, **XXX**
SANTE/7128/2016
(POOL/G2/2016/7128/7128-EN.docx)
D061269/04
[...] (2019) **XXX** draft

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

of **XXX**

amending Regulation (EU) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products

(Text with EEA relevance)

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amending Regulation (EU) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products

(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 1774/2002¹, and in particular Article 7(2), Article 20(11), Article 21(6)(d), Article 27(b) and (c), Article 31(2), Article 40(b), (d) and (e), the second subparagraph of Article 41(1), the first subparagraph of Article 41(3), Article 42(2)(a), (b) and (c) and the first subparagraph of Article 43(3) thereof,

Whereas:

- (1) Commission Regulation (EU) No 142/2011² lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. Those rules also include microbiological standards for raw pet food, requirements concerning certain approved establishments, conditions for imports of horns and horn products, hooves and hoof products, and the rules for exports of processed manure, certain blood, blood products and intermediate products.
- (2) In accordance with Article 26(1) of Regulation (EC) No 1069/2009, plants approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004³ or in accordance with Article 6 of Regulation (EC) No 852/2004⁴ may, under certain conditions, treat, process or store animal by-products generated on-site. Therefore, it is appropriate that approved slaughterhouses may apply certain chemical methods, other than those listed as standard or alternative processing methods, to preserve certain

¹ OJ L 300, 14.11.2009, p 1.

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).

³ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139 30.4.2004, p. 55).

⁴ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p.1).

Category 3 materials generated on-site in order to obtain a liquid volume, which can be more easily stored and transported.

- (3) Chemical preservation, other than authorised as alternative processing method, does not process raw materials into derived products. For the purpose of legal certainty, it is necessary to provide for rules on the storage, transport and subsequent disposal or use of these materials. Article 19 of Regulation (EU) No 142/2011 and Annex IX thereto should be amended accordingly.
- (4) Annex I to Regulation (EU) No 142/2011 provides for a definition of growing media. Growing media are widely used in the production of mushrooms. Definition of growing media should address the use of growing media in mushroom production.
- (5) A definition of "process hygiene criterion" should be introduced in Annex I to Regulation (EU) No 142/2011 in order to replace in point 6 of Chapter II of Annex XIII thereto the current product standard based on Enterobacteriaceae counts with values for the required number of samples and the limits for Enterobacteriaceae as a criterion indicating the acceptable functioning of the production process.
- (6) Annex I to Regulation (EU) No 142/2011 should be amended accordingly.
- (7) In the light of new scientific and technical developments, the temperature parameters for the Brookes' gasification process should be aligned with the existing standards for incineration of animal by-products. Annex IV to Regulation (EU) No 142/2011 should be amended accordingly.
- (8) Chapter II of Annex VIII No 142/2011 sets out requirements for the identification of animal by-products, including labelling. Raw petfood should be labelled accordingly to prevent the contamination of food or the infection of humans.
- (9) Annex VIII to Regulation (EU) No 142/2011 should be amended accordingly.
- (10) Commission Regulation (EC) No 2073/2005⁵ introduced process hygiene criteria to ensure the safety of foodstuffs based on a scientific risk assessment. Following the same principles, the safety of raw petfood may be maintained if provisions on compliance with process hygiene criteria established for meat preparation, i.e. unprocessed meat for human consumption, laid down in point 2.1.8 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005, replace the existing microbiological standards for *Enterobacteriaceae* in the product. Chapter II of Annex XIII to Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (11) For the promotion of science, a derogation should be granted to certain objects in natural history collections. The requirements on game trophies and other preparations as set out in Chapter VI of Annex XIII to Regulation (EU) No 142/2011 should be amended accordingly.
- (12) Chapter XI of Annex XIII to Regulation No 142/2011 sets out specific requirements for fat derivatives. It should be clarified that processing should reach at least the temperature required therein. Chapter XI of Annex XIII Regulation (EU) No 142/2011 should be corrected accordingly.
- (13) The requirements for imports of certain products obtained from bones, horns and hoofs set out in point 2(d)(i) of Section 7 of Chapter II of Annex XIV to Regulation

⁵ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

- (EU) No 142/2011 may be understood as cumulative requirements. Point 2(d)(ii) should be revised in order to clarify that those requirements apply alternatively.
- (14) Chapter V of Annex XIV sets out rules for the export of processed manure. Following revision of requirements for export of organic fertilisers and soil improvers of Category 3 materials laid down in Regulation (EC) No 999/2001⁶, it is necessary to align rules for export of processed manure with the above-mentioned new requirements.
- (15) Article 43 of Regulation (EC) No 1069/2009 stipulates that export of certain Category 1 and 2 materials may be authorised only under harmonised rules. Annex XII as well as Sections 2 and 3 of Chapter II of Annex XIV to Regulation (EU) No 142/2011 provide the conditions under which certain blood, blood products and intermediate products may be imported for the production of final pharmaceutical products or in order to be subject to a particular production step in the manufacturing chain of pharmaceuticals. The export of blood, blood products and intermediate products, which comply with the requirements for the import or placing on the market, should therefore be authorised and the rules for export be established in Chapter V of Annex XIV to Regulation (EU) No 142/2011.
- (16) Chapter V of Annex XIV to Regulation (EU) No 142/2011 should be amended accordingly.
- (17) 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 as follows:

- (1) Article 19 is amended as follows:
- (a) in point (b) the following point is added:
- “(xi) phase transition processes of Category 3 materials, such as blood thermocoagulation, blood centrifugation, containment as set out in Chapter V to this Annex, hydrolysing of hooves, bristles, feathers and hair, destined for processing with processing methods set out in this Regulation.”
- (b) point (d) is replaced by the following:
- “(d) Chapter V, where they store on the farm animal by-products as referred to in point (h) or (i) of Article 24(1) of that Regulation, provided that unprocessed animal by-products are subsequently disposed of as referred to in Article 4 of that Regulation;”;
- (c) the following point is added:
- “(e) Where the operations referred to in points (i) to (vii) and (xi) of point (b) take place on the site of the approved establishment or plant referred to in Article 26(1) of Regulation (EC) No 1069/2009 generating those

⁶ 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).

materials, the competent authority may authorise the operation without registration in accordance with Article 23 or approval in accordance with Article 24(1)(h) of that Regulation, provided that the animal by-products are stored, transported and disposed of or used as unprocessed animal by-products in accordance with Regulation (EC) No 1069/2009."

- (2) Annexes I, IV, VIII, IX, XIII and XIV are amended in accordance with the text set out in 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
Jean-Claude JUNCKER