Commission Regulation (EU) 2020/762 of 9 June 2020 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)

COMMISSION REGULATION (EU) 2020/762

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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 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[(1)], 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 142/2011[(2)] 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 853/2004 of the European Parliament and of the Council of the European Parliament and of the Council[(3)] or in accordance with Article 6 of Regulation (EC) No 852/2004[(4)] 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 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 use 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 to Regulation (EU) 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 2073/2005[(5)] 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 Enterobacteriaecae 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 (EU) 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) of Section 7 of Chapter II of Annex XIV to Regulation (EU) No

142/2011 may be understood as cumulative requirements. Point 2(d) 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 999/2001 of the European Parliament and of the Council[(6)], 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 Annex IX hereto,
— hydrolysing of hooves, pig 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 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, 9 June 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Annexes I, IV, VIII, IX, XIII and XIV to Regulation (EU) No 142/2011 are amended as follows:

(1) in Annex I, point 59 is replaced by the following and point 60 is added:

59. "**growing media**" means materials, including potting soil, other than soil *in situ*, in which plants or mushrooms are grown and which is used independently from soil *in situ*;

60. "**process hygiene criterion**" means a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with general requirements for the safety of feed.;

(2) in Annex IV, Chapter IV, Section 2, point E.2 point (d) is replaced by the following:

(d) Each process unit must have two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber must be designed to give a minimum residence time of two seconds at a temperature of at least 850 °C under all conditions of combustion;;

(3) Annex VIII, Chapter II, point 2(b) is amended as follows:

(i) point (vii) is replaced by the following:

(vii) in the case of raw petfood, "Use as petfood only. Keep apart from food. Wash hands and clean tools, utensils and surfaces after handling this product";;

(ii) a new point (xxi) is added as follows:

(xxi) in the case of materials for detoxification referred to in Chapter VII of Annex VIII, the words: "materials intended for detoxification. Not fit for the placing on the market".;

(4) in Annex IX, Chapter II, point (j) is replaced and a new point (k) is added as follows:

(j) sieving;

(k) phase transition processes of Category 3 materials, such as blood thermocoagulation, blood centrifugation, containment as set out in Chapter V to Annex IX hereto, hydrolyzing of hooves, pig bristles, feathers and hair, destined for processing with processing methods set out in this Regulation.;

(5) Annex XIII is amended as follows:

(a) in Chapter II, point 6 is replaced by the following:

6. Random samples must be taken from raw petfood during production and/or during storage (before dispatch) to verify compliance with the following standards:

Salmonella: absence in 25 g, n = 5, c = 0, m = 0, M = 0.

The process of production of raw petfood shall meet the following process hygiene criterion:

Enterobacteriaceae: n = 5, c = 2, m = 500 in 1 g, M = 5 000 in 1 g

Where:

n	=	number of samples to be tested;
m	=	threshold value for the number of bacteria; the result shall be considered satisfactory if the number of bacteria in all samples does not exceed m;
M	=	maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
c	=	number of samples the bacterial count of which may be between m and M, the sample shall still be considered acceptable if the bacterial count of the other samples is m or less.

Operators shall take measures, as part of their procedures based on hazard analysis and critical control points (HACCP) principles, to ensure that the supply, handling and processing of raw materials and raw petfood under their control are carried out in such a way that the above mentioned safety standards and the process hygiene criterion are met. In the case the safety standards and the process hygiene criterion are not meet the operator shall take proportionate corrective actions in accordance with the written procedure referred to in the introductory sentence of Article 29(1) of Regulation (EC) No 1069/2009 and the procedures based on HACCP principles as set out in points (e) and (f) of Article 29(2) of that Regulation.

The non-compliance and, where determined, its cause, the applied corrective actions and the results of the control measures shall be notified to the competent authority. Where the competent authority is not satisfied that the necessary corrective actions have been taken it can impose on the operator extra actions, including labelling for handling, and may require the microbiological investigation of further samples to be taken by the operator.;

(b) in Chapter VI, point C.1, point (e) is replaced by the following:

(e) are objects in natural history collections or for the promotion of science and are

(i) preserved in media, such as alcohol or formaldehyde, which allow display of the items;

(ii) embedded completely in micro-slides; or

(iii) composed of entire skeletons or parts thereof, bones or teeth, to be exchanged exclusively between museums and educational institutions;;

(c) in Chapter XI, point 1(a) is replaced by the following:

(a) transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);;

(6) Annex XIV is amended as follows:

(a) in Chapter II, Section 7, point 2(d) is replaced by the following:

(d) confirmation that the product is not intended at any stage to be diverted for any use in the manufacturing of food, feed material, organic fertilisers or soil improvers, and

(i) was derived from healthy animals slaughtered in a slaughterhouse; and

(ii) either was dried for a period of 42 days at an average temperature of at least 20 °C; and/or

(iii) was heated for one hour to a temperature of at least 80 °C to the core; and/or

(iv) was incinerated to ash for one hour at a temperature of at least 800 °C to the core; and/or

(v) underwent an acidification process such that the pH was maintained for at least one hour at less than 6 to the core.;

(b) in Chapter II, Section 9, point (a)(i) is replaced by the following:

(i) in the case of materials destined for the production of biodiesel, oleochemical products or for the production of renewable fuels which have undergone the treatment referred to in point L of Section 2 of Chapter IV of Annex IV, animal by-products referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009;;

(c) in Chapter V, the table is replaced by the following:

	Derived products	**Rules for export**
1	— Processed manure	The following derived products must comply at least with the

	— Organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure — Processed animal protein containing processed manure as a mixing component	conditions set out in points (a), (b), (d) and (e) of Section 2 of Chapter I of Annex XI: — Processed manure — Organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure — Processed manure as a mixing component in processed animal protein
2	Blood products and intermediate products	Blood, blood products and intermediate products produced in the EU or imported into the EU in accordance with health requirements laid down in Annex XII or Sections 2 and 3 of Chapter II of this Annex *for use outside the feed chain of farm animals*, provided they comply with the import requirements of the third country of destination.

(**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).

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

(**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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2020/762.