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Subject:	ANNEX to the COMMISSION REGULATION .../... 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 ANNEX.

Encl.: D061269/04 ANNEX



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ANNEX

ANNEX

to the

COMMISSION REGULATION .../...

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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 this Annex, hydrolyzing of hooves, 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=5000 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:

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	Derived products	Rules for export
1	<ul style="list-style-type: none"> • Processed manure; • 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; 	<p>The following derived products must comply at least with the conditions set out in points (a), (b), (d) and (e) of Section 2 of Chapter I of Annex XI:</p> <ul style="list-style-type: none"> • 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 <i>for use outside the feed chain of farm animals</i> , provided they comply with the

		import requirements of the third country of destination.
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