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Commission Regulation (EU) No 142/2011, ANNEX XIII. (See end of Document for details)*

ANNEX XIII

PETFOOD AND CERTAIN OTHER DERIVED PRODUCTS

CHAPTER I

General requirements

Petfood plants and establishments or plants producing derived products referred to in this Annex shall have adequate facilities for:

- (a) storing and treating incoming material under conditions which prevent the introduction of risks to public and animal health;
- (b) disposing of unused animal by-products and derived products remaining after production, unless the unused material is sent for processing or disposal to another establishment or plant, in accordance with this Regulation.

CHAPTER II

Specific requirements for petfood, including dogchews

1. Raw petfood

Operators may only manufacture raw petfood from Category 3 material referred to in Article 10(a) and Article 10(b)(i) and (ii) of Regulation (EC) No 1069/2009.

Raw petfood must be packed in new packaging preventing any leakage.

Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale.

2. Raw material for processed petfood and for dogchews

Operators may manufacture processed petfood and dogchews only from:

- (a) Category 3 material, other than material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009; and
- (b) in the case of imported petfood or petfood produced from imported materials, from Category 1 material comprising of animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC.

3. Processed petfood

(a) Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.

(b) Processed petfood other than canned petfood must:

- (i) be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;
- (ii) be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or

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- (iii) be produced as regards feed material of animal origin exclusively using:
 - animal by-products or derived products from meat or meat products which have been subject to a heat treatment of at least 90 °C throughout their substance;
 - the following derived products which have been produced in accordance with the requirements of this Regulation: milk and milk-based products, gelatine, hydrolysed protein, egg products, collagen, blood products referred to in Section 2 of Chapter II of Annex X, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards;
- (iv) if authorised by the competent authority, be subject to a treatment such as drying or fermentation, which ensures that the petfood poses no unacceptable risks to public and animal health;
- (v) in the case of animal by-products referred to in Article 10(1) and (m) of Regulation (EC) No 1069/2009 and in the case of animal by-products generated by aquatic animals, aquatic and terrestrial invertebrates, and if authorised by the competent authority, be subject to a treatment which ensures that the petfood poses no unacceptable risks to public and animal health.

After production, every precaution must be taken to ensure that such processed petfood is not exposed to contamination.

The processed petfood must be packaged in new packaging.

4. Dogchews must be subjected to a treatment that is sufficient to destroy pathogenic organisms, including salmonella.

After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination.

The dogchews must be packed in new packaging.

5. Random samples must be taken from dogchews and from processed petfood, other than from canned petfood and other than from such processed petfood which has been treated in accordance in point 3(b)(v), during production and/or during storage (before dispatch) to verify compliance with the following standards:

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

Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 300$ 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.

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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, $n = 5$, $c = 0$, $m = 0$, $M = 0$.
Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 5\ 000$ 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.

7. End point for processed petfood and dogchews

The following may be placed on the market without restrictions in accordance with this Regulation:

- (a) processed petfood
- (i) which has been manufactured and packaged in the Union in accordance with point 3 and which has been tested in accordance with point 5; or
 - (ii) which has been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.
- (b) dogchews
- (i) which have been manufactured and packaged in the Union in accordance with point 4 and which has been tested in accordance with point 5; or
 - (ii) which have been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.

CHAPTER III

Specific requirements for flavouring innards for the manufacture of petfood

1. Operators may only use animal by-products which may be used as raw material for processed petfood and dogchews in accordance with point 2 of Chapter II for the production of liquid or dehydrated derived products used to enhance the palatability values of petfood.
2. Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards set out in point 5 of Chapter II of this Annex. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.
3. The end product must be:
 - (a) packed in new or sterilised packaging; or

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- (b) transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected.

CHAPTER IV

Specific requirements for blood and blood products from equidae

The placing on the market of blood and blood products from equidae for purposes other than in feed shall be subject to the following conditions:

1. Blood may be placed on the market for such purposes provided that it has been collected:
 - (a) from equidae which:
 - (i) at inspection on the date of blood collection do not show clinical signs of any of the compulsorily notifiable diseases listed in Annex I to Directive 2009/156/EC and of equine influenza, equine piroplasmosis, equine rhinopneumonitis and equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the OIE, 2010 edition;
 - (ii) have been kept for a period of at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) of Directive 2009/156/EC or restrictions pursuant to Article 5 of that Directive;
 - (iii) for the periods laid down in Article 4(5) of Directive 2009/156/EC had no contact with equidae from holdings which were subject to a prohibition order for animal health reasons pursuant to that Article and for a period of at least 40 days prior to the date of and during blood collection had no contact with equidae from a Member State or third country not considered free of African horse sickness in accordance with points (a) and (b) of the first subparagraph of Article 5(2) of that Directive;
 - (b) under veterinary supervision either:
 - (i) in slaughterhouses registered or approved in accordance with Regulation (EC) No 853/2004; or
 - (ii) in facilities approved, furnished with a veterinary approval number and supervised by the competent authority for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.
2. Blood products may be placed on the market for such purposes provided that:
 - (a) all precautions have been taken to avoid contamination of the blood products with pathogenic agents during production, handling and packaging;
 - (b) the blood products have been produced from blood which:
 - (i) either fulfils the conditions set out in point 1(a); or

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- (ii) has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):
 - heat treatment at a temperature of 65 °C for at least three hours,
 - irradiation at 25 kGy by gamma rays,
 - change in pH to pH 5 for two hours,
 - heat treatment of at least 80 °C throughout their substance.
- 3. Blood and blood products from equidae must be packed in sealed impermeable containers which, in the case of blood from equidae, bear the approval number of the slaughterhouse or facilities of collection referred to in point 1(b).

CHAPTER V

Specific requirements for hides and skins of ungulates and products derived therefrom

A. Establishments and plants

The competent authority may authorise plants handling hides and skins, including limed hides, to supply trimmings and splittings of these hides and skins for the production of gelatine for animal consumption, organic fertilisers or soil improvers, provided that:

- (a) the plant has storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities;
- (b) the storage rooms are kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;
- (c) if raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch;
- (d) in the case of trimmings and splittings derived from limed hides, the trimmings and splittings are submitted to a treatment which ensures that no risks to public and animal health remain before being used for the production of:
 - (i) gelatine for animal consumption; or
 - (ii) organic fertilisers or soil improvers.

B. Placing on the market of animal by-products and of derived products

- 1. Untreated hides and skins may be placed on the market subject to the health conditions applicable to fresh meat pursuant to Directive 2002/99/EC.
- 2. Treated hides and skins may be placed on the market, provided that:
 - (a) they have not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease;

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- (b) the commercial document laid down in Chapter III of Annex VIII contains a statement indicating that all precautions have been taken to avoid contamination with pathogenic agents.
- C. End point for hides and skins
 - 1. Hides and skins of ungulates which pursuant to the decision of an operator are destined for purposes other than human consumption, and which comply with the requirements of Regulation (EC) No 853/2004 for raw materials for gelatine or collagen intended for use in food may be placed on the market without restrictions in accordance with this Regulation.
 - 2. The following treated hides and skins may be placed on the market without restrictions in accordance with this Regulation:
 - (a) hides and skins having undergone the complete process of tanning;
 - (b) 'wet blue';
 - (c) 'pickled pelts';
 - (d) limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).
 - 3. By way of derogation from point C.2, the competent authority may require that consignments of treated hides and skins referred to in point 2(c) and (d) are accompanied by a commercial document in accordance with the model set out under point 6 of Chapter III of Annex VIII, when they are supplied to establishments or plants producing petfood, organic fertilisers or soil improvers or transforming those materials into biogas.

CHAPTER VI

Specific requirements for game trophies and other preparations from animals

A. The provisions of this Chapter are without prejudice to the measures for the protection of wild fauna, adopted pursuant to Regulation (EC) No 338/97.

B. Safe sourcing

Game trophies and other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they originate from:

- (a) species other than ungulates, birds and animals of the biological class Insecta or Arachnida; and
- (b) animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.

C. Safe treatment

- 1. Game trophies or other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they:

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- (a) originate from ungulates or birds which have undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;
 - (b) are mounted ungulates or birds or mounted parts of such animals;
 - (c) have been subject to an anatomical preparation such as by plastination; or
 - (d) are animals of the biological class Insecta or Arachnida which have been subject to a treatment such as drying to prevent any transmission of diseases communicable to humans or animals.
2. Game trophies or other preparations, other than those referred to under points B and C.1, which come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible, may be placed on the market, provided that:
- (a) in the case of game trophies or other preparations solely of bone, horns, hooves, claws, antlers or teeth,
 - (i) they have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
 - (ii) they have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;
 - (iii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
 - (iv) they are accompanied by a health certificate certifying that the conditions set out in (i), (ii) and (iii) have been met;
 - (b) in case of game trophies or other preparations consisting solely of hides or skin,
 - (i) they have been:
 - dried,
 - dry- or wet-salted for a period of at least 14 days before the date of dispatch, or
 - subject to a preservation process other than tanning;
 - (ii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
 - (iii) they are accompanied by a commercial document or a health certificate certifying that the conditions set out in (i) and (ii) have been met.

CHAPTER VII

Specific requirements for wool, hair, pig bristles, feathers, parts of feathers and down

A. Raw material

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1. Untreated wool, untreated hair, untreated pig bristles and untreated feathers, parts of feathers and down must be Category 3 materials referred to in Article 10(b) (iii), (iv) and (v) and Article 10(h) and (n) of Regulation (EC) No 1069/2009.

They must be securely enclosed in packaging and dry.

However, in the case of untreated feathers, parts of feathers and down sent directly from the slaughterhouse to the processing plant, the competent authority may allow a derogation from the requirement to dry materials transported on its territory, provided that:

- (a) all necessary measures are taken to avoid any possible spread of disease;
 - (b) the transport takes place in waterproof containers and/or vehicles which must be cleaned and disinfected immediately after each use.
2. Movements of pig bristles from regions in which African swine fever is endemic shall be prohibited except for pig bristles that have:
 - (a) been boiled, dyed or bleached; or
 - (b) undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing may not be regarded as a form of treatment for the purposes of this provision.
 3. The provisions of point 1 shall not apply to decorative feathers or feathers:
 - (a) carried by travellers for their private use; or
 - (b) in the form of consignments sent to private individuals for non-industrial purposes.

B. End point for wool and hair

Factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain, may be placed on the market without restrictions in accordance with this Regulation.

Member States may authorise the placing on the market of untreated wool and hair from farms or from establishments or plants which have been registered in accordance with Article 23 of Regulation (EC) No 1069/2009 or approved in accordance with Article 24(1)(i) of the same Regulation on their territory without restrictions in accordance with this Regulation, if they are satisfied that no unacceptable risks to public and animal health arise from the wool and from the hair.

C. End point for feathers and down

Feathers, parts of feathers and down which have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes may be placed on the market without restrictions in accordance with this Regulation.

CHAPTER VIII

Specific requirements for furs

End point

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Furs which have been dried at an ambient temperature of 18 °C for two days at a humidity of 55 % may be placed on the market without restrictions in accordance with this Regulation.

CHAPTER IX

Specific requirements for apiculture by-products

Apiculture by-products intended exclusively for use in apiculture must:

1. not come from an area which is subject of a prohibition order associated with an occurrence of:
 - (a) American foulbrood (*Paenibacillus larvae larvae*), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease;
 - (b) acariosis (*Acarapis woodi* (Rennie)), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC;
 - (c) small hive beetle (*Aethina tumida*); or
 - (d) Tropilaelaps mite (*Tropilaelaps* spp.); and
2. meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

CHAPTER X

Specific requirements for rendered fats from Category 1 or Category 2 materials for oleochemical purposes

1. Rendered fats derived from Category 1 material or from Category 2 material which are destined for oleochemical purposes must be produced using any of the processing methods 1 to 5 as set out in Chapter III of Annex IV.
2. Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight.

CHAPTER XI

Specific requirements for fat derivatives

1. The following processes may be used to produce fat derivatives from rendered fats derived from Category 1 and Category 2 material:
 - (a) transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters);
 - (b) saponification with NaOH 12M (glycerol and soap):
 - (i) in a batch process at 95 °C for three hours; or

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- (ii) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or
- (c) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.
- 2. Fat derivatives produced in accordance with this Chapter may only be placed on the market:
 - (a) for uses other than in feed, cosmetics and medicinal products;
 - (b) in addition, in the case of fat derivatives from Category 1 material, for uses other than in organic fertilisers and soil improvers.

CHAPTER XII

Specific requirements for horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

The placing on the market of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers shall be subject to the following conditions:

- (a) they must originate from animals that:
 - (i) either have been slaughtered in a slaughterhouse, after undergoing an ante-mortem inspection, and were found fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation; or
 - (ii) did not show clinical signs of any disease communicable through that product to humans or animals;
- (b) they must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;
- (c) the horns must be removed without opening the cranial cavity;
- (d) at any stage of processing, storage or transport, every precaution shall be taken to avoid cross-contamination;
- (e) they shall be packed either in new packaging or containers; or transported in vehicles or bulk containers which have been disinfected prior to loading using a product approved by the competent authority;
- (f) the packaging or containers must:
 - (i) indicate the type of product (such as horns, horn products, hooves or hoof products);
 - (ii) be marked with the name and address of the approved or registered establishment or plant of destination.

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[^{F1}CHAPTER XIII

Specific requirements for fish oil for the production of medicinal products

End point for fish oil for the production of medicinal products

Fish oil derived from the materials referred to in point A.2 of Section 3 of Chapter II of Annex X, which has been de-acidified with a NaOH solution at a temperature of 80 °C or more and which has subsequently been purified by distillation at a temperature of 200 °C or more, may be placed on the market for the production of medicinal products without restrictions in accordance with this Regulation.]

Textual Amendments

- F1** Inserted by [Commission Regulation \(EU\) No 749/2011 of 29 July 2011 amending Regulation \(EU\) No 142/2011 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 \(Text with EEA relevance\).](#)

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