

ANNEX X

FEED MATERIALS

CHAPTER II

SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

Section 1

Specific requirements for processed animal protein

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than the Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of processed animal protein.

B. Processing standards

1. Processed animal protein of mammalian origin must have been submitted to processing method 1 (pressure sterilisation) as set out in Chapter III of Annex IV.

However,

- (a) porcine blood or fractions of porcine blood for the production of bloodmeal may have been submitted instead to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV, provided that in the case of processing method 7, a heat treatment throughout its substance at a temperature of 80 °C has been applied;
- (b) processed animal protein of mammalian origin
 - (i) may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is subsequently disposed of or used as a fuel for combustion;
 - (ii) where it is exclusively destined for use in petfood, it may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is:
 - transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and
 - consigned directly from a processing plant for Category 3 material to the petfood plant or to an approved storage plant, from where it is directly consigned to a petfood plant.
2. Non-mammalian processed animal protein, with the exception of fishmeal, must have been submitted to any of processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV.
3. Fishmeal must have been submitted to:
 - (a) any of the processing methods set out in Chapter III of Annex IV; or

- (b) another method which ensures that the product complies with the microbiological standards for derived products set in Chapter I of this Annex.

C. Storage

1. Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins or in storage sheds.

Sufficient measures must be taken to minimise condensation inside bins, conveyors or elevators.

2. Products in conveyors, elevators and bins must be protected from casual contamination.
3. Equipment for handling processed animal protein must be maintained in a clean and dry condition and must have adequate inspection points so that equipment can be examined for cleanliness.

All storage facilities must be emptied and cleaned regularly, to the extent necessary to prevent contamination.

4. Processed animal protein must be kept dry.

Leakages and condensation in the storage area must be prevented.

Section 2

Specific requirements for blood products

A. Raw material

Only blood referred to in Article 10(a) and Article 10(b)(i) of Regulation (EC) No 1069/2009 may be used for the production of blood products.

B. Processing standards

Blood products must have been submitted to:

- (a) any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV; or
- (b) another method which ensures that the blood product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

Section 3

**Specific requirements for rendered fats, fish oil
and fat derivatives from Category 3 material**

A. Raw materials

1. Rendered fats

Only Category 3 material, other than Category 3 materials referred to in Article 10(i), (j), (n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of rendered fat.

2. Fish oil

Status: This is the original version (as it was originally adopted).

Only Category 3 material referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 and Category 3 material of aquatic animal origin referred to in Article 10(e) and (f) of that Regulation may be used for the production of fish oil.

B. Processing standards

Unless the fish oil or rendered fats have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, rendered fats must be produced using any of the processing methods 1 to 5 or processing method 7, and fish oils may be produced:

- (a) using processing methods 1 to 7, as set out in Chapter III of Annex IV; or
- (b) in accordance with another method which ensures that the product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

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.

Fat derivatives from Category 3 rendered fats or fish oil shall be produced in accordance with one of the processing methods referred to in Chapter III of Annex IV.

C. Hygiene requirements

Where rendered fat or fish oil is packaged, it must be packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination and all precautions must be taken to prevent its recontamination.

Where bulk transport of those products is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or directly to plants must be clean before use.

Section 4

Specific requirements for milk, colostrum and certain other products derived from milk or colostrum

Part I

General requirements

A. Raw material

Only milk referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk referred to in Article 10(f) and (h) of Regulation (EC) No 1069/2009 may be used for the production of milk, milk-based products and milk-derived products.

Colostrum may only be used provided that it originates from live animals that did not show any signs of disease communicable through the colostrum to humans or animals.

B. Processing standards

1. Milk must be subjected to one of the following treatments:
 - 1.1. sterilisation at an $F_0^{(1)}$ value of three or more;

- 1.2. UHT⁽²⁾ combined with one of the following:
 - (a) a subsequent physical treatment, by:
 - (i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or
 - (ii) lowering the pH below 6 for at least 1 hour;
 - (b) the condition that the milk, milk-based product or milk-derived product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin;
- 1.3. HTST⁽³⁾ applied twice;
- 1.4. HTST in combination with one of the following:
 - (a) a subsequent physical treatment, by:
 - (i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or
 - (ii) lowering the pH below 6,0 for at least 1 hour;
 - (b) the condition that the milk, milk-based product or milk-derived product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin.
2. Milk-based products and milk-derived products must either be subjected to at least one of the treatments provided for in point 1 or be produced from milk treated in accordance with point 1.
3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with point 1 must:
 - (a) either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or
 - (b) have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin.
4. In addition to the requirements set out in points 1, 2 and 3, milk, milk-based products and milk-derived products must meet the following requirements:
 - 4.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;
 - 4.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must be:
 - (a) packed in new containers; or
 - (b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected.
5. Raw milk must be produced under conditions offering adequate guarantees as regards animal health.

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6. Colostrum and colostrum products must:
 - 6.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free as defined in Article 2(2)(d), (f) and (j) of Directive 64/432/EEC;
 - 6.2. have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin;
 - 6.3. have undergone a single HTST treatment⁽³⁾;
 - 6.4. comply with the requirements set out in point 4 of this Part.

Part II

Derogation for the placing on the market of milk processed in accordance with national standards

1. The requirements laid down in points 2 and 3 of this Part shall apply to the processing, use and storage of milk, milk-based products and milk-derived products which are Category 3 material, as referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk referred to in Article 10 (f) and (h) of that Regulation, that have not been processed in accordance with Part I of this Section.
2. The competent authority shall authorise milk processing establishments approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 to supply milk, milk-based products and milk-derived products for the purposes referred to in point 3 of this Part provided the establishment concerned ensures the traceability of the products.
3. Milk, milk-based products and milk-derived products may be supplied and used as feed material:
 - (a) in the Member State concerned and in cross-border areas where the Member States concerned have a mutual agreement to that effect, in the case of derived products, including white water, which have been in contact with raw milk and/or milk pasteurised in accordance with the requirements for heat treatment set out in point II.1(a) or (b) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, if those derived products have been subject to one of the following treatments:
 - (i) UHT;
 - (ii) sterilisation whereby either an Fc value equal or greater than 3 is achieved, or which was carried out at a temperature of at least 115 °C for 15 minutes or an equivalent combination of temperature and time;
 - (iii) pasteurisation or sterilisation, other than that referred to in point (ii), followed by:
 - in the case of dried milk or dried milk-based products or milk-derived products, a drying process;
 - in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6;

- (b) in the Member State concerned,
- (i) in the case of derived products, including white water, which have been in contact with milk that has only been pasteurised in accordance with the requirements for heat treatment set out in point II.1 (a) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, and whey produced from non heat-treated milk-based products, which has been collected at least 16 hours after milk clotting and where the pH must be recorded as < 6,0 before supplying the whey for feeding, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease;
 - (ii) in the case of raw products, including white water that has been in contact with raw milk and other products for which the treatments referred to in point (a) and point (b)(i) cannot be ensured, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of a risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease, and provided that the animals present in the authorised animal holdings can only be moved
 - either directly to a slaughterhouse located in the same Member State, or
 - to another holding in the same Member State, for which the competent authority guarantees that animals susceptible to foot-and-mouth disease may leave the holding only either directly to a slaughterhouse located in the same Member State, or if the animals have been dispatched to a holding not feeding the products referred to in this point (ii), after a 21-day standstill period has elapsed from the introduction of the animals.
4. The competent authority may authorise the supply of colostrum which does not comply with the conditions set out in point B.6 of Part I from one farmer to another farmer within the same Member State for feeding purposes, under conditions which prevent the transmission of health risks.

Part III

Special requirements for centrifuge or separator sludge

Category 3 material comprising of centrifuge or separator sludge must have been subjected to a heat treatment of at least 70 °C for 60 minutes or of at least 80 °C for 30 minutes, before it may be placed on the market for feeding to farmed animals.

Section 5

Specific requirements for gelatine and hydrolysed protein

- A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of gelatine and hydrolysed protein.

B. Processing standards for gelatine

1. Unless the gelatine has been produced in accordance with Section XIV of Annex III to Regulation (EC) No 853/2004, it must be produced by a process that ensures that Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses.

The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

2. After having been subjected to the processes referred to in point 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, shall be prohibited.

C. Other requirements for gelatine

Gelatine must be wrapped, packaged, stored and transported under satisfactory hygiene conditions.

In particular:

- (a) a room or a dedicated place must be provided for storing materials for wrapping and packaging;
- (b) wrapping and packaging must take place in a room or in a place intended for that purpose.

D. Processing standards for hydrolysed protein

Hydrolysed protein must be produced using a production process involving appropriate measures to minimise contamination. Hydrolysed protein derived from ruminants shall have a molecular weight below 10 000 Dalton.

In addition to the requirements of the first paragraph, hydrolysed proteins entirely or partly derived from ruminants' hides and skins shall be produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by exposure of the material to:

- (a) a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; or
- (b) a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar.

Section 6

Specific requirements for dicalcium phosphate

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of dicalcium phosphate.

B. Processing standards

1. Dicalcium phosphate must be produced by a process that comprises the three following stages:
 - (a) firstly, ensures that all bone that is Category 3 material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;
 - (b) secondly, following the part of the process referred to in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7;
 - (c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C.
2. Where dicalcium phosphate is derived from defatted bones, it shall be derived from bones referred to in Article 10(a) of Regulation (EC) No 1069/2009.

Section 7

Specific requirements for tricalcium phosphate

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of tricalcium phosphate.

B. Processing standards

Tricalcium phosphate must be produced by a process that ensures:

- (a) that all bone that is Category 3 material is finely crushed and degreased in counterflow with hot water (bone chips must be less than 14 mm);
- (b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;
- (c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation;
- (d) granulation of the tricalcium phosphate after drying in a fluidised bed with air at 200 °C.

Section 8

Specific requirements for collagen

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of collagen.

B. Processing standards

1. Unless the collagen has been produced in accordance with the requirements for collagen set out in Section XV of Annex III to Regulation (EC) No 853/2004, it must be produced by a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion.

After that treatment collagen may undergo a drying process.

2. The use of preservatives, other than those permitted under Union legislation shall be prohibited.

C. Other requirements

Collagen must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

- (a) a room or a dedicated place must be provided for storing materials for wrapping and packaging;
- (b) wrapping and packaging must take place in a room or in a place intended for that purpose.

Section 9

Specific requirements for egg products

A. Raw materials

Only animal by-products referred to in Article 10(e) and (f) and Article 10(k)(ii) of Regulation (EC) No 1069/2009 may be used for the production of egg products.

B. Processing standards

Egg products must have been:

- (a) submitted to any of the processing methods 1 to 5 or processing method 7 set out in Chapter III of Annex IV;
- (b) submitted to another method and parameters which ensure that the products comply with the microbiological standards for derived products set out in Chapter I; or
- (c) treated in accordance with the requirements for eggs and egg products set out in Chapters I, II and III of Section X of Annex III to Regulation (EC) No 853/2004.

Section 10

Specific requirements for certain Category 3 material

Category 3 material comprising products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise, referred to in Article 10(f) of Regulation (EC) No 1069/2009 may be placed on the market for feeding to farmed animals, provided that:

- (a) the material is not composed of and has not been in contact with material of animal origin which has not undergone processing:
 - (i) in accordance with this Regulation;
 - (ii) as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;
- (b) all necessary precautions have been taken to prevent the contamination of the material.

- (1) F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3, 00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.
- (2) UHT = Ultra High Temperature treatment at 132 °C for at least one second.
- (3) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.