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ANNEX X

FEED MATERIALS

CHAPTER II

SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

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:

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- (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.
 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.

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Part II

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

- [^{F1}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, milk-based products and milk-derived products referred to in Article 10(f) and (h) of that Regulation, that have not been processed in accordance with Part I of this Section.]

Textual Amendments

- F1** Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting 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).

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

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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.

[^{F2}By way of derogation from the first paragraph, the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within Member States which have authorised those alternative parameters, provided operators can demonstrate that the heat treatment according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the parameters set out in the first paragraph.]

Textual Amendments

- F2** Inserted by [Commission Regulation \(EU\) 2015/9 of 6 January 2015 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](#)

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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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- (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.

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