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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 808/2003

of 12 May 2003

amending Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal-by-products not intended for human consumption ⁽¹⁾, and in particular Articles 12(5) and 32(1) thereof,

Whereas:

- (1) The Scientific Steering Committee issued an opinion on 16 and 17 January 2003 on the safety vis-à-vis TSEs of the use of low-capacity incineration plants and co-incineration plants for incinerating potentially TSE infected animal materials.
- (2) In order to take account of that opinion, it is appropriate to amend the provisions of Regulation (EC) No 1774/2002 as regards the operation of low-capacity incineration plants or co-incineration plants for the disposal of the carcasses of certain animals.
- (3) In addition, the Annexes to Regulation (EC) No 1774/2002 should be amended in order to make a number of technical amendments to them to bring them more into conformity with the Articles of that Regulation and to clarify the rules applicable to a number of additional products.
- (4) Additional rules concerning the treatment of wastewater from premises where microbiological or other contamination risks may be present as a consequence of the handling of Category 1 or Category 2 materials should be provided;
- (5) The material error affecting the technical requirements applicable to the processing of by-products pursuant to the processing Method n° 2 should also be corrected;

- (6) While the feed ban provided for in Council Decision 2000/766/EC ⁽²⁾ remains in force, less stringent processing requirements should apply to mammalian processed animals proteins, given the exclusive destination as waste of such material which is a consequence of the ban;
- (7) Regulation (EC) No 1774/2002 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 1774/2002

Regulation (EC) No 1774/2002 is amended as follows:

1. In Article 12(3), point (a) is replaced by the following:

‘(a) be used only for the disposal of dead pet animals, animal by-products as referred to in Articles 4(1) (b), 5(1) and 6(1) to which Directive 2000/76/EC does not apply’;
2. In Article 12(3), the following point (h) is added:

‘(h) fulfil the conditions in Annex IV, Chapter VII when used for the disposal of animal by-products referred to in Article 4(1)(b).’
3. Annexes I to IX are amended in accordance with the Annex to this Regulation.

Article 2

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2003.

⁽¹⁾ OJ L 273, 10.10.2002, p. 1.

⁽²⁾ OJ L 306, 7.12.2002, p. 32.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 May 2003.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Annexes I to IX of Regulation (EC) No 1774/2002 are amended as follows:

1. Annex I is amended as follows:

(a) The specific definitions set out in points 15, 37, 42, and 55 to 58 are replaced by the following:

- '15. "catering waste" means all waste food including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;'
- '37. "manure" means any excrement and/or urine of farmed animals, with or without litter, or guano, that may be either unprocessed or processed in accordance with Chapter III of Annex VIII or otherwise transformed in biogas or composting plants;'
- '42. "processed animal protein" means animal proteins derived entirely from Category 3 material, which have been treated in accordance with Chapter II of Annex V so as to render them suitable for direct use as feed material or other use in feedingstuffs, including petfood, or use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, colostrum, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, tricalcium phosphate and collagen;'
- '55. "unprocessed feathers and parts of feathers" means feathers and parts of feathers that have not been treated with a steam current or by some other method that ensures that no pathogens remain;
- 56. "unprocessed wool" means sheep's wool that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;
- 57. "unprocessed hair" means ruminant hair that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;
- 58. "unprocessed pig bristles" means pig bristles that have not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;'

(b) The following specific definitions are added as points 59 to 63:

- '59. "collagen" means protein-based products derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry and fish.
- 60. "screenings" means visible solid animal materials retained in the waste water screen where a pre-treatment process as referred to in Annex II, Chapter IX, is required.
- 61. "grease and oil mixture" means floating animal materials collected at the surface of waste water grease remover systems where a pre-treatment process as referred to in Annex II, Chapter IX, is required.
- 62. "sludge" means visible solid animal materials or sediments retained in the waste water drains where a pre-treatment process as referred to in Annex II, Chapter IX, is required.
- 63. "material from desanding" means visible solid animal materials or sediments retained in desanding systems where these constitute a pre-treatment process referred to in Annex II, Chapter IX.'

2. Annex II is amended as follows:

(a) In Chapter I, paragraph 2(b) is replaced by the following:

- '(b) (i) in the case of Category 3 material, the words "not for human consumption";
- (ii) in the case of Category 2 material (other than manure and digestive tract content) and processed products derived therefrom, the words "not for animal consumption"; however, when Category 2 material is intended for the feeding of animals referred to in point (c) of Article 23(2) under the conditions provided for in that Article, the label shall instead indicate "for feeding to ..." completed with the name of the specific species of those animal(s) for the feeding of which the material is intended;
- (iii) in the case of Category 1 material and processed products derived therefrom, the words "for disposal only";
- (iv) in the case of manure and digestive tract content, the word "manure";'

(b) In Chapter II, the following paragraph 4 is added:

- '4. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the competent authority.'

(c) In Chapter III, paragraph 1 is replaced by the following:

- '1. During transportation, a commercial document or, when required by this Regulation, a health certificate must accompany animal by-products and processed products except in the case of processed products originating from Category 3 material which are supplied within the same Member State by retailers to final users other than business operators.'

(d) The following Chapter IX is added:

‘CHAPTER IX

Collection of animal material when treating waste water

1. Category 1 processing plants and other premises where specified risk material is removed, slaughterhouses and Category 2 processing plants shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of waste water. The equipment used in the pre-treatment process shall consist of drain traps or screen with apertures or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensures that the solid particles in the waste water passing through them are no more than 6 mm.
 2. Waste water from the premises as referred to in paragraph 1 must enter a pre-treatment process which shall ensure that all waste water has been filtered through the process before being drained off the premises. No grinding or maceration shall take place which could facilitate the passage of animal material through the pre-treatment process.
 3. All animal material retained in the pre-treatment process in premises as referred to in paragraph 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with this Regulation.
 4. Waste water having passed the pre-treatment process in premises referred to in paragraph 1 and waste water from premises only receiving Category 3 material shall be treated in accordance with other relevant Community legislation.’
3. In Annex III, Chapter 2, paragraphs 5 and 10 are deleted.
4. Annex IV is amended as follows:
- (a) In Chapter I, paragraph 1 is replaced by the following:
- ‘1. Incineration or co-incineration plants must be designed, equipped and operated in such a manner as to fulfil the requirements of this Regulation. The following hygiene conditions must be met:
 - (a) Animal by-products must be disposed of as soon as possible after arrival. They must be stored properly until disposal.
 - (b) Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area, thereby ensuring that waste water is treated during the storage referred to in Chapter III.
 - (c) Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control programme must be used for that purpose.
 - (d) Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
 - (e) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.’
- (b) The following Chapter VII is added:

‘CHAPTER VII

Incineration of Category 1 material referred to in Article 4(1)(b)

1. The low-capacity incineration plant must be located on a well-drained hard standing.
2. Livestock must not have access to the low-capacity incineration plant, animal by-products that are awaiting incineration or ash resulting from the incineration of animal by-products. If the low-capacity incineration plant is located on a livestock holding:
 - (a) there must be total physical separation between the incinerator and the livestock and their feed and bedding, with fencing where necessary;
 - (b) equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the farm;
 - (c) the operators must change their outer clothing and footwear before handling livestock or livestock feed.
3. The storage of animal by-products and of ashes must be covered, labelled and leak proof.
4. The operator must check that animal by-products are incinerated in such a way that they are completely reduced to ash. Ash must be disposed of to a landfill approved under Directive 1999/31/EC.

5. Incompletely incinerated animal by-products must not be disposed of to a landfill, but must be re-incinerated or otherwise disposed of in accordance with this Regulation.
 6. The low-capacity incineration plant must be equipped with an afterburner.
 7. The operator must keep records of the quantities, category and species of animal by-products incinerated and the date of incineration.
 8. The competent authority must inspect the low-capacity incineration plant before approval, and at least once a year to monitor compliance with this Regulation.'
5. Annex V is amended as follows:
- (a) In Chapter 1, paragraph (1)(a) is replaced by the following:

'(a) Premises for the processing of animal by-products must not be at the same site as slaughterhouses, unless located in a completely separate building. However, a conveyer system may link an individual processing plant to a slaughterhouse on the same site provided the following conditions are met:

 - (i) there are separate entrances, reception bays, equipment, exits and personnel for the processing plant and the slaughterhouse; and
 - (ii) the animal by-products to be processed originate on the same premises.

Unauthorised persons and animals must not have access to the processing plant.'
 - (b) In Chapter III, paragraph 4 of Method 2 is replaced by the following:

'4. The animal by-products may be cooked in such a manner that the time-temperature requirements are achieved at the same time.'
6. Annex VI is amended as follows:
- (a) Chapter I is amended as follows:
 - (i) Paragraph 7(a)(i) of Chapter I is replaced by the following:

'(i) Category 2 material (other than manure, digestive tract content separated from the digestive tract, milk and colostrum), destined for biogas or composting plants or intended to be used as organic fertilisers or soil improvers, and'
 - (ii) In paragraph 7(b), the second subparagraph is deleted.
 - (b) Chapter II is amended as follows:
 - (i) Paragraphs 1 and 2 are replaced by the following:

'1. If the biogas plant is located on premises where farmed animals are kept, the plant shall be located at an adequate distance to the area where animals are kept and there must be in any case total physical separation between that plant and the animals and their feed and bedding, with fencing where necessary. The biogas plant must be equipped with:

 - (a) a pasteurisation/hygenisation unit, which cannot be by-passed, with:
 - (i) installations for monitoring temperature against time;
 - (ii) recording devices to record continuously the results of those measurements; and
 - (iii) an adequate safety system to prevent insufficient heating; and
 - (b) adequate facilities for the cleaning and disinfecting vehicles and containers upon leaving the biogas plant.

However, a pasteurisation/hygenisation unit is not mandatory for biogas plants that transform only animal by-products that have undergone processing Method 1.

In addition, a pasteurisation/hygenisation unit is not mandatory for biogas plants that transform only Category 3 material that has undergone pasteurisation/hygenisation elsewhere.
 2. If the composting plant is located on premises where farmed animals are kept, the plant shall be located at an adequate distance to the area where animals are kept and there must be in any case total physical separation between that plant and the animals and their feed and bedding, with fencing where necessary. The composting plant must be equipped with:
 - (a) a closed composting reactor, which cannot be by-passed, with:
 - (i) installations for monitoring temperature against time;
 - (ii) recording devices to record, where appropriate continuously, the results of those measurements; and
 - (iii) an adequate safety system to prevent insufficient heating; and

- (b) adequate facilities for cleaning and disinfecting vehicles and containers transporting untreated animal by-products.

However, other types of composting systems may be allowed provided they:

- (i) ensure that there is no access by vermin;
- (ii) are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters;
- (iii) comply with all other requirements of this Regulation.'

- (ii) Paragraph (4)(b) is replaced by the following:

'(b) manure and digestive tract content separated from the digestive tract, milk and colostrum, and'

- (iii) Paragraph 14 is replaced by the following:

'14. However, pending the adoption of rules in accordance with Article 6(2)(g), the competent authority may, when catering waste is the only animal by-product used as raw material in a biogas or composting plant, authorise the use of specific requirements other than those laid down in this Chapter provided that they guarantee an equivalent effect regarding the reduction of pathogens. Those specific requirements may also apply to catering waste when it is mixed with manure, digestive tract content separated from the digestive tract, milk and colostrum provided that the resulting material is considered as if it were from catering waste.

Where manure, digestive tract content separated from the digestive tract, milk and colostrum are the only material of animal origin being treated in a biogas or composting plant, the competent authority may authorise the use of specific requirements other than those specified in this Chapter provided that it:

- (a) does not consider that those material present a risk of spreading any serious transmissible disease;
- (b) considers that the residues or compost are untreated material.'

7. Annex VII is amended as follows:

- (a) Chapter I is amended as follows:

- (i) Paragraph 4 is replaced by the following:

'4. Only Category 3 material listed in points (a) to (j) of Article 6(1) that has been handled, stored and transported in accordance with Articles 7, 8 and 9 may be used for the production of processed animal proteins and other feed material.'

- (ii) The following paragraph 11 is added:

'11. Unused or surplus processed products may after they have been permanently marked:

- (a) be disposed of as waste by incineration or co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;
- (b) be disposed of in a landfill approved under Directive 1999/31/EC; or
- (c) be transformed in a biogas plant or in a composting plant approved in accordance with Article 15.'

- (b) In Chapter II, paragraph 1 is replaced by the following:

'1. Mammalian processed animal protein must have been submitted to processing Method 1.

However, while the feed ban provided for in Council Decision 2000/766/EC remains in force, mammalian processed animal protein may have been submitted to any of the processing Methods 1 to 5 or Method 7, and shall be permanently marked with a stain or otherwise immediately after that processing, before its disposal as waste in accordance with applicable Community legislation.

In addition, while the feed ban provided for in Council Decision 2000/766/EC remains in force, processed animal protein of mammalian origin exclusively destined for use in petfood, which is transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and which is consigned directly from Category 3 processing plant to the petfood plants, may have been submitted to any of the processing Methods 1 to 5 or 7.'

- (c) In Chapter IV, paragraph 1 is replaced by the following:

'1. Unless the rendered fats have been produced in accordance with Chapter II of Annex C to Council Directive 77/99/EEC (*), or Chapter 9 of Annex I to Council Directive 92/118/EEC (**), rendered fats must be produced using Methods 1 to 5 or Method 7, and fish oils may be produced using Method 6, as referred to in Annex V, Chapter III.

Rendered fats derived from ruminant animals must be purified in such a way that the maximum levels of remaining total insoluble impurities does not exceed 0,15 % in weight.

(*) OJ L 26, 31.1.1977, p. 85.

(**) OJ L 62, 15.3.1993, p. 49.'

- (e) In Chapter VI, paragraph 3 is replaced by the following:
- '3. Hydrolysed protein must be produced using a production process involving appropriate measures to minimise contamination of raw Category 3 material. Hydrolysed protein shall have a molecular weight below 10 000 Dalton.

In addition, 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:

- (a) exposure of the material to 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;
- (b) exposure of the material to 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; or
- (c) an equivalent production process approved in accordance with the procedure referred to in Article 33(2).'
- (f) In Chapter VI, paragraph 4 is replaced by the following:
- '4. Member States must authorise the importation of gelatine and hydrolysed proteins if they:
- (a) come from third countries that appear on the list in Part XI of Annex XI;
- (b) come from a processing plant that appears on the list referred to in Article 29(4);
- (c) have been produced in accordance with this Regulation; and
- (d) are accompanied by a health certificate as provided for in Article 29(6).'
- (g) Chapter VII is replaced by the following:

'CHAPTER VII

Specific requirements for dicalcium phosphate

The following conditions apply in addition to the general conditions laid down in Chapter I.

A. Processing standards

1. Dicalcium phosphate must be produced by a process that:
- (a) ensures that all Category 3 bone-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) following the procedure at (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and
- (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, or
- by an equivalent process approved in accordance with the procedure referred to in Article 33(2).
2. Where dicalcium phosphate is derived from defatted bones it shall be derived from bones fit for human consumption following ante and post-mortem inspection.

B. Importation

3. Member States must authorise the importation of dicalcium phosphate if it:
- (a) comes from third countries that appear on the list in Part XI of Annex XI;
- (b) comes from a processing plant that appears on the list referred to in Article 29(4);
- (c) has been produced in accordance with this Regulation; and
- (d) is accompanied by a health certificate as provided for in Article 29(6).'
- (h) The following Chapter VIII is added:

'CHAPTER VIII

Specific requirements for tricalcium phosphate

The following conditions apply in addition to the general conditions laid down in Chapter I.

A. Processing standards

1. Tricalcium phosphate must be produced by a process that ensures:
- (a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

- (b) grinding of the chips below 1 mm before cooking and 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; and
- (d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved in accordance with the procedure referred to in Article 33(2).

B. Importation

2. Member States must authorise the importation of tricalcium phosphate if it:

- (a) comes from third countries that appear on the list in Part XI of Annex XI;
- (b) comes from a processing plant that appears on the list referred to in Article 29(4);
- (c) has been produced in accordance with this Regulation; and
- (d) is accompanied by a health certificate as provided for in Article 29(6).'

8. Annex VIII is amended as follows:

(a) In Chapter II, paragraph 6 is replaced by the following:

'6. Random samples must be taken 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 is considered satisfactory if the number of bacteria in all samples does not exceed m;
- M = maximum value for the number of bacteria; the result is 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 still being considered acceptable if the bacterial count of the other samples is m or less.

However, for canned petfood that has undergone the heat treatment referred to in paragraph 2, sampling and testing for *Salmonella* and *Enterobacteriaceae* may not be necessary.'

(b) In Chapter IV, the second indent of paragraph (3)(e)(i) is replaced by the following:

'— in slaughterhouses approved and supervised by the competent authority of the third country. The Commission and Member States must be notified of the address and approval number of such slaughterhouse or the certificate must indicated them; or'

(c) In Chapter VIII, paragraph 1 is replaced by the following:

'1. (a) Unprocessed wool, unprocessed hair, unprocessed pig bristles and unprocessed feathers and parts of feathers must have been obtained from animals referred to in Article 6(1)(c) or (k). They must be securely enclosed in packaging and dry. However, in the case of unprocessed feather and part of feathers sent directly from the slaughterhouse to the processing plant, the competent authority may allow derogation from the dry requirement, provided that:

- (i) all necessary measures are taken to avoid any possible spread of disease;
- (ii) the transport takes place in leak-proof containers and/or vehicles which must be cleansed and disinfected immediately after each use; and
- (iii) the Member State notifies the Commission when such derogation is given.

(b) Movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles that have:

- (i) been boiled, dyed or bleached; or
- (ii) 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.'

(d) In Chapter IX, paragraph 1 is replaced by the following:

‘1. Apiculture products intended exclusively for use in apiculture must:

- (a) not come from an area which is subject of a prohibition order associated with an occurrence of:
 - (i) American foulbrood, 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; or
 - (ii) acariosis, except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC (*); and
- (b) meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

(*) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54). Directive as last amended by Commission Decision 2001/298/EC (OJ L 102, 12.4.2001, p. 63).’

9. In Annex IX, the following paragraph 2a is added:

‘2a. Entire bodies of dead animals shall be handled as Category 2 material during collection and transportation, without prejudice to the requirement to remove the specific risk material for subsequent disposal before the rest of the body may be used for feeding as provided for in Article 23.’
