

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

TITLE I

GENERAL PROVISIONS

CHAPTER I

Common provisions

Section 1

Subject matter, scope and definitions

Article 1

Subject matter

This Regulation lays down public health and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain.

Article 2

Scope

- 1 This Regulation shall apply to:
 - a animal by-products and derived products which are excluded from human consumption under Community legislation; and
 - b the following products which pursuant to a decision by an operator, which shall be irreversible, are destined for purposes other than human consumption:
 - (i) products of animal origin which may be destined for human consumption under Community legislation;
 - (ii) raw materials for the production of products of animal origin.
- 2 This Regulation shall not apply to the following animal by-products:
 - a entire bodies or parts of wild animals, other than wild game, which are not suspected of being infected or affected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes;
 - b entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice, without prejudice to Regulation (EC) No 853/2004;

- c animal by-products from wild game and from wild game meat referred to in Article 1(3) (e) of Regulation (EC) No 853/2004;
 - d oocytes, embryos and semen destined for breeding purposes;
 - e raw milk, colostrum and products derived therefrom which are obtained, kept, disposed of or used on the farm of origin;
 - f shells from shellfish with the soft tissue and flesh removed;
 - g catering waste, except if it:
 - (i) originates from means of transport operating internationally;
 - (ii) is destined for feeding purposes;
 - (iii) is destined for processing by pressure sterilisation or for processing by methods referred to in point (b) of the first subparagraph of Article 15(1) or for transformation into biogas or for composting;
 - h without prejudice to Community environmental legislation, material from vessels complying with Regulations (EC) No 852/2004 and (EC) No 853/2004, which has arisen in the course of their fishing operations and is disposed of at sea, except material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;
 - i raw pet food originating from retail shops, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;
 - j raw pet food derived from animals which are slaughtered on the farm of origin for private domestic consumption; and
 - k excrement and urine other than manure and non-mineralised guano.
- 3 This Regulation shall be without prejudice to Community veterinary legislation having as its objective the control and eradication of animal diseases.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;
2. 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;
3. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;
4. 'carcase' means carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;
5. 'animal' means any invertebrate or vertebrate animal;
6. 'farmed animal' means:
 - (a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes;

- (b) equidae;
7. 'wild animal' means any animal not kept by humans;
 8. 'pet animal' means any animal belonging to species normally nourished and kept but not consumed, by humans for purposes other than farming;
 9. 'aquatic animals' means aquatic animals as defined in Article 3(1)(e) of Directive 2006/88/EC;
 10. 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country;
 11. 'operator' means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users;
 12. 'user' means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes;
 13. 'establishment' or 'plant' means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel;
 14. 'placing on the market' means any operation the purpose of which is to sell animal by-products or derived products to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;
 15. 'transit' means movement through the Community from the territory of a third country to the territory of another third country, other than by sea or by air;
 16. 'export' means movement from the Community to a third country;
 17. 'transmissible spongiform encephalopathies (TSEs)' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001;
 18. 'specified risk material' means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;
 19. 'pressure sterilisation' means the processing of animal by-products, after reduction in particle size to not more than 50 mm, to a core temperature of more than 133 °C for at least 20 minutes without interruption at an absolute pressure of at least 3 bar;
 20. 'manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter;
 21. 'authorised landfill' means a landfill for which a permit has been issued in accordance with Directive 1999/31/EC;
 22. 'organic fertiliser' and 'soil improver' means materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activities of soils, either separately or together; they may include manure, non-mineralised guano, digestive tract content, compost and digestion residues;
 23. 'remote area' means an area where the animal population is so small, and where disposal establishments or plants are so far away that the arrangements necessary for

the collection and transport of animal by-products would be unacceptably onerous compared to local disposal;

24. 'food' or 'foodstuff' means food or foodstuff as defined in Article 2 of Regulation (EC) No 178/2002;
25. 'feed' or 'feedingstuff' means feed or feedingstuff as defined in Article 3(4) of Regulation (EC) No 178/2002;
26. 'centrifuge or separator sludge' means material collected as a by-product after purification of raw milk and separation of skimmed milk and cream from raw milk;
27. 'waste' means waste as defined in point 1 of Article 3 of Directive 2008/98/EC.

Section 2

Obligations

Article 4

Starting point in the manufacturing chain and obligations

1 As soon as operators generate animal by-products or derived products falling within the scope of this Regulation, they shall identify them and ensure that they are dealt with in accordance with this Regulation (starting point).

2 Operators shall ensure at all stages of collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that animal by-products and derived products satisfy the requirements of this Regulation which are relevant to their activities.

3 Member States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products as referred to in paragraph 2. For that purpose, they shall maintain a system of official controls in accordance with relevant Community legislation.

4 Member States shall ensure that an adequate system is in place on their territory ensuring that animal by-products are:

- a collected, identified and transported without undue delay; and
- b treated, used or disposed of in accordance with this Regulation.

5 Member States may fulfil their obligations under paragraph 4 in cooperation with other Member States or third countries.

Article 5

End point in the manufacturing chain

1 Derived products referred to in Article 33 which have reached the stage of manufacturing regulated by the Community legislation referred to in that Article shall be regarded as having reached the end point in the manufacturing chain, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

The end point in the manufacturing chain may be modified:

- a for products referred to in Article 33(a) to (d), in case of risks to animal health;
- b for products referred to in Article 33(e) and (f), in case of risks to public or animal health.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(6).

2 For derived products referred to in Articles 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

3 In the event of risks to public or animal health, Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency measures shall apply *mutatis mutandis* to the derived products referred to in Articles 33 and 36 of this Regulation.

Section 3

Animal health restrictions

Article 6

General animal health restrictions

1 Animal by-products and derived products from susceptible species shall not be dispatched from holdings, establishments, plants or zones which are subject to restrictions:

- a pursuant to Community veterinary legislation; or
- b due to the presence of a serious transmissible disease:
 - (i) listed in Annex I to Directive 92/119/EEC; or
 - (ii) laid down in accordance with the second subparagraph.

The measures referred to in point (b)(ii) of the first subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2 Paragraph 1 shall not apply where animal by-products and derived products are dispatched under conditions designed to prevent the spread of diseases transmissible to humans or animals.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

Section 4

Categorisation

Article 7

Categorisation of animal by-products and derived products

1 Animal by-products shall be categorised into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.

2 Derived products shall be subject to the rules for the specific category of animal by-products from which they have been derived, unless otherwise specified in this Regulation, or provided for in measures for the implementation of this Regulation which may specify the conditions under which derived products are not subject to those rules adopted by the Commission.

3 Articles 8, 9 and 10 may be amended in order to take into account scientific progress as regards the assessment of the level of risk, provided such progress can be identified on the basis of a risk assessment carried out by the appropriate scientific institution. However, no animal by-products listed in those Articles may be removed from those lists, only changes of categorisation or additions may be made.

4 The measures referred to in paragraphs 2 and 3, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 8

Category 1 material

Category 1 material shall comprise the following animal by-products:

- (a) entire bodies and all body parts, including hides and skins, of the following animals:
 - (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed;
 - (ii) animals killed in the context of TSE eradication measures;
 - (iii) animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;
 - (iv) animals used for experiments as defined by Article 2(d) of Directive 86/609/EEC without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;
 - (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

- (b) the following material:
 - (i) specified risk material;
 - (ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal;
- (c) 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;
- (d) animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;
- (e) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:
 - (i) from establishments or plants processing Category 1 material; or
 - (ii) from other establishments or plants where specified risk material is being removed;
- (f) catering waste from means of transport operating internationally;
- (g) mixtures of Category 1 material with either Category 2 material or Category 3 material or both.

Article 9

Category 2 material

Category 2 material shall comprise the following animal by-products:

- (a) manure, non-mineralised guano and digestive tract content;
- (b) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:
 - (i) from establishments or plants processing Category 2 material; or
 - (ii) from slaughterhouses other than those covered by Article 8(e);
- (c) animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC;
- (d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;
- (e) products of animal origin, other than Category 1 material, that are:
 - (i) imported or introduced from a third country and fail to comply with Community veterinary legislation for their import or introduction into the Community except where Community legislation allows their import or introduction subject to specific restrictions or their return to the third country; or

- (ii) dispatched to another Member State and fail to comply with requirements laid down or authorised by Community legislation except where they are returned with the authorisation of the competent authority of the Member State of origin;
- (f) animals and parts of animals, other than those referred to in Article 8 or Article 10,
 - (i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;
 - (ii) fetuses;
 - (iii) oocytes, embryos and semen which are not destined for breeding purposes; and
 - (iv) dead-in-shell poultry;
- (g) mixtures of Category 2 material with Category 3 material;
- (h) animal by-products other than Category 1 material or Category 3 material.

Article 10

Category 3 material

Category 3 material shall comprise the following animal by-products:

- (a) carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;
- (b) carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation:
 - (i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals;
 - (ii) heads of poultry;
 - (iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of:
 - animals, other than ruminants requiring TSE testing, and
 - ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;
 - (iv) pig bristles;
 - (v) feathers;

- (c) animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) No 853/2004, which did not show any signs of disease communicable to humans or animals;
- (d) blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation:
 - (i) animals other than ruminants requiring TSE testing; and
 - (ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;
- (e) animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and centrifuge or separator sludge from milk processing;
- (f) 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;
- (g) petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;
- (h) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals;
- (i) aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals;
- (j) animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;
- (k) the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:
 - (i) shells from shellfish with soft tissue or flesh;
 - (ii) the following originating from terrestrial animals:
 - hatchery by-products,
 - eggs,
 - egg by-products, including egg shells,
 - (iii) day-old chicks killed for commercial reasons;
- (l) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;
- (m) animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g);

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- (n) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article;
- (o) adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation;
- (p) catering waste other than as referred to in Article 8(f).