

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;

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- 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;

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- (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

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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.

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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.

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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) ^[F1]animals used in a procedure or procedures defined in Article 3 of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes⁽¹⁾, in cases where the competent authority decides that such animals or any of their body

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- parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures 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.

Textual Amendments

- F1** Substituted by [Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes](#) (Text with EEA relevance).

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);

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- (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;

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- (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,

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- 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);
- (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).

CHAPTER II

Disposal and use of animal by-products and derived products

Section 1

Restrictions on use

Article 11

Restrictions on use

- 1 The following uses of animal by-products and derived products shall be prohibited:
 - a the feeding of terrestrial animals of a given species other than fur animals with processed animal protein derived from the bodies or parts of bodies of animals of the same species;
 - b the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste;
 - c the feeding of farmed animals with herbage, either directly by grazing or by feeding with cut herbage, from land to which organic fertilisers or soil improvers, other than manure, have been applied unless the cutting or grazing takes place after the expiry of a waiting period which ensures adequate control of risks to public and animal health and is at least 21 days; and
 - d the feeding of farmed fish with processed animal protein derived from the bodies or parts of bodies of farmed fish of the same species.
- 2 Measures relating to the following may be laid down:
 - a the checks and controls to be carried out to ensure the application of the prohibitions referred to in paragraph 1, including detection methods and tests to be used to verify the

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- presence of materials originating from certain species and thresholds for insignificant amounts of processed animal proteins referred to in points (a) and (d) of paragraph 1 which are caused by adventitious and technically unavoidable contamination;
- b the conditions for the feeding of fur animals with processed animal protein derived from bodies or parts of bodies of animals of the same species; and
 - c the conditions for the feeding of farmed animals with herbage from land to which organic fertilisers or soil improvers have been applied, in particular a modification of the waiting period as referred to in paragraph 1(c).

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(4).

Section 2

Disposal and use

Article 12

Disposal and use of Category 1 material

Category 1 material shall be:

- (a) disposed of as waste by incineration:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (b) recovered or disposed of by co-incineration, if the Category 1 material is waste:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (c) in the case of Category 1 material other than material referred to in Article 8(a)(i) and (ii), disposed of by processing by pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill;
- (d) in the case of Category 1 material referred to in Article 8(f), disposed of by burial in an authorised landfill;
- (e) used as a fuel for combustion with or without prior processing; or
- (f) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

Article 13

Disposal and use of Category 2 material

Category 2 material shall be:

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- (a) disposed of as waste by incineration:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (b) recovered or disposed of by co-incineration, if the Category 2 material is waste:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (c) disposed of in an authorised landfill, following processing by pressure sterilisation and permanent marking of the resulting material;
- (d) used for the manufacturing of organic fertilisers or soil improvers to be placed on the market in accordance with Article 32 following processing by pressure sterilisation, when applicable, and permanent marking of the resulting material;
- (e) composted or transformed into biogas:
 - (i) following processing by pressure sterilisation and permanent marking of the resulting material; or
 - (ii) in the case of manure, digestive tract and its content, milk, milk-based products, colostrum, eggs and egg products which the competent authority does not consider to present a risk for the spread of any serious transmissible disease, following or without prior processing;
- (f) applied to land without processing, in the case of manure, digestive tract content separated from the digestive tract, milk, milk-based products and colostrum which the competent authority does not consider to present a risk for the spread of any serious transmissible disease;
- (g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
- (h) used as a fuel for combustion with or without prior processing; or
- (i) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

Article 14

Disposal and use of Category 3 material

Category 3 material shall be:

- (a) disposed of as waste by incineration, with or without prior processing;
- (b) recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;
- (c) disposed of in an authorised landfill, following processing;

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- (d) processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:
 - (i) for the manufacturing of feed for farmed animals other than fur animals, to be placed on the market in accordance with Article 31, except in the case of material referred to in Article 10(n), (o) and (p);
 - (ii) for the manufacturing of feed for fur animals, to be placed on the market in accordance with Article 36;
 - (iii) for the manufacturing of pet food, to be placed on the market in accordance with Article 35; or
 - (iv) for the manufacturing of organic fertilisers or soil improvers, to be placed on the market in accordance with Article 32;
- (e) used for the production of raw petfood, to be placed on the market in accordance with Article 35;
- (f) composted or transformed into biogas;
- (g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
- (h) in the case of shells from shellfish, other than those referred to in Article 2(2)(f), and egg shells, used under conditions determined by the competent authority which prevent risks arising to public and animal health;
- (i) used as a fuel for combustion with or without prior processing;
- (j) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles;
- (k) in the case of catering waste referred to in Article 10(p) processed by pressure sterilisation or by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or composted or transformed into biogas; or
- (l) applied to land without processing, in the case of raw milk, colostrum and products derived therefrom, which the competent authority does not consider to present a risk of any disease communicable through those products to humans or animals.

Article 15

Implementing measures

- 1 Measures for the implementation of this Section may be laid down relating to the following:
 - a special conditions for the on-board handling and the disposal of material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;
 - b processing methods for animal by-products other than pressure sterilisation, in particular as regards the parameters to be applied for those processing methods, in particular the time, temperature, pressure and size of particles;
 - c parameters for the transformation of animal by-products, including catering waste, into biogas or compost;

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- d conditions for the incineration and co-incineration of animal by-products and derived products;
- e conditions for the combustion of animal by-products and derived products;
- f conditions for the generation and handling of animal by-products referred to in Article 10(c);
- g ensilage of material originating from aquatic animals;
- h permanent marking of animal by-products;
- i the application to land of certain animal by-products, organic fertilisers and soil improvers;
- j the use of certain animal by-products for feeding to farmed animals; and
- k the level of risk to public or animal health with respect to certain material which is considered as unacceptable as referred to in Article 14(d).

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(4).

- 2 Pending the adoption of rules referred to:
- a in points (c), (f) and (g) of the first subparagraph of paragraph 1, Member States may adopt or maintain national rules for:
 - (i) the generation and handling of animal by-products referred to in Article 10(c);
 - (ii) the transformation of animal by-products referred to in Article 10(p); and
 - (iii) for the ensilage of material originating from aquatic animals;
 - b in point (a) of the first subparagraph of paragraph 1, animal by-products referred to therein may be disposed of at sea, without prejudice to Community environmental legislation.

Section 3

Derogations

Article 16

Derogations

By way of derogation from Articles 12, 13 and 14, animal by-products may be:

- (a) in the case of animal by-products referred to in point (a) of the first subparagraph of Article 15(1), handled and disposed of in accordance with special conditions laid down pursuant to that point;
- (b) used for research and other specific purposes in accordance with Article 17;
- (c) in the case of animal by-products referred to in Article 18, used for special feeding purposes in accordance with that Article;
- (d) in the case of animal by-products referred to in Article 19, disposed of in accordance with that Article;
- (e) disposed of or used in accordance with alternative methods which have been authorised in accordance with Article 20, based on parameters which may include

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- pressure sterilisation or other requirements of this Regulation or the implementing measures thereof;
- (f) in the case of Category 2 and Category 3 materials and if authorised by the competent authority, used for the preparation and application to land of bio-dynamic preparations as referred to in Article 12(1)(c) of Regulation (EC) No 834/2007;
- (g) in the case of Category 3 material and, if authorised by the competent authority, used for feeding to pet animals;
- (h) in the case of animal by-products, except for Category 1 material, which arise in the course of surgical intervention on live animals or during birth of animals on farm and, if authorised by the competent authority, disposed of on that farm.

Article 17

Research and other specific purposes

1 The competent authority may, by way of derogation from Articles 12, 13 and 14, authorise the use of animal by-products and derived products for exhibitions, artistic activities, and for diagnostic, educational or research purposes under conditions which ensure the control of risks to public and animal health.

Such conditions shall include:

- a the prohibition of any subsequent use of the animal by-products or derived products for other purposes; and
- b the obligation to dispose of the animal by-products or derived products safely, or to re-dispatch them to their place of origin, if appropriate.

2 In the case of risks to public and animal health which require the adoption of measures for the whole territory of the Community, in particular in the case of newly emerging risks, harmonised conditions for the import and use of the animal by-products and derived products referred to in paragraph 1 may be laid down. Such conditions may include requirements regarding storage, packaging, identification, transport and disposal.

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(4).

Article 18

Special feeding purposes

1 The competent authority may, by way of derogation from Articles 13 and 14, authorise, under conditions which ensure the control of risks to public and animal health, the collection and use of Category 2 material, provided that it comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, and of Category 3 material for feeding to:

- a zoo animals;
- b circus animals;
- c reptiles and birds of prey other than zoo or circus animals;
- d fur animals;
- e wild animals;

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- f dogs from recognised kennels or packs of hounds;
 - g dogs and cats in shelters;
 - h maggots and worms for fishing bait.
- 2 The competent authority may authorise, by way of derogation from Article 12, and in accordance with the conditions laid down pursuant to paragraph 3 of this Article:
- a the feeding of the Category 1 material referred to in Article 8(b)(ii) and of material derived from zoo animals for feeding to zoo animals; and
 - b the feeding of the Category 1 material referred to in Article 8(b)(ii) to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity.
- 3 Measures for the implementation of this Article may be laid down relating to the following:
- a conditions under which the collection and use as referred to in paragraph 1 may be authorised with respect to the movement, storage and use of Category 2 material and of Category 3 material for feeding, including in the case of newly emerging risks; and
 - b conditions under which, in certain cases by way of derogation from the obligation laid down in Article 21(1), the feeding of Category 1 material as referred to in paragraph 2 of this Article may be authorised, including:
 - (i) the endangered or protected species of necrophagous birds and other species in certain Member States to which such material may be fed;
 - (ii) measures to prevent risks to public and animal health.

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(4).

Article 19

Collection, transport and disposal

- 1 The competent authority may, by way of derogation from Articles 12, 13, 14 and 21, authorise the disposal:
- a by burial of dead pet animals and equidae;
 - b by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(a)(v) and (b)(ii), Category 2 and Category 3 materials in remote areas;
 - c by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(b)(ii), Category 2 and Category 3 materials in areas where access is practically impossible or where access would only be possible under circumstances, related to geographical or climatic reasons or due to a natural disaster, which would pose a risk to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionate means of collection;
 - d by means other than burning or burial on site, under official supervision, in the case of Category 2 and Category 3 materials which do not pose a risk to public and animal health, when the amounts of materials do not exceed a particular volume per week, this volume being determined in relation to the nature of the activities carried out and the species of origin of the animal by-products concerned;

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- e by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of animal by-products other than Category 1 material referred to in Article 8(a)(i) in the event of an outbreak of a notifiable disease, if transport to the nearest plant approved for processing or disposal of the animal by-products would increase the danger of propagation of health risks or, in case of a widespread outbreak of an epizootic disease, would mean that the disposal capacities of such plants were exceeded; and
 - f by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of bees and apiculture by-products.
- 2 The animal population of a particular species in the remote areas referred to in paragraph 1(b) shall not exceed a maximum percentage of the animal population of this species in the Member State concerned.
- 3 Member States shall make available to the Commission information on:
- a the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation, and updated information concerning any change to such categorisation; and
 - b the use they make of the authorisations provided for in points (c) and (d) of paragraph 1 with respect to Category 1 and Category 2 materials.
- 4 Measures for the implementation of this Article shall be laid down relating to the following:
- a conditions aimed at ensuring control of risks to public and animal health in the event of burning and burial on site;
 - b the maximum percentage of the animal population as referred to in paragraph 2;
 - c the volume of animal by-products, in relation to the nature of activities and the species of origin, as referred to in paragraph 1(d); and
 - d the list of diseases referred to in paragraph 1(e).

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(4).

Section 4

Alternative methods

Article 20

Authorisation of alternative methods

1 The procedure for authorisation of an alternative method of use or disposal of animal by-products or derived products may be initiated either by the Commission or, following an application, by a Member State or by an interested party, which may represent several interested parties.

2 Interested parties shall send their applications to the competent authority of the Member State where they intend to use the alternative method.

The competent authority shall evaluate, within a period of two months following receipt of a complete application, whether the application complies with the standard format for applications referred to in paragraph 10.

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3 The competent authority shall communicate the applications of the Member States and interested parties, together with a report on its evaluation to the European Food Safety Authority (EFSA) and inform the Commission thereof.

4 When the Commission initiates the procedure for authorisation, it shall send a report on its evaluation to EFSA.

5 EFSA shall assess, within six months following receipt of a complete application, whether the method submitted ensures that risks to public or animal health are:

- a controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or
- b reduced to a degree which is at least equivalent, for the relevant category of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

EFSA shall issue an opinion on the application submitted.

6 In duly justified cases where EFSA requests additional information from applicants, the period provided for in paragraph 5 may be extended.

After consulting the Commission or the applicant, EFSA shall decide on a period within which that information shall be provided to it and inform the Commission and the applicant as appropriate of the additional period needed.

7 Where applicants wish to submit additional information on their own initiative, they shall send it directly to EFSA.

In that case the period provided for in paragraph 5 shall not be extended by an additional period.

8 EFSA shall forward its opinion to the Commission, the applicant and the competent authority of the Member State concerned.

9 Within three months following receipt of the opinion of EFSA and taking account of that opinion, the Commission shall inform the applicant of the proposed measure to be adopted in accordance with paragraph 11.

10 A standard format for applications for alternative methods shall be adopted in accordance with the advisory procedure referred to in Article 52(2).

11 Following receipt of the opinion of EFSA, the following shall be adopted:

- a either a measure authorising an alternative method of use or disposal of animal by-products or derived products; or
- b a measure rejecting the authorisation of such an alternative method.

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(4).

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(1) [^{F1}OJ L 276, 20.10.2010, p. 33.]

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Textual Amendments

F1 Substituted by [Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes \(Text with EEA relevance\).](#)

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