

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 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 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:

- (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;
- (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;
 - 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 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;
- 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;
- 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.

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).