

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 II

OBLIGATIONS OF OPERATORS

CHAPTER I

General obligations

Section 1

Collection, transport and traceability

Article 21

Collection and identification as regards category and transport

1 Operators shall collect, identify and transport animal by-products without undue delay under conditions which prevent risks arising to public and animal health.

2 Operators shall ensure that animal by-products and derived products are accompanied during transport by a commercial document or, when required by this Regulation or by a measure adopted in accordance with paragraph 6, by a health certificate.

By way of derogation from the first subparagraph, the competent authority may authorise the transport of manure between two points located on the same farm or between farms and users of manure within the same Member State without a commercial document or health certificate.

3 Commercial documents and health certificates accompanying animal by-products or derived products during transport shall at least include information on the origin, the destination and the quantity of such products, and a description of the animal by-products or derived products and their marking, when such marking is required by this Regulation.

However, for animal by-products and derived products transported within the territory of a Member State, the competent authority of the Member State concerned may authorise transmission of the information referred to in the first subparagraph by way of an alternative system.

4 Operators shall collect, transport and dispose of Category 3 catering waste, in accordance with national measures foreseen in Article 13 of Directive 2008/98/EC.

5 The following shall be adopted in accordance with the regulatory procedure referred to in Article 52(3):

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- a models for commercial documents which are required to accompany animal by-products during transport; and
 - b models for health certificates and the conditions governing the way they must accompany animal by-products and derived products during transport.
- 6 Measures for the implementation of this Article may be laid down relating to the following:
- a cases where a health certificate is required, having regard to the level of risk to public and animal health arising from certain derived products;
 - b cases where, by way of derogation from the first subparagraph of paragraph 2 and having regard to the low level of risk to public and animal health arising from certain animal by-products or derived products, transport of derived products may take place without the documents or certificates referred to in that paragraph;
 - c requirements for the identification, including labelling, and for the separation of different categories of animal by-products during transport; and
 - d conditions to prevent risks to public and animal health arising during the collection and transport of animal by-products, including conditions for the safe transport of those products with respect to containers, vehicles and packaging material.

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 22

Traceability

1 Operators consigning, transporting or receiving animal by-products or derived products shall keep a record of consignments and related commercial documents or health certificates.

However, the first subparagraph shall not apply when an authorisation to transport animal by-products or derived products without commercial documents or health certificates has been granted in accordance with the second subparagraph of Article 21(2) or in accordance with implementing measures adopted under Article 21(6) (b).

2 The operators referred to in paragraph 1 shall have in place systems and procedures to identify:

- a the other operators to which their animal by-products or derived products have been supplied; and
- b the operators from whom they have been supplied.

This information shall be made available to the competent authorities on request.

3 Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

- a the information to be made available to the competent authorities;
- b the period of time during which this information must be kept.

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Section 2

Registration and approval

Article 23

Registration of operators, establishments or plants

- 1 With a view to registration, operators shall:
 - a before commencing operations, notify the competent authority of any establishments or plants under their control which are active at any stage of the generation, transport, handling, processing, storage, placing on the market, distribution, use or disposal of animal by-products and derived products;
 - b provide the competent authority with information on:
 - (i) the category of animal by-products or derived products under their control;
 - (ii) the nature of the operations performed using animal by-products or derived products as starting material.
- 2 Operators shall provide the competent authority with up-to-date information on any establishments or plants under their control as referred to in point (a) of paragraph 1, including any significant change in activities such as any closure of an existing establishment or plant.
- 3 Detailed rules regarding registration as referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).
- 4 By way of derogation from paragraph 1, no notification with a view to registration shall be required for activities with respect to which establishments generating animal by-products have already been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004; and for activities with respect to which establishments or plants have already been approved in accordance with Article 24 of this Regulation.

The same derogation shall apply for the activities involving the generation of animal by-products on site only, which are carried out on farms or other premises where animals are kept, bred or taken care of.

Article 24

Approval of establishments or plants

- 1 Operators shall ensure that establishments or plants under their control are approved by the competent authority, where such establishments or plants carry out one or more of the following activities:
 - a processing of animal by-products by pressure sterilisation, by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or by alternative methods authorised in accordance with Article 20;
 - b disposal, as waste, by incineration of animal by-products and derived products, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;

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- c disposal or recovery of animal by-products and derived products, if they are waste, by co-incineration, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;
 - d use of animal by-products and derived products as fuel for combustion;
 - e manufacturing of pet food;
 - f manufacturing of organic fertilisers and soil improvers;
 - g transformation of animal by-products and/or derived products into biogas or compost;
 - h handling of animal by-products after their collection, by way of operations such as sorting, cutting, chilling, freezing, salting, removal of hides and skins or of specified risk material;
 - i storage of animal by-products;
 - j storage of derived products intended to be:
 - (i) disposed of by landfill or incineration or intended to be recovered or disposed of by co-incineration;
 - (ii) used as fuel for combustion;
 - (iii) used as feed, excluding establishments or plants approved or registered in accordance with Regulation (EC) No 183/2005;
 - (iv) used as organic fertilisers and soil improvers, excluding storage at a place of direct application.
- 2 The approval referred to in paragraph 1 shall specify if the establishment or plant is approved for operations with animal by-products and/or derived products of:
- a a particular category referred to in Articles 8, 9 or 10; or
 - b more than one category referred to in Articles 8, 9 or 10, indicating if such operations are carried out:
 - (i) permanently under conditions of strict separation which prevent any risk to public and animal health; or
 - (ii) temporarily under conditions which prevent contamination, in response to a shortage of capacity for such products arising due to:
 - a widespread outbreak of an epizootic disease, or
 - other extraordinary and unforeseen circumstances.

Article 25

General hygiene requirements

- 1 Operators shall ensure that establishments or plants under their control carrying out the activities referred to in Article 24(1)(a) and (h):
- a are constructed in a way permitting their effective cleaning and disinfection and where appropriate the construction of floors facilitates the draining of liquids;
 - b have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins for staff;
 - c have appropriate arrangements for protection against pests, such as insects, rodents and birds;
 - d keep installations and equipment in good condition and ensure that measuring equipment is calibrated regularly; and

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- e have appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.
- 2 Any person working in the establishment or plant referred to in paragraph 1 shall wear suitable, clean and, where necessary, protective clothing.
- Where appropriate in a particular establishment or plant:
- a persons working in the unclean sector shall not enter the clean sector without first changing their work clothes and shoes or without having disinfected them;
 - b equipment and machinery shall not be moved from the unclean to the clean sector without first being cleaned and disinfected; and
 - c the operator shall establish a procedure relating to the movements of persons in order to monitor their movements and describe the correct use of footbaths and wheel baths.
- 3 In establishments or plants carrying out the activities referred to in Article 24(1)(a):
- a animal by-products shall be handled in such a way as to avoid risks of contamination;
 - b animal by-products shall be processed as soon as possible. After processing, derived products shall be handled and stored in such a way as to avoid risks of contamination;
 - c where appropriate, during any processing applied to animal by-products and derived products every part of the animal by-product and derived products shall be treated to a given temperature for a given period of time and risks of re-contamination shall be prevented;
 - d the operators shall check regularly the applicable parameters, particularly temperature, pressure, time, size of particles, where appropriate by automatic devices;
 - e cleaning procedures shall be established and documented for all parts of the establishments or plants.

Article 26

Handling of animal by-products within food businesses

- 1 The treatment, processing or storage of animal by-products in establishments or plants approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 or in accordance with Article 6 of Regulation (EC) No 852/2004 shall be carried out under conditions which prevent cross-contamination and if appropriate in a dedicated part of the establishment or plant.
- 2 Raw materials for the production of gelatine and collagen not intended for human consumption may be stored, treated or processed in the establishments specifically authorised in accordance with Regulation (EC) No 853/2004, Annex III, Section XIV, Chapter I, point 5, and Section XV, Chapter I, point 5, provided the transmission of disease risk is prevented by segregation of such raw materials from the raw materials for the production of products of animal origin.
- 3 Paragraphs 1 and 2 shall apply without prejudice to more specific requirements laid down in Community veterinary legislation.

Article 27

Implementing measures

Measures for the implementation of this Section and Section 1 of this Chapter shall be laid down relating to the following:

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- (a) infrastructure and equipment requirements applicable within establishments or plants;
- (b) hygiene requirements applicable to all types of handling of animal by-products and derived products, including measures modifying hygiene requirements for establishments or plants referred to in Article 25(1);
- (c) conditions and technical requirements for the handling, treatment, transformation, processing and storage of animal by-products or derived products and conditions for treatment of waste water;
- (d) evidence to be presented by the operator for the purpose of validation of the treatment, transformation and processing of animal by-products or derived products, on their ability to prevent public and animal health risks;
- (e) conditions for the handling of animal by-products or derived products of more than one category referred to in Articles 8, 9 or 10 in the same establishment or plant:
 - (i) where such operations are carried out separately;
 - (ii) where such operations are carried out temporarily in certain circumstances;
- (f) conditions for the prevention of cross-contamination when animal by-products are stored, treated or processed in a dedicated part of an establishment or plant referred to in Article 26;
- (g) standard transformation parameters for biogas and composting plants;
- (h) requirements applicable to the incineration or co-incineration in plants of high and low capacity as referred to in Article 24(1)(b) and (c); and
- (i) requirements applicable to the combustion of animal by-products and derived products as referred to in Article 24(1)(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).

Section 3

Own checks and hazard analysis and critical control points

Article 28

Own checks

Operators shall put in place, implement and maintain own checks in their establishments or plants in order to monitor compliance with this Regulation. They shall ensure that no animal by-products or derived products suspected or discovered not to comply with this Regulation leave the establishment or plant, unless destined for disposal.

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Article 29

Hazard analysis and critical control points

1 Operators carrying out one of the following activities shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (HACCP) principles for the:

- a processing of animal by-products;
- b transformation of animal by-products into biogas and compost;
- c handling and storage of more than one category of animal by-products or derived products in the same establishment or plant;
- d manufacturing of pet food.

2 Operators as specified in paragraph 1 shall in particular:

- a identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
- b identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
- c establish critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
- d establish and implement effective monitoring procedures at critical control points;
- e establish corrective action when monitoring indicates that a critical control point is not under control;
- f establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;
- g establish documents and records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f).

3 When any modification is made to a product, process or any stage of production, processing, storage or distribution, operators shall review their procedures and make the necessary changes.

4 Measures to facilitate the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

Article 30

National guides to good practice

1 Where necessary, competent authorities shall encourage the development, dissemination and voluntary use of national guides to good practice in particular for the application of HACCP principles as referred to in Article 29. Operators may use such guides on a voluntary basis.

2 The competent authority shall assess national guides to ensure that:

- a they have been developed in consultation with representatives of parties whose interests may be substantially affected, and have been disseminated by sectors of operators; and
- b their contents are practicable for the sectors to which they refer.

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