

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 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;
- 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:

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- 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
- 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:

- (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).