

ANNEX IX

REQUIREMENTS APPLICABLE TO CERTAIN APPROVED AND REGISTERED ESTABLISHMENTS AND PLANTS

CHAPTER I

MANUFACTURING OF PETFOOD

Establishments or plants manufacturing petfood as referred to in Article 24(1)(e) of Regulation (EC) No 1069/2009 shall have adequate facilities for:

- (a) storing and treating incoming material in complete safety; and
- (b) disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or such material must be sent to an incineration plant, a co-incineration plant, a processing plant or, in the case of Category 3 material, to a biogas or composting plant in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009 and with this Regulation.

CHAPTER II

HANDLING OF ANIMAL BY-PRODUCTS AFTER THEIR COLLECTION

The requirements of this Chapter shall apply to the storage of animal by-products, as referred to in Article 24(1)(i) of Regulation (EC) No 1069/2009 and to the following operations involving the handling of animal by-products after their collection, as referred to in Article 24(1)(h) of that Regulation:

- (a) sorting;
- (b) cutting;
- (c) chilling;
- (d) freezing;
- (e) salting or other preservation processes;
- (f) removal of hides and skins;
- (g) removal of specified risk material;
- (h) operations involving the handling of animal by-products which are carried out in compliance with obligations under [F¹veterinary legislation forming part of retained EU law], such as post-mortem examination or the taking of samples;
- (i) hygienisation/pasteurisation of animal by-products destined for transformation into biogas or composting, prior to such transformation or composting in another establishment or plant in accordance with Annex V hereto;
- (j) [F²sieving;]
- (k) [F³phase transition processes of Category 3 materials, such as blood thermocoagulation, blood centrifugation, containment as set out in Chapter V to

Annex IX hereto, hydrolyzing of hooves, pig bristles, feathers and hair, destined for processing with processing methods set out in this Regulation.]

Textual Amendments

- F1** Words in Annex 9 Ch. 2 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(52)(a)**
- F2** Substituted by [Commission Regulation \(EU\) 2020/762 of 9 June 2020 amending Regulation \(EU\) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products \(Text with EEA relevance\)](#).
- F3** Inserted by [Commission Regulation \(EU\) 2020/762 of 9 June 2020 amending Regulation \(EU\) No 142/2011 as regards microbiological standards for raw petfood, requirements concerning approved establishments, technical parameters applicable to the alternative method Brookes' gasification process and hydrolysis of rendered fats, and exports of processed manure, certain blood, blood products and intermediate products \(Text with EEA relevance\)](#).

Section 1

General requirements

1. Premises and facilities where intermediate operations are carried out shall meet at least the following requirements:
 - (a) They must be adequately separated from thoroughfares through which contamination may be spread and from other premises such as slaughterhouses. The layout of plants shall ensure the total separation of Category 1 and Category 2 material from Category 3 material respectively, from reception until dispatch, unless in a completely separate building.
 - (b) The plant must have a covered space to receive and dispatch animal by-products, unless the animal by-products are being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid animal by-products.
 - (c) The plant must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.
 - (d) The plant must have adequate facilities including lavatories, changing rooms, washbasins for staff and, if appropriate, office space which can be made available to the staff performing official controls.
 - (e) The plant must have appropriate arrangements for protection against pests, such as insects, rodents and birds.
 - (f) Where it is necessary for the purpose of achieving the objectives of this Regulation, plants must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring and recording of those temperatures.
2. The plant shall be equipped with adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and for the

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vehicles, other than ships, in which they are transported. Adequate facilities shall be available for the disinfecting of vehicle wheels.

Section 2

Hygiene requirements

1. The sorting of animal by-products shall be carried out in such a way as to avoid any risk of the propagation of animal diseases.
2. At all times during storage, animal by-products shall be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.
3. Animal by-products shall be stored properly, including under appropriate temperature conditions, until re-dispatched.

Section 3

Processing standards for hygienisation/pasteurisation

Hygienisation/pasteurisation as referred to in point (i) of the initial paragraph of this Chapter shall be carried out in accordance with the processing standards referred to in point 1 of Section 1 of Chapter I of Annex V or in accordance with alternative transformation parameters which have been authorised in accordance with point 1 of Section 2 of Chapter III of the same Annex.

CHAPTER III

REQUIREMENTS FOR STORAGE OF DERIVED PRODUCTS

Section 1

General requirements

Premises and facilities storing derived products shall meet at least the following requirements:

1. Premises and facilities storing derived products from Category 3 material must not be at the same site as premises storing derived products from Category 1 or Category 2 material, unless cross-contamination is prevented due to the layout and management of the premises, such as by means of storage in completely separate buildings.
2. The plant must:
 - (a) have a covered space to receive and dispatch the derived products, unless the derived products are:
 - (i) being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid products; or
 - (ii) received in packaging, such as in big bags, or in covered leak-proof containers or means of transport;

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- (b) be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids;
 - (c) have adequate facilities including lavatories, changing rooms and washbasins for staff;
 - (d) have appropriate arrangements for protection against pests, such as insects, rodents and birds.
3. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which the derived products are received and the vehicles, other than ships, in which they are transported.
 4. Derived products must be stored properly until redispached.

Section 2

Specific requirements for storage of certain milk, milk-based products and milk-derived products

1. The storage of the products referred to in Part II of Section 4 of Chapter II of Annex X shall take place at an appropriate temperature to avoid any risk to public or animal health in a dedicated approved or registered storage establishment or plant or in a dedicated, separate storage area within an approved or registered storage establishment or plant.
2. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in Chapter I of Annex X.

CHAPTER IV

REGISTERED OPERATORS

1. Operators of registered plants or establishments or other registered operators shall handle animal by-products and derived products under the following conditions:
 - (a) premises must be constructed in a way permitting their effective cleaning and disinfection, where appropriate;
 - (b) premises must have appropriate arrangements for protection against pests, such as insects, rodents and birds;
 - (c) installations and equipment must be kept in hygienic condition, where necessary;
 - (d) animal by-products and derived products must be stored under conditions preventing contamination.
2. Operators shall keep records in a form which is accessible to the competent authority.
3. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, shall in particular:

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- (a) have information at their disposal with regard to the identification of their vehicles, which allows the verification of the use of the vehicles for the transport of animal by-products or derived products;
- (b) clean and disinfect their vehicles, as appropriate;
- (c) take all other necessary measures to prevent contamination and the spreading of diseases communicable to humans or animals.

[^{F4}CHAPTER V

CONTAINMENT METHODS

Section 1

General provisions

1. Materials resulting from a containment method may be used or disposed of only within [^{F5}Great Britain] where that containment method is authorised by the [^{F6}relevant] competent authority.

Textual Amendments

- F5** Words in Annex 9 Ch. 5 Section 1 point 1 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(52)(b)(i)(aa)**
- F6** Word in Annex 9 Ch. 5 Section 1 point 1 inserted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(52)(b)(i)(bb)**

2. The competent authority of a [^{F7}constituent nation] shall make the results of official controls available to the competent authority of another [^{F7}constituent nation] upon request, where a containment method is used for the first time in that [^{F7}constituent nation], in order to facilitate the introduction of the new containment method.

Textual Amendments

- F7** Words in Annex 9 Ch. 5 Section 1 point 2 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(52)(b)(ii)**

Section 2

Methodology

- A. Aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration.
 1. [^{F8}Application]

The process of aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration may be used in [^{F9}Great Britain].

Textual Amendments

- F9** Words in Annex 9 Ch. 5 Section 2 point A(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(54)(a)(ii)**

Following aerobic maturation and storage of material, the [^{F10}relevant competent authority] must ensure that the materials are collected and disposed of within [^{F11}Great Britain].

Textual Amendments

- F10** Words in Annex 9 Ch. 5 Section 2 point A(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(54)(a)(iii)(aa)**
- F11** Words in Annex 9 Ch. 5 Section 2 point A(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(54)(a)(iii)(bb)**

Textual Amendments

- F8** Annex 9 Ch. 5 Section 2 point A(1) heading substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(54)(a)(i)**

2. Starting materials

For this process, only the following materials of animals of the porcine species may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of Regulation (EC) No 1069/2009.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding, provided this holding is not subject to restrictions due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species. This method may not be used for animals which have died due to those diseases or have been killed for diseases control purposes, or parts of those animals.

3. Methodology

3.1. General principles

The method is a process authorised by the competent authority.

The site must be constructed and laid out in accordance with [^{F12}retained EU law] for the protection of the environment, in order to prevent odours and risks to soil and groundwater.

Textual Amendments

F12 Words in Regulation substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1388), regs. 1(2)(c), **13(2)(a)**

The operator must:

- (a) take preventive measures against access of animals and put in place a documented pest control programme;
- (b) put in place procedures to prevent the spreading of diseases;
- (c) put in place procedures to prevent the spreading of used sawdust outside the closed system.

The process must be carried out in a closed system which consist of several cells, with a waterproof floor and delimited by solid walls. Any waste water must be collected; the cells must be connected with a drainpipe fitted with a 6 mm grid to capture solids.

Size and number of the cells must be adapted to the mortality level defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 with sufficient capacity for farm mortalities occurring during an eight-month period at least.

3.2. Phases

3.2.1. Filling and storage phase

The fallen pigs and other porcine material must be individually covered in sawdust and piled up until the cell is full. First a layer of at least 30 centimetres of sawdust must be placed on the ground. The carcasses and other porcine material must then be placed on this first layer of sawdust and each layer of carcasses and other porcine material must be covered with a layer of sawdust at least 30 cm thick.

Personnel must not walk on the stored material.

3.2.2. Maturing phase

When the cell is full and a rise in temperature allows the degradation of all the soft tissues, the maturation period starts and must last at least 3 months.

At the end of the filling and storage phase and during all of the maturation phase, the operator must monitor the temperature in each cell with a temperature sensor placed between 40 cm and 60 cm beneath the pile surface of the latest built layer.

The electronic reading and monitoring of the temperature must be recorded by the operator.

At the end of the filling and storage phase, the temperature monitoring is an indicator of a satisfactory pile layout. The temperature must be measured by an automatic recording device. The aim is to reach 55 °C during 3 consecutive days, revealing that the maturing process is active and that the pile layout is effective and that the maturing phase has started.

The operator must monitor the temperature once a day and the following measures shall be taken depending on the outcome of these measurements:

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- (a) where the temperature of 55 °C or more is maintained during 3 consecutive days, the pile may be removed after a 3 consecutive months maturing phase, or may remain stored on the premises awaiting a later removal;
- (b) where the temperature of 55 °C is not reached during 3 consecutive days, measures defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be set by the operator; if needed, the competent authority may stop the processing method and the material must be disposed of in compliance with Article 13 of the aforementioned Regulation.

A time limit for the storage phase may be determined by the competent authority.

3.2.3. Transport and incineration or co-incineration

The transport of the resulted material after the maturation phase to the approved incineration or co-incineration plant is subject to controls referred to in Regulation (EC) No 1069/2009 or [F13the Control of Pollution (Amendment) Act 1989].

Textual Amendments

F13 Words in Annex 9 Ch. 5 Section 2 point A(3.2.3) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(54)(b)**

B. Hydrolysis with subsequent disposal

1. [F14Application]

The process of hydrolysis with subsequent disposal may be used in [F15Great Britain].

Textual Amendments

F15 Words in Annex 9 Ch. 5 Section 2 point B(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(55)(b)**

Following hydrolysis, the authorising competent authority must ensure that the materials are collected and disposed of within [F16Great Britain].

Textual Amendments

F16 Words in Annex 9 Ch. 5 Section 2 point B(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(55)(c)**

Textual Amendments

F14 Annex 9 Ch. 5 Section 2 point B(1) heading substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(55)(a)**

2. Starting materials

Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011, ANNEX IX. (See end of Document for details)

For this process, only the following materials of porcine origin may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of that Regulation.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding and provided this holding is not subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species, or animals that have been killed for disease control purposes.

3. Methodology

Hydrolysis with subsequent disposal is a temporary storage on the spot. It shall be carried out according to the following standards:

- (a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) (‘ the container ’) and which has been placed at a dedicated site in accordance with points (c) and (d) (‘ the dedicated site ’).
- (b) The container must:
 - (i) have a device to close it;
 - (ii) be waterproof, leak-proof and hermetically sealed;
 - (iii) be coated in a way which prevents corrosion;
 - (iv) be equipped with a device for controlling emissions in accordance with point (e).
- (c) The container must be placed in a dedicated site which is physically separate from the holding.

That site must have dedicated access routes for the movement of materials and for collection vehicles.
- (d) The container and the site must be constructed and laid out in accordance with [F12retained EU law] for the protection of the environment, in order to prevent odours and risks to soil and groundwater.
- (e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.
- (f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.
- (g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.
- (h) The operator must:
 - (i) take preventive measures against birds, rodents, insects and other vermin;

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- (ii) put in place a documented pest control programme.
- (i) The operator must keep records of:
 - (i) any placing of material into the container;
 - (ii) any collection of hydrolysed material from the container.
- (j) The operator must empty the container at regular intervals for a check:
 - (i) for the absence of corrosion;
 - (ii) to detect and prevent possible leakage of liquid materials into the ground.
- (k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009 or Article 14 of that Regulation for Category 3 materials.
- (l) The process must be carried out in a batch mode.
- (m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited.]

Textual Amendments

- F4** Inserted by [Commission Regulation \(EU\) 2015/9 of 6 January 2015 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX IX.