

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 [^{F1}Great Britain] 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 [^{F2}constituent nation], the competent authority of the [^{F2}constituent nation] concerned may authorise transmission of the information referred to in the first subparagraph by way of an alternative system.

[^{F3}4 Operators must collect, transport and dispose of Category 3 catering waste so as to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular:

- a without risk to water, air, soil, plants or animals;
- b without causing a nuisance through noise or odours; and
- c without adversely affecting the countryside or places of special interest.]

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5 ^[F4]The appropriate authority may make available or publish, in such manner as appears to the appropriate authority to be appropriate, from time to time]:

- a models for commercial documents which are required to accompany animal by-products during transport; and
- b models for health certificates ^[F5]which are required to] accompany animal by-products and derived products during transport.

^[F6]5A The appropriate authority may, by regulations, lay down conditions governing the way in which model health certificates must accompany animal by-products and derived products during transport.]

6 ^[F7]The appropriate authority may, by regulations, lay down measures for the implementation of this Article relating to the following matters]:

- 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.

^{F8} ...

Textual Amendments

- F1** Words in Art. 21(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), **12(13)(a)**
- F2** Words in Art. 21(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), **12(13)(b)**
- F3** Art. 21(4) 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), **12(13)(c)**
- F4** Words in Art. 21(5) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(13)(a)(i)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 21(5)(b) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(13)(a)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Art. 21(5A) inserted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(13)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 21(6) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(13)(c)(i)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 21(6) omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(13)(c)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

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 [^{F9}regulations made] 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 [^{F10}The appropriate authority may, by regulations, make such provision for the implementation of this Article as the appropriate authority considers to be necessary or expedient, including provisions relating to]:

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

Textual Amendments

- F9** Words in Art. 22(1) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(14)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in Art. 22(3) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(14)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

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:

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- (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.

[^{F11}3 The appropriate authority may, by regulations, make detailed rules relating to registration under paragraph 1.]

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.

Textual Amendments

F11 Art. 23(3) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(15)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

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 [^{F12}the Environmental Permitting (England and Wales) Regulations 2016 or the Pollution Prevention and Control (Scotland) Regulations 2012];
- 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 [^{F13}the Environmental Permitting (England and Wales) Regulations 2016 or the Pollution Prevention and Control (Scotland) Regulations 2012];
- 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;

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- 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.

Textual Amendments

- F12** Words in Art. 24(1)(b) 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), **12(14)**
- F13** Words in Art. 24(1)(c) 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), **12(14)**

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;

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- 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 [F14 veterinary legislation forming part of retained EU law].

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

Textual Amendments

F14 Words in [Art. 26\(3\)](#) 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), **12(15)**

Article 27

Implementing measures

[^{F15}The appropriate authority may, by regulations, lay down measures for the implementation of this Section and Section 1 of this Chapter relating to the following matters]:

- (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).

^{F16}

Textual Amendments

F15 Words in [Art. 27](#) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(16)(a)** (with [reg. 12](#)); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

F16 Words in Art. 27 omitted (31.12.2020) by virtue of The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, 8(16)(b) (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

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.

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.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

[^{F17} The appropriate authority may, by regulations, make such provision as the appropriate authority considers necessary or expedient to facilitate the implementation of this Article.]

Textual Amendments

F17 Art. 29(4) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/588), regs. 1, **8(17)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

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.

CHAPTER II

Placing on the market

Section 1

Animal by-products and derived products for feeding to farmed animals excluding fur animals

Article 31

Placing on the market

1 Animal by-products and derived products destined for feeding to farmed animals, excluding fur animals, may only be placed on the market provided:

- a they are or they are derived from Category 3 material other than material referred to in Article 10(n), (o) and (p);
- b they have been collected or processed, as applicable, in accordance with the conditions for pressure sterilisation or other conditions to prevent risks arising to public and animal health in accordance with measures adopted pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 2 of this Article; and
- c they come from approved or registered establishments or plants, as applicable for the animal by-product or derived product concerned.

2 [^{F18}The appropriate authority may, by regulations, lay down measures for the implementation of this Article] relating to the public and animal health conditions for the

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

collection, processing and treatment of animal by-products and derived products referred to in paragraph 1.

F19
 ...

Textual Amendments

- F18** Words in Art. 31(2) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(18)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 31(2) omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(18)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Section 2

Organic fertilisers and soil improvers

Article 32

Placing on the market and use

- 1 Organic fertilisers and soil improvers may be placed on the market and used provided:
- a they are derived from Category 2 or Category 3 material;
 - b they have been produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health, in accordance with the requirements laid down pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 3 of this Article;
 - c they come from approved or registered establishments or plants, as applicable; and
 - d in the case of meat-and-bone meal derived from Category 2 material and processed animal proteins intended to be used as or in organic fertilisers and soil improvers, they have been mixed with a component to exclude the subsequent use of the mixture for feeding purposes and marked when required by measures adopted under paragraph 3.

In addition, digestion residues from transformation into biogas or compost may be placed on the market and used as organic fertilisers or soil improvers.

[^{F20}Nothing in this Regulation prevents the appropriate authority from] imposing additional conditions for or restricting the use of organic fertilisers and soil improvers, provided that such rules are justified on grounds of the protection of public and animal health.

- 2 By way of derogation from point (d) of paragraph 1, mixing shall not be required for materials whose use for feeding purposes is excluded due to their composition or packaging.

- 3 [^{F21}The appropriate authority may, by regulations, lay down measures for the implementation of this Article relating to the following matters]:

- a public and animal health conditions for the production and use of organic fertilisers and soil improvers;
- b components or substances for the marking of organic fertilisers or soil improvers;
- c components to be mixed with organic fertilisers or soil improvers;
- d supplementary conditions, such as the methods to be used for marking and the minimum proportions to be observed when preparing the mixture, in order to exclude the use of such fertilisers or soil improvers for feeding purposes; and

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- e cases where the composition or packaging allows the materials to be exempted from the mixing requirement.

F22
...

Textual Amendments

- F20** Words in Art. 32(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), **12(16)**
- F21** Words in Art. 32(3) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(19)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 32(3) omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(19)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Section 3

Derived products regulated by certain other [^{F23}retained EU law]

Article 33

Placing on the market

Operators may place on the market the following derived products:

- (a) cosmetic products as defined in [^{F24}Article 2(1)(a) of Regulation [1223/2009/EC](#)];
- (b) active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;
- (c) medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;
- (d) in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;
- (e) veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;
- (f) medicinal products as defined in Article 1(2) of Directive 2001/83/EC.

Textual Amendments

- F24** Words in Art. 33(a) 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), **12(17)**

Article 34

Manufacture

1 The import, collection and movement of animal by-products and derived products destined for establishments or plants for the manufacture of the derived products referred to in Article 33 and the manufacture of those derived products shall be carried out in accordance with [^{F25}the following:]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

- [^{F26}a Regulation 1223/2009/EC in the case of cosmetic products;
- b the Medical Devices Regulations 2002 in the case of active implantable medical devices, medical devices and in vitro diagnostic medical devices;
 - c the Veterinary Medicines Regulations 2013 in the case of veterinary medicinal products;
 - d the Human Medicines Regulations 2012 in the case of medicinal products.]

Unused material from such establishments or plants shall be disposed of in accordance with that legislation.

2 However, this Regulation shall apply where the ^{F27}... legislation referred to in [^{F28}paragraph 1(a) to (d)] does not provide for conditions controlling potential risks to public and animal health in accordance with the objectives of this Regulation.

Textual Amendments

- F25** Words in Art. 34(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), **12(18)(a)**
- F26** Words in Art. 34(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), **12(18)(b)**
- F27** Word in Art. 34(2) omitted (E.W.S.) (31.12.2020) by virtue of [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), **12(18)(c)(i)**
- F28** Words in Art. 34(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), **12(18)(c)(ii)**

Textual Amendments

- F23** 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 \(S.I. 2020/1388\)](#), **reg. 12(2)**

Section 4

Other derived products

Article 35

Placing on the market of pet food

Operators may place pet food on the market provided:

- (a) the products are derived:
 - (i) from Category 3 material, other than material referred to in Article 10(n), (o) and (p);
 - (ii) in the case of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c), subject to

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

- conditions laid down pursuant to point (a) of the first paragraph of Article 40;
or
- (iii) in the case of raw petfood, from material referred to in Article 10(a) and (b) (i) and (ii); and
- (b) they ensure the control of risks to public and animal health by safe treatment in accordance with Article 38, where safe sourcing in accordance with Article 37 does not ensure sufficient control.

Article 36

Placing on the market of other derived products

Operators may place on the market derived products, other than the products referred to in Articles 31, 32, 33 and 35, provided:

- (a) those products are:
 - (i) not intended for use for the feeding to farmed animals or for application to land from which such animals are to be fed; or
 - (ii) intended for feeding to fur animals; and
- (b) they ensure the control of risks to public and animal health by:
 - (i) safe sourcing in accordance with Article 37;
 - (ii) safe treatment in accordance with Article 38, where safe sourcing does not ensure sufficient control; or
 - (iii) verifying that the products are only used for safe end uses in accordance with Article 39 where safe treatment does not ensure sufficient control.

Article 37

Safe sourcing

- 1 Safe sourcing shall include the use of material:
 - a from which no unacceptable risks to public and animal health arise;
 - b which has been collected and transported from the point of collection to the manufacturing establishment or plant under conditions which exclude risks to public and animal health; or
 - c which has been imported into [F29Great Britain] and transported from the point of first entry to the manufacturing establishment or plant under conditions which exclude risks to public and animal health.

2 For the purpose of safe sourcing, operators shall provide documentation of the requirements of paragraph 1, including, where necessary, proof of the safety of bio-security measures taken in order to exclude risks arising to public and animal health from starting material.

Such documentation shall be kept available to the competent authority upon request.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

In the case referred to in point (c) of paragraph 1, the consignments shall be accompanied by a health certificate corresponding to a model ^{F30}made available or published by the appropriate authority, in accordance with point (b) of Article 21(5)].

Textual Amendments

- F29** Words in Art. 37(1)(c) 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), **12(19)**
- F30** Words in Art. 37(2) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(20)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Article 38

Safe treatment

Safe treatment shall include application of a manufacturing process to the material used which reduces to an acceptable level risks to public and animal health arising from the material used or from other substances resulting from the manufacturing process.

It shall be ensured that the derived product poses no unacceptable risks to public and animal health, in particular by means of testing of the end product.

Article 39

Safe end uses

Safe end uses shall include the use of derived products:

- (a) under conditions which pose no unacceptable risks to public and animal health; or
- (b) which may pose a risk to public and animal health, for specific purposes provided that such use is justified by objectives set out in ^{F23}retained EU law], in particular for the protection of public and animal health.

Textual Amendments

- F23** 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 \(S.I. 2020/1388\)](#), **reg. 12(2)**

Article 40

Implementing measures

^{F31}The appropriate authority may, by regulations, lay down measures for the implementation of this Section relating to the following matters]:

- (a) conditions for the placing on the market of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c);

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

- (b) conditions for the safe sourcing and movement of material to be used under conditions which exclude risks to public and animal health;
- (c) documentation as referred to in the first subparagraph of Article 37(2);
- (d) parameters for the manufacturing process as referred to in the first paragraph of Article 38, in particular as regards the application of physical or chemical treatments to the material used;
- (e) testing requirements applicable to the end product; and
- (f) conditions for the safe use of derived products which pose a risk to public or animal health.

F32

Textual Amendments

- F31** Words in Art. 40 substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(21)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in Art. 40 omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(21)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

Import, transit and export

Article 41

Import and transit

1 Animal by-products and derived products shall be imported into, or sent in transit through, [^{F33}Great Britain] in accordance with:

- a the relevant requirements of this Regulation [^{F34}the Implementing Regulation and any regulations made by the appropriate authority under this Regulation] for the particular animal by-product or derived product which are at least as stringent as those applicable to the production and marketing of such animal by-products or derived products within [^{F35}Great Britain];
- b conditions recognised [^{F36}by the appropriate authority] to be at least equivalent to the requirements applicable to the production and marketing of such animal by-products or derived products under [^{F23}retained EU law]; ^{F37}...
- c in the case of animal by-products and derived products referred to in Articles 33, 35 and 36, the requirements set out in those [^{F38}Articles; or]
- [^{F39}d the special transitional import arrangements set out in Schedule 5 to the England Trade Regulations or equivalent provisions in the Wales Trade Regulations or the Scotland Trade Regulations, and Annex 6 to the Official Controls Regulation.]

[^{F40}Where, pursuant to point (b), the appropriate authority recognises conditions as being at least equivalent to the requirements applicable to the production and marketing of particular animal by-products or derived products under retained EU law, the appropriate authority must make available or publicise that recognition.]

2 By way of derogation from paragraph 1, the import and transit of:

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- a specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;
- b animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006;
- c Category 1 material, Category 2 material and products derived therefrom which are not intended for the manufacture of derived products referred to in Articles 33, 35 and 36, shall only take place [^{F41}pursuant to point (d) of paragraph 1 or] provided that rules for their import have been adopted in accordance with Article 42(2)(a);
- d animal by-products and derived products destined for the purposes referred to in Article 17(1) shall take place in accordance with national measures which ensure the control of risks to public and animal health, pending the adoption of harmonised conditions referred to in Article 17(2).

3 [^{F42}The appropriate authority may, by regulations, impose requirements relating to the import and transit of Category 3 material and products derived from Category 3 material.]

Those requirements may specify that consignments:

- a must come from a third country or part of a third country listed in accordance with paragraph 4;
- b must come from establishments or plants approved or registered by the competent authority of the third country of origin and listed by that authority for that purpose; and
- c must be accompanied at the point of entry into [^{F43}Great Britain] where the veterinary checks take place by documentation such as a commercial document or a health certificate and where appropriate by a declaration, which corresponds to a model laid down pursuant to [^{F44}Article 42(3)].

^{F45}
...

4 [^{F46}The appropriate authority may, by regulations, specify the third countries or parts of third countries from which animal by-products or derived products may be imported or transit through Great Britain.

In deciding whether to specify a third country or part of a third country in regulations made under the first subparagraph, the appropriate authority must, in particular, take into account]:

- a the legislation of the third country;
- b the organisation of the competent authority and its inspection services in the third country, the powers of those services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation;
- c the actual health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for [^{F47}Great Britain];
- d the assurances the third country can give regarding compliance with the relevant health conditions;
- e experience of marketing the product from the third country and the results of import checks carried out;
- f the result of any [^{F48}inspections by the competent authority] in the third country;
- g the health status of the livestock, other domestic animals and wildlife in the third country, having particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the [^{F49}United Kingdom];
- h the regularity and speed with which the third country supplies information about the existence of infectious animal diseases in its territory, in particular the diseases listed in

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the Terrestrial Animal Health Code and the Aquatic Animal Health Code of the World Organisation for Animal Health;

- i the regulations on the prevention and control of infectious animal diseases in force in the third country and their implementation, including rules on imports from other third countries.

The lists of establishments or plants referred to in point (b) of the second subparagraph of paragraph 3 shall be kept up to date and communicated to the [^{F50}appropriate authority] and made available to the public.

Textual Amendments

- F23** 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 \(S.I. 2020/1388\)](#), **reg. 12(2)**
- F33** Words in Art. 41(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), **12(20)(a)(i)**
- F34** Words in Art. 41(1)(a) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(a)(i)(aa)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F35** Words in Art. 41(1)(a) 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), **12(20)(a)(ii)**
- F36** Words in Art. 41(1)(b) inserted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(a)(i)(bb)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F37** Word in Art. 41(1)(b) omitted (E.W.S.) (31.12.2020) by virtue of [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), **12(20)(a)(iii)**
- F38** Words in Art. 41(1)(c) 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), **12(20)(a)(iv)**
- F39** Art. 41(1)(d) 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), **12(20)(a)(v)**
- F40** Words in Art. 41(1) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(a)(ii)** (with reg. 12) (as amended by S.I. 2020/1463, regs. 1(2)(a), **6(5)(d)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F41** Words in Art. 41(2)(c) 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), **12(20)(b)**
- F42** Words in Art. 41(3) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(b)(i)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F43** Words in Art. 41(3)(c) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(b)(ii)(aa)** (with reg. 12) (as substituted by S.I. 2020/1463, regs. 1(2)(a), **6(5)(d)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F44** Words in Art. 41(3)(c) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(b)(ii)(bb)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F45** Words in Art. 41(3)(c) omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(b)(iii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Art. 41(4) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(c)(i)** (with reg. 12) (as amended by S.I. 2020/1463, regs. 1(2)(a), **6(5)(d)(iii)(aa)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

- F47** Words in Art. 41(4)(c) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(c)(ii)** (with reg. 12), (as substituted by S.I. 2020/1463, regs. 1(2)(a), **6(5)(d)(iii)(bb)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F48** Words in Art. 41(4)(f) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(c)(iii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F49** Words in Art. 41(4)(g) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(22)(c)(iv)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F50** Words in Art. 41(4) 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), **12(20)(c)**

Article 42

Implementing measures

1 ^[F51]The appropriate authority may, by regulations, make such provision as the appropriate authority considers necessary or expedient to implement Article 41 and regulations made under this paragraph] may exclude animal by-products or derived products manufactured in certain establishments or plants from import or transit in order to protect public or animal health ^{F52}....

2 ^[F53]The appropriate authority may, by regulations, make provision with respect to the implementation of Article 41 relating to the following matters]:

- a conditions for the import and transit of Category 1 and Category 2 materials and for products derived therefrom;
- b restrictions regarding public or animal health applicable to imported Category 3 material or products derived therefrom which may be laid down by reference to ^[F54]lists of third countries or parts of third countries identified in the Implementing Regulation or in regulations made under] Article 41(4) or for other public or animal health purposes;
- c conditions for the manufacture of animal by-products or derived products in establishments or plants in third countries; such conditions may include the arrangements for controls of such establishments or plants by the competent authority concerned and may exempt certain types of establishments or plants handling animal by-products or derived products from approval or registration as referred to in point (b) of the second subparagraph of Article 41(3); and

^[F55]d the conditions under which it can be stated that consignments of animal by-products or derived products have been collected or manufactured in accordance with the requirements of this Regulation;]

^{F56} ...

^[F57]3. The appropriate authority may make available or publish, in such manner as appears to the appropriate authority to be appropriate, from time to time, models for health certificates, commercial documents and declarations which are to accompany consignments of animal by-products or derived products.]

Textual Amendments

- F51** Words in Art. 42(1) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(23)(a)(i)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F52** Words in Art. 42(1) omitted (31.12.2020) by virtue of [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(23)(a)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II. (See end of Document for details)

- F53** Words in Art. 42(2) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(23)(b)(i)(aa)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in Art. 42(2)(b) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(23)(b)(i)(bb)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F55** Art. 42(2)(d) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(23)(b)(i)(cc)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F56** Words in Art. 42(2) omitted (31.12.2020) by virtue of The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(23)(b)(ii)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F57** Art. 42(3) inserted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(23)(c)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

Article 43

Export

1 The export of animal by-products and derived products destined for incineration or landfill shall be prohibited.

2 The export of animal by-products and derived products to third countries which are not members of the OECD for use in a biogas or composting plant shall be prohibited.

3 Category 1 material, Category 2 material and products derived therefrom shall only be exported for purposes other than those referred to in paragraphs 1 and 2 provided that [^{F58}the export takes place in accordance with the rules relating to export in Article 25(4) of the Implementing Regulation and in any regulations made by the appropriate authority under the second subparagraph.]

[^{F59}The appropriate authority may, by regulations, impose requirements and otherwise regulate the export of Category 1 and 2 material and products derived from such material for purposes other than those referred to in paragraphs 1 and 2.]

4 Article 12 of Regulation (EC) No 178/2002 concerning food and feed exported from [^{F60}Great Britain] shall apply mutatis mutandis to the export of Category 3 material or products derived therefrom in compliance with this Regulation.

- 5 By way of derogation from paragraphs 3 and 4, the export of:
- specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;
 - animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006.

Textual Amendments

- F58** Words in Art. 43(3) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(24)(a)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Art. 43(3) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **8(24)(b)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Art. 43(4) 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), **12(21)**

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE II.