

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 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 [^{F1}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 collection, processing and treatment of animal by-products and derived products referred to in paragraph 1.

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Textual Amendments

- F1** 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)
- F2** 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.

[^{F3}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 [^{F4}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
- e cases where the composition or packaging allows the materials to be exempted from the mixing requirement.

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Textual Amendments

- F3** 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)**
- F4** 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)

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, CHAPTER II. (See end of Document for details)

F5 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 ^{F6}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 ^{F7}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

F7 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 ^{F8}the following:]

- ^{F9}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.

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, CHAPTER II. (See end of Document for details)

2 However, this Regulation shall apply where the ^{F10}... legislation referred to in [^{F11}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

- F8** 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)**
- F9** 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)**
- F10** 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)**
- F11** 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

- F6** 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 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.

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, CHAPTER II. (See end of Document for details)

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 [F12Great 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.

In the case referred to in point (c) of paragraph 1, the consignments shall be accompanied by a health certificate corresponding to a model [F13made available or published by the appropriate authority, in accordance with point (b) of Article 21(5)].

Textual Amendments

- F12** 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)**

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, CHAPTER II. (See end of Document for details)

F13 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 ^[F6]retained EU law], in particular for the protection of public and animal health.

Textual Amendments

F6 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

^[F14]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);
- (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

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, CHAPTER II. (See end of Document for details)

- (f) conditions for the safe use of derived products which pose a risk to public or animal health.

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Textual Amendments

- F14** 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)
- F15** 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)

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, CHAPTER II.