

*Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

**EXITING THE EUROPEAN UNION  
ANIMALS  
ENVIRONMENTAL PROTECTION  
FOOD  
INTELLECTUAL PROPERTY**

The Environment, Food and Rural Affairs  
(Amendment) (EU Exit) Regulations 2019

*Made* - - - - *\*\*\**

*Coming into force in accordance with regulation 1*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(1).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

In relation to Parts 2 and 3 of this instrument, there has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(2).

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(1) 2018 c. 16.

(2) OJ No L 31, 1.2.2002, p 1, to which there are amendments not relevant to these Regulations.

## PART 1

### Introductory

#### Citation and commencement

1. These Regulations may be cited as the Environment, Food and Rural Affairs (Amendment) (EU Exit) Regulations 2019 and come into force on the later of exit day or the day after the day on which they are made.

## PART 2

### Amendment of subordinate legislation relating to food and drink in England

#### The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007

2. In the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007(3) after regulation 9 insert—

##### “Transitional provision: withdrawal from the EEA and the EU

9A.—(1) The following waters are accredited, that is to say treated for the purposes of these Regulations as if they were natural mineral waters recognised by the Secretary of State under regulation 4(1)(d)(i)—

- (a) established EU recognised natural mineral waters;
- (b) established Icelandic recognised natural mineral waters;
- (c) established Norwegian recognised natural mineral waters.

(2) The accreditation in paragraph (1) continues to have effect in relation to a natural mineral water to which sub-paragraph (a), (b) or (c) of that paragraph applies until the relevant accreditation cessation date.

(3) In the case of an established EU recognised natural mineral water, if the Secretary of State is of the opinion that there is at least one established recognised UK mineral water that is not treated by the responsible authority in at least one member State as a recognised mineral water for the purposes of [Directive 2009/54/EC](#)(4), the Secretary of State may notify the Commission that the accreditation provided for in paragraph (1)(a) in relation to established EU recognised natural mineral waters is to cease.

(4) In the case of an established Icelandic recognised natural mineral water, if the Secretary of State is of the opinion that there is at least one established recognised UK mineral water that is not treated as a recognised mineral water in Iceland for the purposes of [Directive 2009/54/EC](#), the Secretary of State may notify the Icelandic Food and Veterinary Authority that the accreditation provided for in paragraph (1)(b) in relation to established Icelandic recognised natural mineral waters is to cease.

(5) In the case of an established Norwegian recognised natural mineral water, if the Secretary of State is of the opinion that there is at least one established recognised UK mineral water that is not treated in Norway as a recognised mineral water for the purposes of [Directive 2009/54/EC](#), the Secretary of State may notify the Norwegian Food Safety

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(3) [S.I. 2007/2785](#), to which there are amendments not relevant to these Regulations.

(4) OJ No L 164, 26.6.2009, p. 45.

Authority that the accreditation provided for in paragraph (1)(c) in relation to established Norwegian recognised natural mineral waters is to cease.

(6) No notification may be given under paragraph (3), (4) or (5) before the end of the period of six months beginning on the day on which exit day falls.

(7) The accreditation cessation date specified in a notification given under paragraph (3), (4) or (5) must be a date that is at least six months after the date on which the notification is given, beginning with the day after the day on which that notification is given.

(8) The Secretary of State must publish a copy of any notification given under paragraph (3), (4) or (5) in such manner as appears appropriate to the Secretary of State in order to bring its effect to the notice of those that the Secretary of State considers likely to be, or representative of those likely to be, affected in England as soon as is reasonably practicable.

(9) The Secretary of State must from time to time publish, in such manner as appears appropriate to the Secretary of State, a list of the names of the established EU, Icelandic and Norwegian recognised natural mineral waters that are treated as accredited natural mineral waters under paragraph (1) (“the paragraph 9 list”).

(10) Where a notification is given under paragraph (3), (4) or (5), the Secretary of State must update the paragraph 9 list as soon as reasonably practicable after the accreditation cessation date specified in the notification.

(11) The paragraph 9 list is to be treated as conclusive evidence that the waters are accredited natural mineral waters for the purposes of these Regulations.

(12) In this regulation—

“accreditation cessation date” means the cessation date as notified by the Secretary of State under paragraph (3), (4) or (5);

“[Directive 2009/54/EC](#)” means [Directive 2009/54/EC](#) as incorporated into the EEA agreement, and as it had effect, immediately before exit day;

“established EU recognised natural mineral water” means—

(a) a natural mineral water extracted from the ground in any member State—

- (i) that immediately before exit day had the status of a recognised natural mineral water for the purposes of [Directive 2009/54/EC](#), and
- (ii) for which that recognition remains in force;

(b) a natural mineral water extracted from the ground in a third country—

- (i) that immediately before exit day had the status of a recognised natural mineral waters for the purposes of [Directive 2009/54/EC](#), having been recognised by any member State as a natural mineral water for the purpose of [Directive 2009/54/EC](#) based on a certificate (“Article 1(2) certificate”) of the type referred to in the second subparagraph of Article 1(2) of [Directive 2009/54/EC](#) issued by the responsible authority in the country of extraction,
- (ii) for which that recognition remains in force, and
- (iii) for which the Article 1(2) certificate remains valid;

“established Icelandic recognised natural mineral water” means a natural mineral waters extracted from the ground in Iceland—

- (a) that immediately before exit day had the status of a recognised natural mineral waters for the purposes of [Directive 2009/54/EC](#), and
- (b) for which that recognition remains in force;

“established Norwegian recognised natural mineral water” means a natural mineral water extracted from the ground in Norway—

- (a) that immediately before exit day had the status of a recognised natural mineral water for the purpose of Directive 2009/54/EC, and
- (b) for which that recognition remains in force;

“established recognised UK natural mineral water” means a natural mineral water extracted from the ground in the United Kingdom—

- (a) that immediately before exit day had the status of a recognised natural mineral water for the purposes of [Directive 2009/54/EC](#), and
- (b) for which that recognition remains in force;

“member State” means a member State of the EU as constituted immediately after exit day;

“third country” has the same meaning as in [Directive 2009/54/EC](#) as it had effect immediately before exit day.”.

## PART 3

### Amendment of retained direct EU legislation relating to food and drink

#### **Regulation (EC) No 110/2008 of the European Parliament and of the Council**

3.—(1) Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks is amended as follows.

(2) In Article 1—

- (a) in paragraph 3, for the words from “the regulatory” to the end substitute “paragraphs 4 to 6”;
- (b) after paragraph 3 insert—

“4. A derogation may be granted:

- (a) by regulations, or
- (b) on application, by administrative decision, where regulations have not been made or where regulations have been made but do not apply in a particular case.

5. An application of the type referred to in the paragraph 4(b) may be made:

- (a) in relation to an operator intending to export a consignment of a spirit drink to a relevant third country from England, to the Secretary of State;
- (b) in relation to an operator intending to export a consignment of a spirit drink to a relevant third country from Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
- (c) in relation to an operator intending to export a consignment of a spirit drink to a relevant third country from Scotland, the Scottish Ministers;
- (d) in relation to an operator intending to export a consignment of a spirit drink to a relevant third country from Wales, the Welsh Ministers.

6. An application of the type referred to in paragraph 4(b) must be made in relation to one type of spirit drink and on a consignment by consignment basis.

7. In this Regulation ‘consignment’ means a quantity of one type of spirit drink covered by a single document required for customs formalities and may be composed of more than one lot.”.

(3) In Article 2a, after the definition of ‘third country’ insert—

“‘type A regulations’ means any regulations made under:

- (a) Article 1(3);
- (b) Article 5(1)(e);
- (c) Article 12(3);
- (d) Article 27(2);
- (e) Article 28(2), in so far as they do not relate to matters arising in connection with Chapter 3;

‘type B regulations’ means any regulations made under:

- (a) Article 17(8b);
- (b) Article 18(3);
- (c) Article 27(1);
- (d) Article 28(2), in so far as they relate to matters arising in connection with Chapter 3.”.

(4) In Article 5(1)(e), for the words from “shall be decided” to the end substitute “may be specified in regulations”.

(5) In Article 12(3)—

- (a) omit the words from the beginning to “Article 25(3)”;
- (b) at the end insert as a new sentence—

“Regulations may specify derogations in respect of this requirement.”.

(6) For Article 17(8) substitute—

“8. The Secretary of State must decide whether to register the geographical indication, taking into account any objection raised in accordance with paragraph 7.

9. After making a decision under this Article, the Secretary of State must publish in such manner as appears to be appropriate to the Secretary of State:

- (a) a notice informing the applicant and the public of the decision made under this Article in relation to the application, and
- (b) if the application is granted, a copy of the approved technical file relating to the geographical indication.”.

(7) In Article 18—

- (a) number the existing paragraph as paragraph 1;
- (b) in that paragraph 1—
  - (i) for “Commission” substitute “Secretary of State”;
  - (ii) omit the words from “in accordance” to the end;
- (c) after that paragraph insert—

“2. The Secretary of State’s decision under paragraph 1 must be published in such manner as appears to be appropriate to the Secretary of State.

3. Where the Secretary of State decides to cancel a registration, Annex 3 must be amended, by regulations, to remove the entry relating to the geographical indication from that Annex.”.

(8) For Article 25 substitute—

*“Article 25*

*Type A regulations: general*

1. The power to make type A regulations is exercisable by:
  - (a) in relation to England, the Secretary of State;
  - (b) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
  - (c) in relation to Scotland, the Scottish Ministers;
  - (d) in relation to Wales, the Welsh Ministers.
2. But the power to make type A regulations may be exercised by the Secretary of State for the whole or part of the United Kingdom if consent is given by:
  - (a) for regulations applying in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
  - (b) for regulations applying in relation to Scotland, the Scottish Ministers;
  - (c) for regulations applying in relation to Wales, the Welsh Ministers.
3. Type A regulations may:
  - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct minor EU legislation);
  - (b) make different provision for different purposes.

*Article 25a*

*Type B regulations: general*

1. The power to make type B regulations is exercisable by the Secretary of State.
2. Type B regulations may:
  - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct minor EU legislation);
  - (b) make different provision for different purposes.

*Article 25b*

*Type A and B regulations: the Secretary of State*

1. Type A and B regulations made by the Secretary of State are to be made by statutory instrument.
2. A statutory instrument containing type A or B regulations made by the Secretary of State is subject to annulment in pursuance of a resolution of either House of Parliament.

*Article 25c*

*Type A regulations: Northern Ireland*

1. A power of the Department of Agriculture, Environment and Rural Affairs to make type A regulations is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979<sup>(5)</sup>.

2. Type A regulations made by the Department of Agriculture, Environment and Rural Affairs are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954<sup>(6)</sup> as if they were a statutory instrument within the meaning of that Act.

*Article 25d*

*Type A regulations: the Scottish Ministers*

1. For type A regulations made by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(7)</sup>.

2. Type A regulations made by the Scottish Ministers are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

*Article 25e*

*Type A regulations: the Welsh Ministers*

1. Type A regulations made by the Welsh Ministers are to be made by statutory instrument.

2. A statutory instrument containing type A regulations made by the Welsh Ministers is subject to annulment in pursuance of a resolution of the National Assembly for Wales.”.

(9) For Article 27 substitute—

*“Article 27*

*Power to make regulations*

1. Regulations may be made to make such provision as appears necessary to the Secretary of State in relation to the implementation of Chapter 3 of this Regulation.

2. Except in relation to matters covered by Chapter 3, regulations may be made to make such provision as appears necessary to the person making the regulations in relation to the implementation of this Regulation.”.

(10) In Article 28—

(a) in paragraph 1—

(i) for the words before point (a) substitute “Regulations may be made”;

(ii) omit point (a);

(iii) in point (c) omit “Community”;

(b) in paragraph 2—

(i) for the words from the beginning to “adopted” substitute “Regulations may be made”;

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<sup>(5)</sup> S.I. 1979/1573 (N.I. 12).

<sup>(6)</sup> 1954 c.33 (N.I.). Section 41(6) was amended by S.I. 1999/663.

<sup>(7)</sup> 2010 asp 10.

- (ii) omit “Community”.

### **Regulation (EU) No 1169/2011 of the European Parliament and of the Council**

4.—(1) Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers is amended as follows.

(2) In Article 2(2), after point (z) insert—

- “(z1) ‘type C regulations’ means any regulations made under a provision of this Regulation listed in Annex 16;
- (z2) ‘type D regulations’ means any regulations made under a provision of this Regulation listed in Annex 17;
- (z3) ‘type E regulations’ means any regulations made under Article 23(2);”.

(3) In Article 3—

- (a) in paragraph 2, for the words from the beginning to “taking” substitute “Type C, D and E regulations must take”;
- (b) in paragraph 3, for “food information law establishes” substitute “type C, D or E regulations establish”.

(4) In Article 9—

- (a) in paragraph 3—
  - (i) in the first subparagraph, for the words from “the Commission” to “referred to in” substitute “regulations are made under”;
  - (ii) in the second subparagraph—
    - (aa) for “, the Commission, taking into account” substitute “and”;
    - (bb) for the words from “, may establish” to “Article 51,” substitute “is taken into account, regulations may be made to establish”;
- (b) in paragraph 4—
  - (i) for “the Commission may adopt implementing acts” substitute “regulations may be made”;
  - (ii) omit the second sentence.

(5) In Article 10(2)—

- (a) in the first subparagraph, for the words from “the Commission” to the end substitute “regulations may amend Annex 3.”;
- (b) omit the second subparagraph.

(6) In Article 12—

- (a) in paragraph 3—
  - (i) for “, the Commission, taking into account” substitute “and”;
  - (ii) for the words from “, may establish” to “Article 51,” substitute “is taken into account, regulations may establish”;
- (b) in paragraph 4—
  - (i) for “the Commission may adopt implementing acts” substitute “regulations may be made”;
  - (ii) omit the second sentence.

(7) In Article 13(4)—



- (a) in the first subparagraph, for the words from “the Commission” to “Article 51,” substitute “regulations may be made to”;
  - (b) in the second subparagraph, for the words from “the Commission” to “Article 51,” substitute “regulations may be made to”.
- (8) In Article 19(2), for the words from “the Commission” to “Article 51,” substitute “regulations may be made, in exceptional cases, to”.
- (9) In Article 21(2)—
- (a) in the first subparagraph, for the words from “Commission” to the end substitute “appropriate authority must systematically re-examine the list in Annex 2. Where considered necessary by the appropriate authority, that list must be updated by regulations”;
  - (b) omit the second subparagraph.
- (10) In Article 23(2)—
- (a) for “the Commission may” substitute “regulations may be made to”;
  - (b) omit the words from “, by means” to “Article 51,”.
- (11) In Article 24(3)—
- (a) for “the Commission may adopt implementing acts” substitute “regulations may be made”;
  - (b) omit the second sentence.
- (12) In Article 26—
- (a) in paragraph 2(b), for the words from “shall be” to the end substitute “is subject to Commission Implementing Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry and any regulations made under paragraph 8”;
  - (b) in paragraph 3, for the second subparagraph substitute—  
“The application of the first subparagraph is subject to any regulations made under paragraph 8 concerning the application of that subparagraph.”;
  - (c) for paragraph 8 substitute—  
“8. Regulations may be made:
    - (a) concerning the application of paragraphs 2(b) and 3;
    - (b) to revoke Regulation (EU) No 1337/2013.”.
- (13) In Article 27(2)—
- (a) for “The Commission may adopt implementing acts” substitute “Regulations may be made”;
  - (b) omit the second sentence.
- (14) In Article 30(6), for the words from “the Commission” to “Article 51,” substitute “regulations may”.
- (15) In Article 31—
- (a) in paragraph 2—
    - (i) for the words from the beginning to “conversion factors” substitute “Regulations may amend Annex 14 to require specified conversion factors to be used”;
    - (ii) omit the second sentence;

- (b) in paragraph 4, in the second subparagraph—
  - (i) for “The Commission may adopt implementing acts setting” substitute “Regulations may set”;
  - (ii) omit the second sentence.
- (16) In Article 33(5), for the words from “the Commission” to the end substitute “regulations may regulate the way in which per portion and per consumption unit indications are to be expressed for specific categories of food. The actual consumption behaviour of consumers as well as dietary recommendations must be taken into account when making such regulations”.
- (17) In Article 34—
  - (a) in paragraph 5, in the second subparagraph, for “the Commission may adopt implementing acts regarding” substitute “regulations may be made relating to”;
  - (b) in paragraph 6—
    - (i) for “the Commission may adopt implementing acts setting” substitute “regulations may set”;
    - (ii) omit the second sentence.
- (18) In Article 35(6)—
  - (a) for “the Commission shall adopt implementing acts” substitute “regulations may be made”;
  - (b) omit the second sentence.
- (19) In Article 36—
  - (a) in paragraph 3—
    - (i) in the first subparagraph, in the words before point (a), for “The Commission shall adopt implementing acts” substitute “Regulations may be made”;
    - (ii) omit the second subparagraph;
  - (b) in paragraph 4, for the words from “the Commission” to “Article 51,” substitute “regulations may”.
- (20) In Article 46, for the words from “the Commission” to “Article 51,” substitute “regulations may”.
- (21) For Article 51 substitute the Articles in the Schedule.
- (22) After Annex 15 insert—

“ANNEX 16

*TYPE C REGULATIONS: LIST OF SPECIFIED PROVISIONS*

Article 9(3)  
Article 9(4)  
Article 10(2)  
Article 19(2)  
Article 21(2)  
Article 24(3)  
Article 26(8)  
Article 27(2)  
Article 30(6)

Article 31(2)

Article 31(4)

Article 33(5)

Article 34(5)

Article 34(6)

Article 35(6)

Article 36(3)

Article 36(4)

#### ANNEX 17

##### *TYPE D REGULATIONS: LIST OF SPECIFIED PROVISIONS*

Article 12(3)

Article 12(4)

Article 13(4)

Article 46”.

#### **Regulation (EU) No 251/2014 of the European Parliament and of the Council**

5.—(1) Regulation (EU) No 251/2014 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products is amended as follows.

(2) In Article 4—

(a) in paragraph 2—

(i) in the first subparagraph, for the words from “Commission” to “Article 33” substitute “Secretary of State may make regulations”;

(ii) in the second subparagraph, for “Commission” substitute “Secretary of State”;

(b) in paragraph 3—

(i) in the first subparagraph—

(aa) for the words from “Commission” to “acts,” substitute “Secretary of State may, by regulations, specify the”;

(bb) omit the third sentence;

(ii) omit the second subparagraph.

(3) In Article 31(2), in the first subparagraph—

(a) for the words from “Commission” to “rules” substitute “Secretary of State may make regulations”;

(b) omit “by the Member States”;

(c) after “application of” insert “Chapter 2 of”.

(4) In Article 32—

(a) in paragraph 2, in the words before point (a), for the words from “Commission” to “lay” substitute “Secretary of State may make regulations laying”;

(b) in paragraph 3—

(i) in the first subparagraph—

- (aa) for the words before point (a) substitute—
    - “The Secretary of State may, by regulations, make”;
  - (bb) in point (c), for “Member States, the competent authorities” substitute “the competent authorities in the United Kingdom and in”;
  - (ii) omit the second subparagraph.
- (5) In Article 33—
- (a) in paragraph 4, for “Article 28” substitute “Article 4(2), 28 or 32(2)”;
  - (b) after paragraph 4 insert—
    - “5. The Secretary of State may not make regulations under Article 4(2) or (3), the first subparagraph of Article 31(2), the first subparagraph of Article 32(1), or Article 32(2) or (3) (“the relevant powers”) without the consent of:
      - (a) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
      - (b) in relation to Scotland, the Scottish Ministers;
      - (c) in relation to Wales, the Welsh Ministers.
    - 6. Where any of the parties mentioned in (a) to (c) of paragraph 5 requests the Secretary of State to make regulations under any of the relevant powers, the Secretary of State must have regard to that request.”.

### **Commission Delegated Regulation (EU) 2019/33**

6.—(1) Commission Delegated Regulation (EU) 2019/33 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation is amended as follows.

- (2) In Article 13—
  - (a) in paragraph 1—
    - (i) in the first subparagraph—
      - (aa) for “Commission may adopt implementing acts granting” substitute “Secretary of State may, by regulations, grant”;
      - (bb) for “a Member State” substitute “the United Kingdom”;
    - (ii) in the second subparagraph—
      - (aa) in the words before point (a) omit “Article 96(3) or”;
      - (bb) in point (b), after “market” insert “in the United Kingdom”;
  - (b) in paragraph 2—
    - (i) in the words before point (a), for “Commission may adopt implementing acts extending” substitute “Secretary of State may, by regulations, extend”;
    - (ii) in point (a), for “Commission” substitute “Secretary of State”.
- (3) In Article 15(2)—
  - (a) for “Commission” substitute “Secretary of State”;
  - (b) for “it shall publish the application for a Union” substitute “the Secretary of State must publish, in such manner as appears appropriate to the Secretary of State, the application for a non-standard”;

- (c) omit the words from “in the *Official*” to “series”;
  - (d) for the second sentence substitute “The Secretary of State, taking into account any admissible objection that has been lodged, must decide whether to approve or reject the application.”.
- (4) In Article 28—
- (a) in paragraph 3—
    - (i) for “Commission” substitute “Secretary of State”;
    - (ii) for the words from “it shall” to the end substitute “the Secretary of State must publish the application in such manner as appears appropriate to the Secretary of State”;
  - (b) in paragraph 5, for the words from “Commission shall” to the end substitute “Secretary of State must reject the application”.
- (5) In Article 35, in the first paragraph—
- (a) for the words from the beginning to “Commission” substitute “The Secretary of State”;
  - (b) omit “a Member State.”;
  - (c) for “adopt implementing acts cancelling” substitute “cancel”.

## PART 4

### Amendment of retained direct EU legislation relating to genetically modified organisms

#### **Regulation (EC) No 1830/2003 of the European Parliament and of the Council**

7.—(1) Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC is amended as follows.

- (2) In Article 3, after paragraph 13(8) insert—
- “14. ‘Appropriate authority’ means—
- (a) in relation to England, the Secretary of State;
  - (b) in relation to Wales, the Welsh Ministers;
  - (c) in relation to Scotland, the Scottish Ministers;
  - (d) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
- but the appropriate authority is the Secretary of State if consent is given by—
- (a) in relation to Wales, the Welsh Ministers;
  - (b) in relation to Scotland, the Scottish Ministers;
  - (c) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
15. ‘Relevant food standards authority’ means—
- (a) in relation to England, Wales and Northern Ireland, the Food Standards Agency;
  - (b) in relation to Scotland, Food Standards Scotland.”.

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(8) Paragraph 13 in Article 3 was inserted by S.I. 2019/90.

(3) In Article 4(7)(9), for the words from “established” to “retained EU law” substitute “referred to in, or, where relevant, the thresholds established or amended under, Article 4A of this Regulation”.

(4) After Article 4 insert—

*“Article 4A*

*Amending thresholds*

1. In relation to the thresholds provided for in Article 21 of [Directive 2001/18/EC](#) of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council [Directive 90/220/EEC](#)(10) or established by virtue of any other relevant retained EU law, an appropriate authority may, by regulations, make provision establishing or amending, where relevant, thresholds mentioned in or established under Article 21(2) or (3) of that Directive.

2. Before making regulations under paragraph 1, the appropriate authority must consult the relevant food standards authority.”.

(5) For Article 8 substitute—

*“Article 8*

*Unique identifiers*

1. An appropriate authority may, by regulations, make provision for the purposes of adapting the system, as amended from time to time, and as relevant, for assigning unique identifiers to GMOs referred to in Articles 2 and 3 of [Commission Regulation \(EC\) No 65/2004](#)(11).

2. Before making regulations under paragraph 1, the appropriate authority—

- (a) must take account of developments in international fora, and
- (b) must consult the relevant food standards authority.”.

(6) For Article 9(2)(12) substitute—

“2. An appropriate authority may—

- (a) publish technical guidance on sampling and testing for the purposes of facilitating the implementation of this Regulation;
- (b) make provision, by regulations, on sampling and testing for the purposes mentioned in point (a), having first consulted the relevant food standards authority.”.

(7) For Article 10 substitute—

*“Article 10*

*Regulations*

1. Regulations made by the Secretary of State or the Welsh Ministers under this Regulation are to be made by statutory instrument.

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(9) Article 4 was amended by [S.I. 2019/90](#).

(10) OJ No L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p. 30).

(11) Articles 2 and 3 were amended by [S.I. 2019/90](#).

(12) Article 9 was amended by [S.I. 2019/90](#).

2. For regulations made by the Scottish Ministers under this Regulation, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(13)</sup>.

3. Any power of the Department of Agriculture, Environment and Rural Affairs to make regulations under this Regulation is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979<sup>(14)</sup>.

4. A statutory instrument containing regulations made by the Secretary of State under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

5. A statutory instrument containing regulations made by the Welsh Ministers under this Regulation is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

6. Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

7. Regulations made by the Department of Agriculture, Environment and Rural Affairs under this Regulation are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) Act 1954<sup>(15)</sup> as if they were a statutory instrument within the meaning of that Act.

8. Such regulations may—

- (a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);
- (b) make different provision for different purposes.”.

## PART 5

### Amendment of retained direct EU legislation relating to the import of and trade in animals and animal products

#### Commission Regulation (EC) No 599/2004

8.—(1) [Commission Regulation \(EC\) No 599/2004](#) concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin is amended as follows.

(2) In Article 1 —

(a) for the first unnumbered paragraph substitute—

“1. Health certificates required to be used for imports from the European Union, with the exception of health certificates for registered equidae, must be presented on the basis of the standard model certificates published by the appropriate authority from time to time.

2. In paragraph 1 “the appropriate authority” means the Secretary of State (in relation to England), the Welsh Ministers (in relation to Wales), the Scottish Ministers (in relation to Scotland) and the Department of Agriculture, Environment and Rural Affairs (in relation to Northern Ireland); but the appropriate authority is the Secretary of State if consent is given—

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<sup>(13)</sup> 2010 asp 10.

<sup>(14)</sup> S.I. 1979/1573 (N.I. 12).

<sup>(15)</sup> 1954 c. 33 (N.I.). Section 41(6) was amended by S.I. 1999/663.

- (a) in relation to Northern Ireland, by the Department of Agriculture, Environment and Rural Affairs;
- (b) in relation to Scotland, by the Scottish Ministers;
- (c) in relation to Wales, by the Welsh Ministers.”;
- (b) in the second unnumbered paragraph, for “These model certificates” substitute—
  - “3. Health certificates must”.
- (3) Omit Article 2 and the Annex.

### Commission Decision 2009/821/EC

9.—(1) Commission Decision 2009/821/EC drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces is amended as follows.

- (2) In Article 1(1)—
  - (a) in the words before point (a) omit “lays down”;
  - (b) for point (a) substitute—
    - “(a) makes provision for the publication of a list of approved border inspection posts.”;
  - (c) at the beginning of points (b) and (c) insert “lays down”.

### Commission Implementing Decision 2011/630/EU

10.—(1) Commission Implementing Decision 2011/630/EU on imports into the Union of semen of domestic animals of the bovine species, is amended as follows.

- (2) In Annex 1—
  - (a) in the title of the Table, for “Member States are to authorise imports of semen of domestic animals of the bovine species” substitute “imports of semen of domestic animals of the bovine species are to be authorised under Article 2”;
  - (b) in footnote 1, for “is set out in” substitute “shall be based, subject to any changes that may be appropriate, on”;
  - (c) in footnote 2—
    - (i) for “are set out in” substitute “shall be based, subject to any changes that may be appropriate, on”;
    - (ii) for “with”, in the first place that it occurs, substitute “as modified by”;
  - (d) in footnote 3, for the words from “a Member State “ to “Directive 64/432/EEC” substitute “the United Kingdom as being an ‘officially tuberculosis-free bovine herd’ as described in paragraphs 1(a) to (c) of Annex A to Council Directive 64/432/EEC”.

### Commission Implementing Decision 2012/137/EU

11.—(1) Commission Implementing Decision 2012/137/EU on imports into the Union of semen of domestic animals of the porcine species is amended as follows.

- (2) In Annex 1—
  - (a) in the title of the Table, for “Member States are to authorise imports of semen of domestic animals of the porcine species” substitute “imports of semen of domestic animals of the porcine species are to be authorised under Article 2”;



- (b) in the footnote—
- (i) after “certificate” insert “as published by the appropriate authority from time to time”;
  - (ii) for “is set out in” substitute “shall be based, subject to any changes that may be appropriate, on”;
  - (iii) for “with” substitute “as modified by”.

### **Commission Implementing Regulation (EU) 2018/659**

**12.**—(1) Commission Implementing Regulation (EU) 2018/659 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae is amended as follows.

(2) In Article 2, in the second column of point (d), for “one of the territories listed in Annex I to Council [Directive 97/78/EC](#)”, substitute “the United Kingdom”.

(3) In Article 21, in point (b), omit “referred to in Article 7(1) of [Directive 2009/156/EC](#)”.

Date

*Name*  
Parliamentary Under Secretary of State  
Department for Environment, Food and Rural  
Affairs

## SCHEDULE

Regulation 4

### Regulation (EU) No 1169/2011 of the European Parliament and of the Council: new Articles 51 to 51f

#### *“Article 51*

##### *Type C regulations: general*

1. The power to make type C regulations is exercisable by the appropriate authority.
2. But the power to make type C regulations under a provision specified in paragraph 5 may be exercised by the Secretary of State for the whole or part of the United Kingdom if consent is given by:
  - (a) for regulations applying in relation to Northern Ireland, the Department of Health;
  - (b) for regulations applying in relation to Scotland, the Scottish Ministers;
  - (c) for regulations applying in relation to Wales, the Welsh Ministers.
3. The power to make type C regulations under Article 21(2) to update the list in Annex 2 may only be exercised by the Secretary of State for the whole or part of the United Kingdom if:
  - (a) the Secretary of State considers it necessary to update the list,
  - (b) to the extent that the regulations will apply to Northern Ireland, the Department of Health considers it necessary to update the list,
  - (c) to the extent that the regulations will apply to Scotland, the Scottish Ministers consider it necessary to update the list, and
  - (d) to the extent that the regulations will apply to Wales, the Welsh Ministers consider it necessary to update the list.
4. Type C regulations may:
  - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct minor EU legislation);
  - (b) make different provision for different purposes.
5. The specified provisions are:
  - (a) Article 10(2);
  - (b) Article 21(2);
  - (c) Article 24(3);
  - (d) Article 26(8);
  - (e) Article 27(2);
  - (f) Article 34(6);
  - (g) Article 36(3).

#### *Article 51a*

##### *Type D regulations: general*

1. The power to make type D regulations is exercisable:
  - (a) as regards matters concerning the regulation of, and obligation to provide, particulars of the type specified in Article 9(1)(e):

- (i) in relation to Great Britain, by the Secretary of State;
- (ii) in relation to Northern Ireland, by the Department for the Economy;
- (b) as regards other matters, by the appropriate authority.

2. But in relation to the power to make type D regulations under a provision specified in paragraph 4 as regards a matter covered by paragraph 1(b), the Secretary of State may make regulations for the whole or part of the United Kingdom if consent is given by:

- (a) for regulations applying in relation to Northern Ireland, the Department of Health;
- (b) for regulations applying in relation to Scotland, the Scottish Ministers;
- (c) for regulations applying in relation to Wales, the Welsh Ministers.

3. Type D regulations may:

- (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct minor EU legislation);
- (b) make different provision for different purposes.

4. The specified provisions are:

- (a) Article 12(4);
- (b) Article 13(4);
- (c) Article 46.

#### *Article 51b*

##### *Type E regulations: general*

1. The power to make type E regulations is exercisable:
  - (a) in relation to Great Britain, by the Secretary of State;
  - (b) in relation to Northern Ireland, by the Department for the Economy.
2. Type E regulations may:
  - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct minor EU legislation);
  - (b) make different provision for different purposes.

#### *Article 51c*

##### *Type C, D and E regulations: the Secretary of State*

1. Type C, D and E regulations made by the Secretary of State are to be made by statutory instrument.

2. Except as specified in paragraphs 5 and 6, a statutory instrument containing type C regulations made by the Secretary of State is subject to annulment in pursuance of a resolution of either House of Parliament.

3. A statutory instrument containing type D regulations made by the Secretary of State is subject to annulment in pursuance of a resolution of either House of Parliament.

4. A statutory instrument containing type E regulations made by the Secretary of State may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
5. Except as specified in paragraph 6, a statutory instrument containing regulations made by the Secretary of State under Article 10(2), 21(2) or 30(6) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
6. A statutory instrument containing regulations made by the Secretary of State made under Article 21(2) may be made without a draft of the instrument being laid before, and approved by a resolution of, each House of Parliament if it contains a declaration that the Secretary of State is of the opinion that, by reason of urgency, it is necessary to make the regulations without a draft being so laid and approved.
7. After an instrument is made in accordance with paragraph 6, it must be laid before each House of Parliament.
8. Regulations contained in an instrument made in accordance with paragraph 6 cease to have effect at the end of the period of one month beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament.
9. In calculating the period of one month, no account is to be taken of any time during which:
  - (a) Parliament is dissolved or prorogued, or
  - (b) either House of Parliament is adjourned for more than four days.
10. If regulations cease to have effect as a result of paragraph 8, that does not:
  - (a) affect the validity of anything previously done under the regulations;
  - (b) prevent the making of new regulations.

#### *Article 51d*

##### *Type C, D and E Regulations: Northern Ireland*

1. A power of the Department of Health to make type C or D regulations and the Department for the Economy to make type D or E regulations is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979.
2. Except as specified in paragraphs 5 and 6, type C regulations made by the Department of Health are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954 as if they were a statutory instrument within the meaning of that Act.
3. Type D regulations are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954 as if they were a statutory instrument within the meaning of that Act.
4. Type E regulations may not be made unless a draft of the regulations has been laid before, and approved by a resolution of, the Northern Ireland Assembly.
5. Except as specified in paragraph 6, regulations made under Article 10(2), 21(2) or 30(6) may not be made unless a draft of the regulations has been laid before, and approved by a resolution of, the Northern Ireland Assembly.
6. Regulations made under Article 21(2) may be made without a draft of the regulations being laid before, and approved by a resolution of, the Northern Ireland Assembly if they

contain a declaration that the Department of Health is of the opinion that, by reason of urgency, it is necessary to make the regulations without a draft being so laid and approved.

7. After regulations are made in accordance with paragraph 6, they must be laid before the Northern Ireland Assembly.

8. Regulations made in accordance with paragraph 6 cease to have effect at the end of the period of one month beginning with the day on which they are made unless, during that period, the regulations are approved by a resolution of the Northern Ireland Assembly.

9. In calculating the period of one month, no account is to be taken of any time during which the Northern Ireland Assembly is:

- (a) dissolved,
- (b) in recess for more than four days, or
- (c) adjourned for more than six days.

10. If regulations cease to have effect as a result of paragraph 8, that does not:

- (a) affect the validity of anything previously done under the regulations;
- (b) prevent the making of new regulations.

#### *Article 51e*

##### *Type C and D Regulations: the Scottish Ministers*

1. For type C and D regulations made by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

2. Except as specified in paragraphs 4 and 5, type C regulations made by the Scottish Ministers are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

3. Type D regulations made by the Scottish Ministers are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

4. Except as specified in paragraph 5, regulations made by the Scottish Ministers under Article 10(2), 21(2) or 30(6) are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

5. Regulations made under Article 21(2) may be made without being subject to the affirmative procedure if the regulations contain a declaration that the Scottish Ministers are of the opinion that, by reason of urgency, it is necessary to make the regulations without them being subject to that procedure.

6. After regulations are made in accordance with paragraph 5, they must be laid before the Scottish Parliament.

7. Regulations made in accordance with paragraph 5 cease to have effect at the end of the period of one month beginning with the day on which they are made unless, during that period, the regulations are approved by resolution of the Scottish Parliament.

8. In calculating the period of one month, no account is to be taken of any time during which the Scottish Parliament is:

- (a) dissolved, or
- (b) in recess for more than four days.

9. If regulations cease to have effect as a result of paragraph 7, that does not:

- (a) affect the validity of anything previously done under the regulations;

- (b) prevent the making of new regulations.

*Article 51f*

*Type C and D regulations: the Welsh Ministers*

1. Type C and D regulations made by the Welsh Ministers are to be made by statutory instrument.
2. Except as specified in paragraphs 4 and 5, a statutory instrument containing type C regulations made by the Welsh Ministers is subject to annulment in pursuance of a resolution of the National Assembly for Wales.
3. A statutory instrument containing type D regulations made by the Welsh Ministers is subject to annulment in pursuance of a resolution of the National Assembly for Wales.
4. Except as specified in paragraph 5, a statutory instrument containing regulations made under Article 10(2), 21(2) or 30(6) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.
5. A statutory instrument containing regulations made under Article 21(2) may be made without a draft of the instrument being laid before, and approved by a resolution of, the National Assembly for Wales if it contains a declaration that the Welsh Ministers are of the opinion that, by reason of urgency, it is necessary to make the regulations without a draft being so laid and approved.
6. After a statutory instrument is made in accordance with paragraph 5, it must be laid before the National Assembly for Wales.
7. Regulations contained in a statutory instrument made in accordance with paragraph 5 cease to have effect at the end of the period of one month beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of the National Assembly for Wales.
8. In calculating the period of one month, no account is to be taken of any time during which the National Assembly for Wales is:
  - (a) dissolved, or
  - (b) in recess for more than four days.
9. If regulations cease to have effect as a result of paragraph 7, that does not:
  - (a) affect the validity of anything previously done under the regulations;
  - (b) prevent the making of new regulations.”

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**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively

and other deficiencies (in particular under section 8(2)(a), (b), (d), (f) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

Part 2 amends subordinate legislation relating to natural mineral water in England.

Part 3 amends retained direct EU legislation relating to food and drink.

Part 4 amends retained direct EU legislation relating to genetically modified organisms.

Part 5 amends retained direct EU legislation relating to the import of and trade in animals and animal products.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.