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STATUTORY INSTRUMENTS

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**2019 No. 640**

**EXITING THE EUROPEAN UNION  
AGRICULTURE  
FOOD**

**The Specific Food Hygiene (Amendment  
etc.) (EU Exit) Regulations 2019**

*Made - - - - 18th March 2019*

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 8(1) of the European Union (Withdrawal) Act 2018<sup>(1)</sup>.

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.

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 there has been open and transparent public consultation during the preparation of these Regulations.

**PART 1**

**Introduction**

**Citation and commencement**

1. These Regulations may be cited as the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

**Interpretation**

2. In these Regulations—

“Regulation (EC) 853/2004” means Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin;

“Regulation (EC) 854/2004” means Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;

“Regulation (EU) 101/2013” means Commission Regulation (EU) No. 101/2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcasses;

“Regulation (EU) 2015/1474” means Commission Regulation (EU) 2015/1474 concerning the use of recycled hot water to remove microbiological surface contamination from carcasses;

“Regulation (EU) 636/2014” means Commission Implementing Regulation (EU) No. 636/2014 on a model certificate for the trade of unskinned large wild game.

## PART 2

### Amendment of retained direct EU legislation

#### Amendment of Regulation (EC) 853/2004

3. Regulation (EC) 853/2004 is amended as follows.
4. In Article 1—
  - (a) in paragraph 4, for “Member States” substitute “The appropriate authority” and, in both places in which it occurs, omit “national”;
  - (b) in paragraph 5—
    - (i) in point (b)(ii), omit “, in accordance with national law,”;
    - (ii) in point (c)—
      - (aa) for “Member States” substitute “The appropriate authority”;
      - (bb) omit “national” and “situated on their territory”.
5. In Article 2, at the end, insert new paragraphs 5, 6 and 7—
  5. “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 Northern Ireland devolved authority;
  6. “prescribe” means prescribe by regulations;
  7. “Northern Ireland devolved authority” means the Department of Health.”.
6. In Article 3, for paragraph 2, substitute—
 

“2. Food business operators shall not use any substance other than potable water—or, when Regulation (EC) No. 852/2004 or this Regulation permits its use, clean water—to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Food Safety Authority. Those measures, designed to amend non-essential elements of this Regulation by, among other things, supplementing it, shall be prescribed by the appropriate authority. Food business operators must comply with any conditions for use that may be prescribed. The use of an approved substance does not affect the food business operator’s duty to comply with the requirements of this Regulation.”.
7. In Article 4—

- (a) in paragraph 1, omit “manufactured in the Community”;
- (b) in paragraph 5, in point (a), omit “Community”.

**8.** In Article 6—

- (a) in the heading, for “Community” substitute “United Kingdom”;
- (b) in paragraph 1—
  - (i) in point (a), in both places in which it occurs, omit “third”;
  - (ii) in point (b) (ii), omit “or in approved Community establishments”;
  - (iii) in point (c) (iii), omit “Community”.

**9.** Omit Article 8.

**10.** Omit Article 9.

**11.** In Article 10—

- (a) for paragraph 1, substitute—

“**1.** The appropriate authority may prescribe amendments to Annexes 2 and 3 to take account of—

- (a) the development of guides to good practice;
- (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5 of Regulation (EC) No 852/2004;
- (c) the technological developments and their practical consequences and consumer expectations with regard to food composition;
- (d) scientific advice, particularly new risk assessments;
- (e) microbiological and temperature criteria for foodstuffs; and
- (f) changes in patterns of consumption.”;

- (b) for paragraph 2, substitute—

“**2.** Without prejudice to the general application of Article 10(1), the appropriate authority may, provided that they do not affect the achievement of the objectives of this Regulation, prescribe exemptions from Annexes 2 and 3.”;

- (c) for paragraph 3, substitute—

“**3.** Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation adapting the requirements set down in Annex 3 where that legislation does not compromise the achievement of the objectives of this Regulation and—

- (a) the adaptations have the aim of—
  - (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; or
  - (ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints;
- (b) in cases not involving the matters at (a), the adaptations apply only to the construction, layout and equipment of establishments.”;

- (d) omit paragraphs 4, 5, 6 and 7;

- (e) for paragraph 8, substitute—

“**8.** Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation—

- (a) prohibiting or restricting the placing on the market raw milk or raw cream intended for direct human consumption;
- (b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex 3, Section 9 as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.”.

**12.** In Article 11—

- (a) at the beginning, for the first un-numbered paragraph, substitute—  
“Without prejudice to the general application of Article 10(1), the appropriate authority may prescribe implementing measures or amendments to Annex 2 or 3—”;
- (b) in paragraph 5, omit “in cooperation with the relevant Community Reference Laboratory”.

**13.** In Article 12—

- (a) for the heading, substitute “Regulations and devolved powers”;
- (b) for the Article, substitute—
  - “1. Any power to make regulations under this Regulation—
    - (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
    - (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
    - (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 ([SI 1979/1573 \(NI 12\)](#)) (and not by statutory instrument).
  - 2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(2)</sup> (Scottish statutory instruments).
  - 3. Any power to make regulations under this Regulation includes power—
    - (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
    - (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
  - 4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations under this Regulation is subject to annulment in pursuance of a resolution—
    - (a) in the case of England, of either House of Parliament;
    - (b) in the case of Wales, of the National Assembly for Wales;
    - (c) in the case of Scotland, of the Scottish Parliament;
    - (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954<sup>(3)</sup>.
  - 5. In this Regulation, any power—

<sup>(2)</sup> 2010 asp 10.

<sup>(3)</sup> 1954 c.33.

- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
- (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
- (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
- (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

**14.** In Article 13—

- (a) in the heading, omit “European”;
- (b) for the Article, substitute—

“The appropriate authority must consult the Food Safety Authority on matters falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex 3, Section 3, to other animal species.”.

**15.** Omit Article 14.

**16.** After Article 15, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**17.** In Annex 1, in paragraph 1, in point 1.5, omit “under the applicable law in the Member State concerned”.

**18.** In Annex 2—

(1) In Section 1—

- (a) for Part B, substitute—

“**5.** The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.

**6.** The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

**7.** When applied in an establishment located within the United Kingdom, the mark must be oval in shape and include the abbreviation “UK” or the words “United Kingdom”. Products imported into the United Kingdom from establishments located outside the United Kingdom must not be marked in any way which indicates or suggests that they were produced in the United Kingdom.

**8.** When applied in an establishment located within a third country, the mark must indicate the name of the country in which the establishment is located, which may be written out in full or as shown as a two-letter code in accordance with the relevant ISO standard.”;

- (b) in Part C, in paragraph 14, for “Community”, substitute “United Kingdom.”.

(2) In Section 3, in paragraph 3, in point (a), for “[Commission Regulation \(EC\) No 2075/2005](#)”, substitute “[Commission Regulation \(EC\) No. 2015/1375](#)”.

(3) In Section 4, in paragraph 2, for “[Directive 2000/13/EC](#)”, substitute “Regulation (EU) 1169/2011”.

**19.** In Annex 3—

- (1) In Section 1, in Chapter 7, in paragraph 3, in point (b)(viii), in the first footnote reference, omit “of the Member State”.
- (2) In Section 2, in Chapter 6, in paragraph 9, for “in the same Member State as the farm of production”, substitute “within the United Kingdom”.
- (3) In Section 3, in paragraph 3a, in point (a), omit “Member State or” and “which is not under health restrictions in accordance with Union law or national legislation”.
- (4) In Section 4, in Chapter 2—
- (a) at paragraph 4(a), in the fifth paragraph, omit “in the Member State”;
  - (b) omit paragraph 8(b).
- (5) In Section 5, in Chapter 4, in paragraph 1, omit “if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require”.
- (6) In Section 7—
- (a) in Chapter 1, in paragraph 4, for the first sentence, substitute—  
“The registration document must be in English or in English and Welsh and contain at least the information specified below.”;
  - (b) in Chapter 7, in paragraph 2, for “[Directive 2000/13/EC](#)”, substitute “[Regulation \(EU\) 1169/2011](#)”.
- (7) In Section 8—
- (a) in paragraph 1, in the second paragraph, for “Union”, substitute “United Kingdom”;
  - (b) in Chapter 2, for paragraph 4, substitute—  
“**4.** Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with [Regulation \(EC\) No. 854/2004](#) and notify the competent authority of where the fishery products are landed.”;
  - (c) in Chapter 4, in Part B, omit paragraph 4.
- (8) In Section 9—
- (a) in Chapter 1, in point 3—
    - (i) omit paragraph 1(b);
    - (ii) in paragraph 2, omit “and with the existing national criteria referred to in point 1(b) in case of colostrum”;
  - (b) in Chapter 4, in paragraph 1, for the first sentence, substitute—  
“In addition to the requirements of [Regulation \(EU\) No. 1169/2011](#), except in the cases envisaged in Article 16(1) and (2) of that Regulation, labelling must clearly show—”;
  - (c) in Chapter 5, in paragraph 2, for “consigning country”, substitute “United Kingdom”.
- (9) In Section 14, in Chapter 3, in paragraph 1, in sub-paragraph (a), omit “Community”.

#### **Amendment of Regulation (EC) 854/2004**

**20.** Regulation (EC) 854/2004 is amended as follows.

**21.** In Article 2—

- (a) in paragraph 1, in point (c), omit “of a Member State”;
- (b) in paragraph 2, for point (b), substitute—

- “**(b)** the definitions of ‘animal by-products’, ‘TSEs’ (transmissible spongiform encephalopathies) and ‘specified risk material’ laid down in Regulation [\(EC\) No 1069/2009](#)”;
- (c)** at the end, insert new paragraphs 3 and 4—
- “**3.** “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 Northern Ireland devolved authority.
- 4.** “Northern Ireland devolved authority” means the Department of Health.”.
- 22.** In Chapter 2, in the heading, omit “Community”.
- 23.** In Article 3, in paragraph 2, for “Member States”, substitute “the United Kingdom or any part of it”.
- 24.** In Article 4—
- (a) in paragraph 1, for “Member States shall”, substitute “The appropriate authority must”;
- (b) in paragraph 2, in sub-paragraph (c), for “1774/2002”, substitute “1069/2009”;
- (c) in paragraph 5, in both places in which it occurs, for “Community legislation”, substitute “retained EU law”;
- (d) in paragraph 8, in sub-paragraph (a) for “1”, substitute “2”.
- 25.** In Article 5—
- (a) in the opening words, for “Member States shall”, substitute “The appropriate authority must”;
- (b) in paragraph 5, in sub-paragraph (a), for “Member States”, substitute “Competent authorities”;
- (c) in paragraph 6, in both places in which occurs, for “Member States”, substitute “Competent authorities”;
- (d) in paragraph 7, for “Member States”, substitute “Competent authorities”.
- 26.** In Article 6, for “Member States”, substitute “Competent authorities”.
- 27.** In Article 7, for “Member States”, substitute “Competent authorities”.
- 28.** In Article 8, for “Member States”, substitute “The appropriate authority”.
- 29.** In Article 11—
- (a) for paragraph 1, substitute—
- “**1.** Products of animal origin are to be imported only from a third country or a part of a third country that appears on a list drawn up and updated by the competent authority.”;
- (b) for the opening words of paragraph 2, substitute—
- “**2.** A third country is to appear on such a list only if an official control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in Article 48(3) of Regulation [\(EC\) No. 882/2004](#). However, a third country may appear on such a list without an official control having taken place if—”;
- (c) in paragraph 4—
- (i) in sub-paragraph (i), for “Community”, substitute “United Kingdom”;

(ii) for sub-paragraph (k), substitute—

“(k) the results of official controls carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following an official control”;

(d) in paragraph 5, for “Commission”, substitute “appropriate authority”.

**30.** In Article 12—

(a) in paragraph 1—

(i) in each place in which it occurs, for “Community”, substitute “United Kingdom”;

(ii) in sub-paragraph (a), omit “, in accordance with the procedure referred to in Article 19(2),”;

(b) in paragraph 2—

(i) in both places in which occurs, for “Community”, substitute “United Kingdom”;

(ii) in sub-paragraph (b), for “Commission”, substitute “appropriate authority”;

(c) in paragraph 3, for “Commission”, substitute “appropriate authority”;

(d) in paragraph 4—

(i) omit sub-paragraph (a);

(ii) for sub-paragraph (b), substitute—

“(b) Imports are to be authorised from establishments appearing on the list 10 working days after the day on which the appropriate authority makes it available to the public.”;

(iii) for sub-paragraph (c), substitute—

“(c) The appropriate authority must modify the list whenever it considers that modification of the list is necessary in the light of relevant information such as inspection reports.”;

(e) in paragraph 5, for “Commission”, substitute “appropriate authority”.

**31.** In Article 13—

(a) in paragraph 3—

(i) in sub-paragraph (b)—

(aa) for “Community”, substitute “official control”;

(bb) in sub-paragraph (i) for “Article 18(18)”, substitute “Article 46(3)(a) of Regulation (EC) No. 882/2004”;

(b) in paragraph 4, for “Commission”, substitute “appropriate authority”.

**32.** In Article 14—

(a) in paragraph 1, for “Community”, substitute “United Kingdom”;

(b) in paragraph 3, for “Community legislation”, substitute “retained EU law”;

(c) for paragraph 4, substitute—

“4. Exemptions from paragraph 1 may be prescribed when it is possible to obtain the guarantees referred to in paragraph 2 of this Article in another manner.”.

**33.** In Article 15—

(a) in paragraph 1, for “Community”, substitute “United Kingdom”;



- (b) in paragraph 2—
  - (i) in sub-paragraph (a), for “list drawn up and updated in accordance with the procedure set out in Article 12(4)”, substitute “prescribed list”;
  - (ii) in sub-paragraph (b), in point (i), in each indent, for “Community”, substitute “United Kingdom”;
  - (iii) in sub-paragraph (b), in point (ii)—
    - (aa) for “a Member State”, substitute “the United Kingdom”;
    - (bb) in the first indent, substitute—

“all fishery products from the vessel concerned that are destined for placing on the market in the United Kingdom are landed directly in the United Kingdom”;
    - (cc) in the second indent, for “that Member State”, substitute “the United Kingdom” and for “Community” substitute “United Kingdom”;
    - (dd) in the third indent, for “that Member State”, substitute “the United Kingdom” and for “Community requirements” substitute “retained EU law”;
  - (iv) in sub-paragraph (c), for “Commission”, substitute “appropriate authority”;
  - (v) for paragraph 4, substitute—

“4. The appropriate authority may prescribe detailed rules for the implementation of this Article.”.

**34. Omit Article 16.**

**35. In Article 17—**

- (a) for paragraph 1, substitute—

“1. The appropriate authority may prescribe amendments of, or additions to, Annexes 1, 2, 3, 4, 5 and 6 to take account of scientific and technical progress.”;
- (b) for paragraph 2, substitute—

“2. The appropriate authority may prescribe exemptions from Annexes 1, 2, 3, 4, 5 and 6 provided that they do not compromise the achievement of the objectives of this Regulation.”;
- (c) for paragraph 3, substitute—

“3. Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation adapting the requirements set down in Annex 1 where that legislation does not compromise the achievement of the objectives of this Regulation and where the adaptations—

  - (a) concern in particular the food chain information or the presence of the competent authority in establishments; and
  - (b) have the aim of—
    - (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food;
    - (ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographical constraints; or
    - (iii) permitting pilot projects to take place in order to test new approaches to hygiene controls on meat.”;

(d) omit paragraphs 4, 5, 6, 7 and 8.

**36.** In Article 18—

(a) at the beginning, for the first paragraph, substitute—

“Without prejudice to the general application of Article 17(1), implementing measures and amendments to Annexes 1, 2, 3, 4, 5 or 6 may be prescribed by the appropriate authority to specify—”;

(b) in paragraph 13, for “Community”, substitute “National”;

(c) in paragraph 16, for “Commission”, substitute “appropriate authority”.

**37.** In Article 19—

(a) for the heading, substitute “Regulations and devolved powers”;

(b) for the Article, substitute—

“**1.** Any power to make regulations under this Regulation—

(a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

(b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;

(c) so far as exercisable by a Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 ([SI 1979/1573 \(NI 12\)](#)) (and not by statutory instrument).

**2.** For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(4) (Scottish statutory instruments).

**3.** Any power to make regulations under this Regulation includes power—

(a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);

(b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

**4.** Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations under this Regulation is subject to annulment in pursuance of a resolution—

(a) in the case of England, of either House of Parliament;

(b) in the case of Wales, of the National Assembly for Wales;

(c) in the case of Scotland, of the Scottish Parliament;

(d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(5).

**5.** In this Regulation, any power—

(a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;

(b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;

(4) 2010 asp 10.

(5) 1954 c.33.

- (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
- (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

**38.** In Article 20—

- (a) in the heading, omit “European”;
- (b) at the beginning, in the first paragraph, for “Commission shall”, substitute “appropriate authority must” and omit “European”.

**39.** Omit Article 21.

**40.** After Article 22, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**41.** In Annex 1, Section 1—

- (a) in Chapter 1, in both places in which it occurs, for “Community legislation”, substitute “retained EU law”;
- (b) in Chapter 2—
  - (i) in Part B, in paragraph 2, for “Union legislation”, substitute “retained EU law”;
  - (ii) in Part C, for “relevant Community and national rules”, substitute “retained EU law”;
  - (iii) in Part D—
    - (aa) in paragraph 1, for “Union legislation”, substitute “retained EU law”;
    - (bb) in paragraph 2, sub-paragraph (b)(ii), for “Community legislation”, substitute “retained EU law”;
  - (iv) in Part E, for “specific Community rules”, substitute “retained EU law”;
  - (v) in Part F, at sub-paragraph (1)(d) for “Union legislation”, substitute “retained EU law”;
- (c) in Chapter 3—
  - (i) for paragraph 3, substitute—

“**3.** The health mark must be an oval mark at least 6.5 cm wide by 4.5 cm high bearing the following information in perfectly legible characters—

- (a) the mark must indicate the approval number of the establishment;
- (b) when applied in an establishment located in the United Kingdom, the mark must be oval in shape and include the abbreviation “UK” or the words “United Kingdom” which must be shown in capital letters. Meat imported into the United Kingdom from slaughterhouses located outside the United Kingdom must not be marked in any way which indicates or suggests that it was produced in the United Kingdom;
- (c) when applied in an establishment located in a third country, the mark must indicate the name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO standard.”;

- (ii) in paragraph 5, for “Community rules”, substitute “retained EU law”.

**42.** In Annex 1, Section 2—

- (a) in Chapter 1—

- (i) at paragraph 2, omit point (c);
  - (ii) at paragraph 4, in both places in which it occurs, for “Union legislation”, substitute “retained EU law”;
  - (b) in Chapter 2, at paragraph 4, sub-paragraph (c), for “Community legislation”, substitute “retained EU law”;
  - (c) in Chapter 3, at paragraph 6, for “Community legislation”, substitute “retained EU law”;
  - (d) in Chapter 4, at paragraph 4, for “Community legislation”, substitute “retained EU law”;
  - (e) in Chapter 5, at paragraph 1—
    - (i) in each place in which it occurs, for “Community legislation”, substitute “retained EU law”;
    - (ii) in sub-paragraph (e), for “Union legislation”, substitute “retained EU law”.
- 43.** In Annex 1, Section 3—
- (a) in Chapter 2—
    - (i) at paragraph 3, sub-paragraph (e)—
      - (aa) for “Union legislation”, substitute “retained EU law”;
      - (bb) omit “This concerns animals susceptible to the particular disease in question that come from the particular region as defined in Article 2 of Council [Directive 64/432/EEC](#)”;
  - (b) in Chapter 3—
    - (i) in Part A—
      - (aa) in the opening words, for “Member States”, substitute “competent authorities”;
      - (bb) for point (b), substitute—
        - “(b) The competent authority must decide, in principle and on a case-by-case basis, whether to permit the implementation of the system described above. Where the competent authority decides in principle in favour of this system, it shall inform the appropriate authority of that decision and its associated conditions. For food business operators implementing the system, the actual use of the system is optional. Food business operators shall not be forced by the competent authority to introduce the system described here. Where the competent authority is not convinced that the food business operator satisfies the requirements, the system shall not be implemented in that establishment. In order to assess this, the competent authority shall carry out an analysis of the production and inspection records, the type of activities undertaken in the establishment, the history of compliance with rules, the expertise, professional attitude and sense of responsibility of the slaughterhouse staff in regard to food safety, together with other relevant information.”;
  - (c) in Chapter 4, in Part A—
    - (i) at paragraph 2, sub-paragraph (a), for “national and Community legislation”, substitute “retained EU law”;
    - (ii) for paragraph 7, substitute—

“7. Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation regulating official veterinarians working on a part-time basis and who are responsible for inspecting small businesses.”.

**44.** In Annex 1, Section 4—

- (a) in Chapter 4, at paragraph 2, sub-paragraph (b)(iii), for “Community legislation”, substitute “retained EU law”.
- (b) in Chapter 5, for “Community legislation”, substitute “retained EU law”;
- (c) in Chapter 8, in Part A, omit paragraph 2a;
- (d) in Chapter 9—
  - (i) in both places in which it occurs, for “Community legislation”, substitute “retained EU law”;
  - (ii) in Part G, in paragraph 1—
    - (aa) omit sub-paragraph (c);
    - (bb) omit paragraph 3.

**45.** In Annex 2, in Chapter 2—

- (a) in Part B, at paragraph 8, for “[Commission Regulation \(EC\) No. 466/2001](#)”, substitute “[Regulation \(EC\) No. 1881/2006](#)”;
- (b) in Part C, at paragraph 2, for “Community legislation”, substitute “retained EU law”.

**46.** In Annex 3, in Chapter 1—

- (a) for paragraph 2, substitute—
  - “2. However, subject to paragraph 3, official controls of vessels—
    - (a) may be carried out when vessels call at a port in the United Kingdom;
    - (b) concern all vessels landing fishery products at ports in the United Kingdom irrespective of flag; and
    - (c) may, if necessary, when the competent authority of the third country the flag of which the vessel is flying is carrying out the official control, be carried out while the vessel is at sea or when it is in a port in the United Kingdom or in a third country.”;
- (b) for paragraph 3(a), substitute—
  - “(a) In the case of an inspection of a factory or freezer vessel flying the flag of the United Kingdom carried out with a view to approval of the vessel, the competent authority is to carry out inspections in such a manner as to comply with the requirements of Article 3, particularly the time limits of Article 3(2). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in a third country.”;
- (c) for paragraph 3(b), substitute—
  - “(b) When the competent authority has granted the vessel conditional approval in accordance with Article 3, that competent authority may authorise a competent authority of a third country that appears on a list of third countries from which imports of fishery products are permitted drawn up in accordance with Article 11, to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval in accordance with Article 3(4). If necessary, that

competent authority may inspect the vessel while it is at sea or when it is in a port in a third country.”;

(d) for paragraph 4, substitute—

“4. When the competent authority authorises the competent authority of a third country to carry out inspections on its behalf in accordance with paragraph 3, the two competent authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the competent authority of the third country the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.”.

47. In Annex 3—

(a) in Chapter 2, in each place in which it occurs, for “Community legislation”, substitute “retained EU law”;

(b) in Chapter 3, in both places in which it occurs, for “Community legislation”, substitute “retained EU law”.

48. In Annex 4, in Chapter 1, in paragraph 1, in the final paragraph, for “Community provisions”, substitute “retained EU law”.

49. In Annex 6—

(a) in paragraph 1, for “Community”, substitute “United Kingdom”;

(b) for paragraph 2 substitute—

“2. Certificates must be drawn up in English or in English and Welsh and those languages of the third country in which the border inspection takes place, or be accompanied by a certified translation into that language or languages.”;

(c) in paragraph 3, for “Community”, substitute “United Kingdom”.

#### **Amendment of Regulation (EU) 101/2013**

50. Regulation (EU) 101/2013 is amended as follows.

51. After Article 2, omit the words “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

#### **Amendment of Regulation (EU) 2015/1474**

52. Regulation (EU) 2015/1474 is amended as follows.

53. After Article 2, omit the words “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

## **PART 3**

### **Revocation of retained direct EU legislation**

#### **Revocation of Regulation (EU) 636/2014**

54. Regulation (EU) 636/2014 is revoked.

Signed by authority of the Secretary of State for Health and Social Care.

18th March 2019

*Steve Brine*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

## EXPLANATORY NOTE

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

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the UK from the European Union. In particular, the Regulations address the deficiency specified in section 8(2)(b) of that Act, namely the conferral of functions by retained EU law on, or in relation to, EU entities which no longer have functions in that respect under EU law in relation to the United Kingdom.

These Regulations make amendments to legislation in the field of food and, in particular, amend legislation relating to specific hygiene rules for food of animal origin and organisation of official controls on products of animal origin for human consumption. Part 2 amends retained direct EU legislation for the whole of the United Kingdom. Part 3 revokes retained direct EU legislation for the whole of the United Kingdom.

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