

**2019 No. 665**

**EXITING THE EUROPEAN UNION**

**AGRICULTURE**

**FOOD**

**ANIMALS**

**The Official Controls for Feed, Food and Animal Health and  
Welfare (Amendment etc.) (EU Exit) Regulations 2019**

*Made* - - - -

*22nd March 2019*

*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 the European Union (Withdrawal) Act 2018(a).

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 Official Controls for Feed, Food and Animal Health and Welfare (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

## PART 2

### Amendment of subordinate legislation

#### **Amendment of the Meat (Official Controls Charges) (England) Regulations 2009**

2. The Meat (Official Controls Charges) (England) Regulations 2009<sup>(a)</sup> are amended as follows—

- (a) omit regulation 2(2);
- (b) for the heading to Schedule 1, substitute “Definitions of retained EU law”.

#### **Amendment of the Official Feed and Food Controls (England) Regulations 2009**

3. The Official Feed and Food Controls (England) Regulations 2009<sup>(b)</sup> are amended as follows—

- (a) in regulation 2, in paragraph (1), insert ““third country” means a country or state other than the United Kingdom”;
- (b) in regulation 4—
  - (i) in paragraph (1), for “member States” substitute “the Secretary of State”;
  - (ii) in paragraph (4), for “EU legislation”, substitute “retained EU law”;
- (c) in regulation 5, in paragraph (1), for “member States”, substitute “the Secretary of State”;
- (d) omit regulations 14, 15 and 16;
- (e) in regulation 17—
  - (i) omit paragraph (3);
  - (ii) in paragraph (5), omit subparagraphs (a) and (b);
- (f) in regulation 19—
  - (i) in subparagraph (1)(a), omit “14, 15 or”;
  - (ii) in subparagraph (1)(b), omit “14, 15 or”;
- (g) in regulation 20(2), omit “or regulation 16”;
- (h) in regulation 22, omit ““the relevant territories” means the territories referred to in Annex I to Regulation 882/2004”;
- (i) in regulation 28(1), omit (b) and (d);
- (j) omit regulation 44;
- (k) in Schedule 4—
  - (i) in the first entry in Column 2 of the Table, omit the reference to the following provisions of Regulation No. 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules—
    - (aa) Article 19(3);
    - (bb) Article 34;
    - (cc) Article 35(3) and (4);
    - (dd) Article 36;
    - (ee) Article 37(1);
    - (ff) Articles 38 and 39;

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<sup>(a)</sup> S.I. 2009/1574, amended by S.I. 2014/1240.

<sup>(b)</sup> S.I. 2009/3255, amended by S.I. 2010/2280, S.I. 2010/2503, S.I. 2011/136, S.I. 2013/264, S.I. 2013/2996, S.I. 2014/2748, S.I. 2015/454, and S.I. 2018/731.

- (gg) Article 40(2) and (4);
- (hh) Article 52(1);
- (ii) in the second entry in Column 2 of the Table, omit the reference to the following provisions of Regulation No. 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules—
  - (aa) Article 34;
  - (bb) Article 35(3);
  - (cc) Articles 36;
  - (dd) Article 37(1);
  - (ee) Articles 38 and 39;
  - (ff) Article 40(2) and (4);
- (l) in Schedule 5—
  - (i) in the first entry in Column 2 of the Table, omit the reference to the following provisions of Regulation No. 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules—
    - (aa) Article 19(3);
    - (bb) Article 34;
    - (cc) Article 35(3) and (4);
    - (dd) Article 36;
    - (ee) Article 37(1);
    - (ff) Articles 38 and 39;
    - (gg) Article 40(2) and (4);
    - (hh) Article 52(1);
  - (ii) in the second entry in Column 2 of the Table, omit the reference to the following provisions of Regulation No. 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules—
    - (aa) Article 34;
    - (bb) Article 35(3);
    - (cc) Article 36;
    - (dd) Article 37(1);
    - (ee) Article 38 and 39;
    - (ff) Article 40(2) and (4);
- (m) in Schedule 6, for the first entry in Column 2 of the Table, substitute—

“Requirement that feed and food business operators or their representatives give adequate prior notification of the estimated date and time of physical arrival of the consignment at the designated point of entry and of the nature of the consignment in the manner indicated in that Article (common entry document to be completed and transmitted at least one working day in advance) and Article 7 (common entry document to be drawn up in English, or in English and Welsh).”.

## PART 3

### Amendment of retained direct EU legislation

#### **Regulation (EC) No. 882/2004 of the European Parliament and of the Council**

4. Regulation (EC) No. 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules is amended as follows.

5. In Article 1, omit paragraphs 2 and 3.

6. In Article 2—

- (a) in paragraph 1, for “Community” substitute “Food Safety Authority”;
- (b) in paragraph 3, omit “, whether at Community or national level”;
- (c) in paragraph 4, omit “of a Member State”;
- (d) for paragraph 15, substitute—

“15. “importation” has the same meaning as it has for the purposes of the Customs and Excise Management Act 1979(a), and “import” must be construed accordingly”;

(e) for paragraph 16, substitute—

“16. “introduction” means importation as defined in point 15 above, and the placing of goods under a procedure referred to in any enactment governing the United Kingdom’s customs arrangements, including the entry of those goods into a free zone or warehouse;”;

(f) after paragraph 20, insert—

“21. “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 Health or the Department of Agriculture, Environment and Rural Affairs;

22. “prescribe” means prescribe by regulations;

23. “Food Safety Authority” means—

- (a) as regards England, Wales and Northern Ireland, the Food Standards Agency;
- (b) as regards Scotland, Food Standards Scotland;

24. “third country” means a country or state other than the United Kingdom.”.

7. In the heading to Title 2, omit “By Member States”.

8. In Article 3—

- (a) in paragraph 1, for “Member States” substitute “The competent authority”;
- (b) for paragraph 4, substitute—

“4. Official controls shall be applied, with the same care, to exports to, and imports from, any country.”;

- (c) omit paragraph 5;
- (d) for paragraph 6, substitute—

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(a) 1979 c. 2.

“6. The competent authority may check compliance of food and feed with relevant law by means of non-discriminatory checks of imported goods, and may require operators who have imported goods delivered to them to report the arrival of such goods to them.”;

(e) for paragraph 7 substitute—

“7. If, during a check by a competent authority carried out at the place of destination or during storage or transport, non-compliance is established, the competent authority must take appropriate measures which may include re-dispatch to the third country of origin.”.

**9. In Article 4—**

(a) in paragraph 1, for “Member States” substitute “The appropriate authority”;

(b) for paragraph 3, substitute—

“3. Where competence to carry out official controls is conferred on other authorities, efficient and effective coordination must be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.”;

(c) omit paragraph 7.

**10. In Article 5—**

(a) in paragraph 1, omit the second subparagraph;

(b) omit paragraph 4.

**11. In Article 7—**

(a) In paragraph 2, for “The rules of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data”, substitute “Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and the Data Protection Act 2018(a)”;

(b) in paragraph 3, at the fourth indent, for “national and Community legislation”, substitute “United Kingdom legislation and retained EU law”.

**12. In Article 8—**

(a) For paragraph 2, substitute—

“2. The appropriate authority must ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.”;

(b) For paragraph 4, substitute—

“4. The appropriate authority may establish guidelines for official controls. The guidelines may, in particular, contain recommendations concerning official controls on—

(a) the implementation of HACCP principles;

(b) management systems that feed or food business operators operate with a view to meeting the requirements of feed or food law;

(c) the microbiological, physical and chemical safety of feed and food.”.

**13. In Article 10, in paragraph 2, in point (d), for “Community legislation”, substitute “retained EU law”.**

**14. In Article 11—**

(a) for paragraph 1, substitute—

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(a) 2018 c. 12.

“1. Sampling and analysis methods used in the context of official controls must comply with retained EU law and other relevant enactments, or—

- (a) to extent to which retained EU law and other relevant enactments make no provision in respect of the methods, with internationally recognised rules or protocols; or
- (b) in the absence of such rules or protocols, with other methods fit for the intended purpose or developed in accordance with scientific protocols.”;

(b) omit paragraph 4.

**15.** In Article 12, at paragraph 2, omit “European” and “Community”.

**16.** In Article 13—

(a) for paragraph 1, substitute—

“1. The appropriate authority must draw up and maintain operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.”;

(b) in paragraph 3, for “Member States”, substitute “The appropriate authority”;

(c) omit paragraph 4.

**17.** for Article 14(3), substitute—

“3. Satisfactory results of checks on goods that are placed under a procedure referred to in any enactment governing the United Kingdom’s custom arrangements, including the entry of those goods into a free zone or warehouse, does not affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.”.

**18.** In Article 15—

(a) for paragraph 1, substitute—

“1. The competent authority must carry out regular official controls on feed and food of non-animal origin not included in the scope of Directive 97/78/EC, imported into the United Kingdom. It must organise these controls on the basis of the multi-annual national control plan drawn up in accordance with Articles 41 to 43 and in the light of potential risks. The controls shall cover all aspects of feed and food law.”;

(b) in paragraph 2—

(i) omit “into one of the territories”;

(ii) for “Annex I”, substitute “Article 17”;

(c) for paragraph 3, substitute—

“3. These controls may also be carried out on goods that are placed under a procedure referred to in any enactment governing the United Kingdom’s custom arrangements, including the entry of those goods into a free zone or warehouse.”;

(d) for paragraph 5, substitute—

“5. The appropriate authority must prescribe feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into the United Kingdom and lay down the frequency and nature of these controls, together with the fees which may be charged by competent authorities in respect of the performance of the controls.”.

**19.** In Article 16(3)—

(a) in the first place in which it occurs, for “Member States” substitute “competent authority”;

- (b) for the final sentence, substitute “The competent authority must ensure that the equipment and methodology are adequate for measuring the limit values laid down under food law and feed law.”.

20. For Article 17, substitute—

**“Points of entry and prior notification**

1. The appropriate authority must for the organisation of the official controls referred to in Article 15(5)—

- (a) designate particular points of entry in the United Kingdom which have access to the appropriate control facilities for different types of feed and food;
- (b) require feed and food business operators responsible for consignments to give prior notification to the competent authority of their arrival and nature.

2. The appropriate authority may apply the same rules for other feed of non-animal origin.”.

21. In Article 19—

- (a) in subparagraph 1, in point (a), for “Community” substitute “United Kingdom”;
- (b) omit paragraph 3.

22. In Article 20—

- (a) in paragraph 1, for “Community” substitute “retained EU”;
- (b) for paragraph 2, substitute—

“2. The competent authority must ensure that special treatment takes place in establishments under its control and in accordance with such conditions as the appropriate authority may prescribe.”.

23. In Article 21—

- (a) in subparagraph 1, in point (b), for “Community” substitute “United Kingdom”;
- (b) omit paragraph 4.

24. In Article 23—

- (a) for paragraph 1, substitute—

“1. Specific pre-export checks that a third country carries out on feed and food immediately prior to export to the United Kingdom with a view to verifying that the exported products satisfy the United Kingdom’s requirements may be prescribed by the appropriate authority. The checks may apply only to feed and food originating in the third country concerned and may apply to one or more products.”;

- (b) for paragraph 2, substitute—

“2. Competent authorities must carry out official controls on feed and food imported in accordance with the checks prescribed by the appropriate authority.”;

- (c) for paragraph 3, substitute—

“3. The checks which the appropriate authority may prescribe must ensure that—

- (a) feed or food exported to the United Kingdom meets the respective requirements of feed and food law;
- (b) the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in feed and food law.”;

- (d) in paragraph 4, for “approval”, substitute “pre-export checks”;

- (e) in paragraph 5, for “Community” substitute “relevant competent authority in the United Kingdom”;

(f) for paragraph 6 substitute—

“6. The competent authority or control body of the exporting country must ensure the official certification of each consignment checked prior to dispatch. The appropriate authority may prescribe a form for such certificates.”;

(g) for paragraph 7 substitute—

“7. When official controls on imports in accordance with paragraph 2 reveal significant non-compliance, the relevant competent authority must immediately notify the appropriate authority and the operators concerned; the competent authority must increase the number of consignments checked and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.”.

**25.** For Article 24(4), substitute—

“4. In the case of release for free circulation, competent authorities and customs services must work together in accordance with the requirements laid down in any enactment governing the United Kingdom’s customs arrangements.”.

**26.** In Article 25—

(a) for paragraph 1, substitute—

“1. The appropriate authority may prescribe measures necessary to ensure the uniform implementation of official controls on the introduction of feed and food.”;

(b) in paragraph 2—

(i) for point (a), substitute—

“(a) feed and food imported or placed under a customs procedure or that are to be handled in free zones or warehouses;”;

(ii) omit point (e);

(iii) in point (g), for “Community”, substitute “United Kingdom”.

**27.** For Article 26, substitute—

#### **“Currency conversion rate**

In this Regulation, any rates, fees or charges denominated in euro (“EUR”) are to be read as converted into pounds sterling (“GBP”) using an exchange rate of GBP1 = EUR1.1413.”.

**28.** In Article 27—

(a) in paragraph 1, for “Member States” substitute “The appropriate authority”;

(b) in paragraph 2, for “Member State” substitute “the appropriate authority”;

(c) in paragraph 3—

(i) omit the words from “However” to “Directive 85/73/EEC”;

(ii) for the subparagraph, substitute—

“The appropriate authority must prescribe updates to the rates in Annex 4, Section B and Annex 5, Section B at least every two years, in particular to take account of inflation.”;

(d) in paragraph 5, for “Member States” substitute “the appropriate authority”;

(e) in paragraph 6, for “Member States” substitute “the appropriate authority”, and omit from “provided that” to the end of the paragraph;

(f) in paragraph 10, for “Member States” substitute “the appropriate authority”;

(g) for paragraph 12, substitute—

“12. The appropriate authority must make public the method of calculation of fees.”.

**29.** In Article 28, for “under Community or national law” substitute “in retained EU law”.



30. In Article 30, for paragraph 1, substitute—

- “1. The appropriate authority may prescribe—
- (a) the circumstances in which official certification is required;
  - (b) model certificates;
  - (c) qualifications of certifying staff;
  - (d) the principles to be respected to ensure reliable certification, including electronic certification;
  - (e) the procedures to be followed in case of withdrawal of certificates and for replacement certificates;
  - (f) consignments that are split into smaller consignments or that are mixed with other consignments;
  - (g) documents that must follow goods after official controls have been carried out.”.

31. In Article 31, in paragraph 2, for point (f), substitute—

- “(f) The competent authorities must maintain up-to-date lists of approved establishments and make them available to the public.”.

32. Omit Articles 32 and 33.

33. Omit Title 4.

34. For Article 41, substitute—

**“Multi-annual national control plans**

In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No. 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, the appropriate authority and the Food Safety Authority must jointly prepare a single integrated multi-annual national control plan.”.

35. In Article 42—

- (a) for paragraph 1 substitute—

“1. The appropriate authority and the Food Safety Authority must jointly implement the multi-annual national control plan and regularly update it in the light of developments.”;

- (b) in paragraph 2—

- (i) in the opening words, omit “in the Member State concerned”;
- (ii) omit point (k);

- (c) in paragraph 3—

- (i) in point (c), omit “national”;
- (ii) in point (d), omit “Member States”;
- (iii) omit point (e);
- (iv) in point (h) for “a Member State” substitute “the United Kingdom”.

36. In Article 43—

- (a) in paragraph 1, in the opening words, for “guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2). These guidelines shall in particular”, substitute “the need to”;
- (b) omit paragraph 2.

37. In Article 44—

- (a) in paragraph 1, in the opening words, for the opening sentence, substitute “The appropriate authority must within six months of the end of the calendar year publish a report indicating—”;

(b) for paragraph 2, substitute—

“2. In order to promote the consistent presentation of this report and in particular of the results of official controls, the information referred to in paragraph 1 shall take account of guidelines contained in the Annex to Commission decision 2008/654/EC.”;

(c) omit paragraphs 3, 4, 5 and 6.

**38. In Title 6—**

(a) in the heading, omit “Community”;

(b) in Chapter 1, in the heading, omit “Community”.

**39. In Article 45—**

(a) for the heading, substitute “Controls in the United Kingdom”;

(b) for paragraph 1, substitute—

“1. For the purpose of verifying that official controls are taking place in the United Kingdom in accordance with the multi-annual national control plans referred to in Article 41, the appropriate authority may from time to time—

(a) identify an audit body;

(b) in cooperation with relevant competent authorities, instruct the audit body to carry out general and specific audits.”;

(c) in paragraph 2—

(i) in point (c), omit “in Member States”;

(ii) in point (d), omit “in Member States”;

(d) for paragraph 3, substitute—

“3. The appropriate authority must report on the findings of each general or specific audit undertaken of official control activities. Such report shall, if appropriate, contain recommendations on the improvement of compliance with feed and food law and animal health and animal welfare rules. Any report, together with any comments on the report by relevant competent authorities, must be made publicly available.”;

(e) omit paragraph 4;

(f) in paragraph 5—

(i) in the opening words, for “Member States shall” substitute “Competent authorities must”;

(ii) in point (a), omit “resulting from Community controls”;

(iii) in point (b), for “Commission experts”, substitute “auditors”;

(iv) in point (c), for “Commission experts”, substitute “auditors”;

(g) omit paragraph 6.

**40. In Article 46—**

(a) for the heading substitute “Controls in third countries”;

(b) in paragraph 1—

(i) for the opening paragraph, substitute—

“1. The appropriate authority may carry out official controls in third countries, in order to verify, on the basis of the information referred to in Article 47(1), the compliance or equivalence of their legislation with retained EU law relating to feed, food and animal and plant health and animal welfare, and shall have particular regard to—”;

(ii) in point (f), omit “the Commission and”;

(iii) in point (h), for “Community” substitute “United Kingdom feed, food and animal and plant health and animal welfare”;

- (c) in paragraph 2, for “Commission” substitute “appropriate authority”;
- (d) in paragraph 3—
  - (i) in the opening words, omit “Community”;
  - (ii) in point (a), for “Community” substitute “United Kingdom”;
  - (iii) in point (b), for “Community” substitute “retained EU”;
  - (iv) in point (d), for “Commission services or other inspection bodies have” substitute “appropriate authority has”;
  - (v) in point (e), omit “of Member States”;
  - (vi) for the final subparagraph, substitute—

“The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be prescribed by the appropriate authority.”;

- (e) in paragraph 4, for “The procedure and detailed rules for controls in third countries may be determined or amended in accordance with the procedure referred to in Article 62(3)”, substitute “The appropriate authority may prescribe the procedure and detailed rules for controls in third countries”;
- (f) for paragraph 5, substitute—
 

“5. If, during a control, a serious risk to human or animal health is identified, the appropriate authority must, in exercise of relevant powers, immediately adopt any necessary emergency measures or safeguard provisions.”;
- (g) for paragraph 6 substitute—
 

“6. Any audit report shall, if appropriate, contain recommendations and such report must be made publicly available.”;
- (h) omit paragraph 7.

**41. In Article 47—**

- (a) for the opening words of paragraph 1, substitute—
 

“1. Countries intending to export goods to the United Kingdom must provide to the relevant competent authority the following accurate and up-to-date information on the general organisation and management of sanitary control systems—”;
- (b) in paragraph 2, in both places in which it occurs, for “Community” substitute “United Kingdom”;
- (c) in paragraph 3—
  - (i) in point (a), for “Community” substitute “United Kingdom”;
  - (ii) in point (b), for “Community” substitute “United Kingdom”;
- (d) in paragraph 4, omit the words “in accordance with the procedure referred to in Article 62(3)”;
- (e) omit paragraph 5.

**42. In Article 48—**

- (a) for paragraph 1, substitute—
 

“1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by retained EU law and in particular by Regulation (EC) No. 854/2004, they may, if necessary, be prescribed by the appropriate authority.”;
- (b) in paragraph 2, at point (a), for “one of the territories referred to in Annex I”, substitute “the United Kingdom”;
- (c) in paragraph 3, for “Community” substitute “United Kingdom”;

- (d) in paragraph 4—
  - (i) in point (e)(i), omit “in the Community”, and for the second mention of “Community” substitute “United Kingdom”;
  - (ii) in point (e)(iii), for “Commission” substitute “appropriate authority”;
- (e) in paragraph 5 omit “Community”.

**43. In Article 49—**

- (a) in paragraph 1—
  - (i) omit “, in accordance with the procedure referred to in Article 62(3),”;
  - (ii) for “Community” substitute “United Kingdom”;
- (b) in paragraph 2, in point (b), for “Community” substitute “United Kingdom”;
- (c) in paragraph 3, omit “in accordance with the same procedure and”.

**44. In Article 50—**

- (a) in paragraph 1—
  - (i) in the opening words, omit “In accordance with the procedure referred to in Article 62(3)”;
  - (ii) in point (a), for “Community” substitute “United Kingdom”;
  - (iii) in point (b), for “Community” substitute “United Kingdom”;
  - (iv) in point (c), for “Member States” substitute “the United Kingdom”;
  - (v) in point (d), for “Community” substitute “United Kingdom”;
  - (vi) in point (e), for “Community” substitute “United Kingdom”;
- (b) omit paragraph 2.

**45. In Article 51—**

- (a) in paragraph 1—
  - (i) in the opening words—
    - (aa) for “Commission” substitute “appropriate authority”;
    - (bb) omit “of Member States”;
    - (cc) omit “in Member States”;
  - (ii) in point (a), omit “Community”;
  - (iii) in point (c), for “Community” substitute “United Kingdom”;
- (b) omit paragraph 3.

**46. In Title 6, omit Chapter 4.**

**47. In Article 54, in paragraph 4, for “Member State” substitute “country”.**

**48. Omit Articles 55, 56, 62 and 63.**

**49. Insert a new Article 63A—**

*“Article 63A*

**Regulations and devolved powers**

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(a) (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(b) (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 made 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(c).

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;

(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.

6. Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation relating to or affecting food or feed.”

**50.** Omit Articles 64, 65 and 66.

**51.** In Annex 1—

(a) for the heading, substitute “EU member States”;

(b) omit point 28.

**52.** In Annex 2—

(a) in Chapter 1, in point 10, omit “, including communication between Member States and the Commission”;

(b) in Chapter 2, omit point 7.

**53.** In Annex 4—

(a) in the heading omit “Community”;

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(a) SI 1979/1573 (NI 12).

(b) 2010 asp 10.

(c) 1954 c. 33.

- (b) in Section A, for “Member States” substitute “relevant competent authorities”;
- (c) in Section B—
  - (i) in the opening paragraph, for “Member States” substitute “Relevant competent authorities”;
  - (ii) in Chapter 5, in the last sentence, for “Member States” substitute “Relevant competent authorities”.

**54. In Annex 5—**

- (a) in the heading, for “Community” substitute “United Kingdom”;
- (b) in Section A, for “Member States” substitute “relevant competent authorities”;
- (c) in Section B, in Chapter 4—
  - (i) in the heading for “through the Community” substitute “through the United Kingdom”;
  - (ii) in the unnumbered paragraph for “Community” substitute “United Kingdom”;
- (d) in Section B, in Chapter 5, for point 2, substitute—
 

“2. A lower level of fee may be applied to imports from certain countries.”.

**55. Omit Annexes 7 and 8.**

**Commission Decision 2006/677**

**56.** Commission Decision 2006/677 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules is amended as follows.

**57. Omit Article 2.**

**58. In the Annex—**

- (a) in point 1—
  - (i) in the second paragraph—
    - (aa) omit “Member State” in the second line;
    - (bb) for “Member States” substitute “United Kingdom”;
- (b) in point 4, omit “in a Member State”;
- (c) in point 5.1, in the concluding paragraph, for “a Member State” substitute “the United Kingdom”;
- (d) in Point 5.2, in the third paragraph, in each place in which it occurs, for “Member States” substitute “relevant competent authority”;
- (e) in the Table, at the end of point 5.2, in the heading in the fourth column of the first row, omit “(within Member States)”;
- (f) in the Note to the Table in point 5.2, for “Member States” substitute “Relevant competent authorities”;
- (g) in point 6.4—
  - (i) in the first sentence, omit the words from “, particularly” to “decentralised”;
  - (ii) in the third sentence, for “Member State and to the Commission” substitute “United Kingdom”;
- (h) in Point 6.5, in the first sentence, for “Member States should ensure that competent authorities” substitute “Relevant competent authorities must”.

## Commission Decision 2008/654

59. Commission Decision 2008/654 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No. 882/2004 is amended as follows.

60. Omit Article 2.

61. In the Annex—

- (a) in the heading to the Annex omit “Member States”;
- (b) in paragraph 1, for “Member States” substitute “relevant competent authorities”;
- (c) in paragraph 2—
  - (i) in the opening words, omit “Member States”;
  - (ii) in point (b), omit “in the Member State”;
  - (iii) in the unnumbered subparagraph which commences “The process”—
    - (aa) omit “Member States in”;
    - (bb) in both places in which it occurs, omit “their”;
  - (iv) omit the final subparagraph, from “The information provided” to the end;
- (d) omit paragraph 3;
- (e) in paragraph 4—
  - (i) in the opening subparagraph omit “the relevant Community legislation, and in particular, the definitions in”;
  - (ii) in the second subparagraph, in the opening words, for “In addition the” substitute “The”;
  - (iii) omit point (a);
- (f) omit points 6 and 7;
- (g) in point 8—
  - (i) in the second subparagraph—
    - (aa) for “Member States” substitute “relevant competent authorities”;
    - (bb) for “Member State” substitute “competent authority”;
  - (ii) in the fourth subparagraph—
    - (aa) for “Community legislation” substitute “retained EU law”;
    - (bb) for “Member States” substitute “relevant competent authorities”;
  - (iii) in the fifth subparagraph—
    - (aa) for “Community legislation” substitute “retained EU law”;
    - (bb) for “Member States” substitute “relevant competent authorities”;
  - (iv) omit the sixth and seventh subparagraphs;
- (h) in point 9—
  - (i) in paragraph (a), for “Member State” substitute “competent authority”;
  - (ii) in the final subparagraph—
    - (aa) omit “of the Member State”;
    - (bb) for “Member State” substitute “relevant competent authority”;
- (i) in point 9.1, in the first subparagraph, for “Member States” substitute “competent authorities”;
- (j) in point 9.2.2.3, in the opening words, omit “in the Member State”;
- (k) in point 9.4.2, in the opening words, for “Member State” substitute “competent authority”;

- (l) in point 9.6—
  - (i) in the opening words, omit “Particular attention should be paid to the need to ensure that amendments made in response to the factors referred to in Article 42(3), Article 44(5) and Article 45(5)(a) of Regulation (EC) No. 882/2004 are addressed and explained”;
  - (ii) in paragraph (e), omit “Member States”;
  - (iii) in paragraph (j), for “a Member State” substitute “the United Kingdom”.

**Regulation (EU) No 2017/625 of the Parliament and of the Council**

**62.** Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products is amended as follows.

**63.** Omit Articles 92 to 99.

**64.** For Article 100, substitute—

*“Article 100*

**Designation of reference laboratories**

1. The appropriate authority must designate laboratories to act as national reference laboratories.
2. These national reference laboratories must—
  - (a) cooperate internationally in their area of competence;
  - (b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Articles 11 and 12 of Regulation (EC) No 882/2004 of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
  - (c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
  - (d) ensure the dissemination of any information required by the competent authority;
  - (e) provide scientific and technical assistance to the competent authority;
  - (f) where necessary, conduct training courses for the staff of official laboratories;
  - (g) upon request by the appropriate authority, actively assist the appropriate authority in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens;
  - (h) be responsible for carrying out other specific duties as required by the competent authority;
  - (i) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.
3. National reference laboratories must—
  - (a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as national reference laboratories;
  - (b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;



- (c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national and international level are taken into account in their work;
- (e) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations;
- (f) where relevant, be equipped to comply with relevant biosecurity standards.

4. The appropriate authority must communicate the name and address from time to time of national reference laboratories to the public.

5. In this Article, “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 Health or the Department of Agriculture, Environment and Rural Affairs.”.

**65.** For Article 101, substitute—

**“Responsibilities and tasks of national reference laboratories**

The appropriate authority may prescribe additional tasks and responsibilities for national reference laboratories, provided that these tasks and responsibilities are limited to those made necessary by new or emerging risks, new or emerging animal diseases or pests of plants or where new legal requirements so warrant.”.

**66.** Insert a new Article 101A—

*“Article 101A*

**Regulations and devolved powers**

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<sup>(a)</sup> (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>(b)</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 made under this Regulation is subject to annulment in pursuance of a resolution—

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<sup>(a)</sup> S.I. 1979/1573 (NI 12).

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

- (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>(a)</sup>.

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;
- (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.

6. Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation relating to or affecting food or feed.”.

**67.** After Article 167, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

## PART 4

### Revocation of retained direct EU legislation

#### **Commission Regulation (EU) No. 415/2013**

**68.** Commission Regulation (EU) No. 415/2013 laying down additional responsibilities and tasks for the EU reference laboratories for rabies, bovine tuberculosis and bee health, amending Regulation (EC) No. 737/2008 and repealing Regulation (EU) No. 87/2011 is revoked.

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

*Stephen Hammond*  
Minister of State,

22nd March 2019

Department of Health and Social Care

#### **EXPLANATORY NOTE**

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

These Regulations are made in exercise of the powers in section 8 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 United Kingdom 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.

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(a) 1954 c. 33.

Part 2 amends subordinate legislation as it applies in England, and Part 3 amends retained direct EU legislation for the whole of the United Kingdom. Part 4 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.

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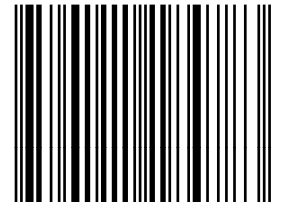
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