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DRAFT STATUTORY INSTRUMENTS

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**2019 No.**

**The Materials and Articles in Contact with  
Food (Amendment) (EU Exit) Regulations 2019**

**PART 3**

**Amendment of retained direct EU legislation**

**Amendment of Regulation 1935/2004**

- 11.** Regulation 1935/2004 is amended as follows.
- 12.** In Article 1—
  - (a) omit “internal”;
  - (b) omit “in the Community”.
- 13.** In Article 2, in paragraph 2, after point (d), insert—
  - “(e) “prescribe”, means prescribe by regulations;
  - (f) “appropriate authority” means—
    - (i) in relation to England, the Secretary of State;
    - (ii) in relation to Wales, the Welsh Ministers;
    - (iii) in relation to Scotland, the Scottish Ministers;
    - (iv) in relation to Northern Ireland, the Northern Ireland devolved authority;
  - (g) “Food Safety Authority” means—
    - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (ii) as regards Scotland, Food Standards Scotland;
  - (h) “Northern Ireland devolved authority” means the Department of Health.”.
- 14.** In Article 4—
  - (a) in paragraph 1, for “the Community provisions applicable to food, such as the provisions of [Directive 89/107/EEC](#) on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food”, substitute “retained EU law and any other enactment applicable to food”;
  - (b) in paragraph 2, for “the relevant Community provisions applicable to food shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of this Regulation and its implementing measures”, substitute “retained EU law and any other enactment applicable to food”.
- 15.** In Article 5—
  - (a) in paragraph 1—
    - (i) in the opening words, for “adopted or amended by the Commission”, substitute “prescribed by the appropriate authority”;

(ii) for subparagraph (m), substitute—

“provisions requiring the appropriate authority to establish and maintain a publicly available Register of authorised substances, processes, or materials or articles;”;

(iii) omit the three unnumbered paragraphs which immediately follow subparagraph 1;

(b) omit paragraph 2.

**16.** Omit Article 6.

**17.** In Article 7—

(a) in both places in which it occurs (including the heading), omit “European”;

(b) omit “, hereinafter referred to as ‘the Authority’”.

**18.** For Article 9, substitute—

*“Application for authorisation of a new substance*

**1.** To obtain the authorisation referred to in Article 8(1), the following procedure applies—

(a) an application is to be submitted to the appropriate authority accompanied by the following—

(i) the name and address of the applicant;

(ii) a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by the Food Safety Authority;

(iii) a summary of the technical dossier;

(b) the appropriate authority must—

(i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt; the acknowledgement must state the date of receipt of the application;

(ii) inform the Food Safety Authority without delay;

(iii) make the application and any supplementary information supplied by the applicant available to the Food Safety Authority.

**2.** The Food Safety Authority must publish detailed guidelines concerning the preparation and the submission of the application.”.

**19.** In Article 10—

(a) in the heading, for “Authority”, substitute “Food Safety Authority”;

(b) in paragraph 1—

(i) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;

(ii) omit “, the Commission and the Member States”;

(c) in paragraph 2, in each place in which it occurs, for “Authority”, substitute “Food Safety Authority”;

(d) in paragraph 3—

(i) in the opening words, for “Authority”, substitute “Food Safety Authority”;

(ii) in point (b), omit “, the Commission and the Member States”;

- (e) in paragraph 5—
    - (i) for “Authority”, substitute “Food Safety Authority”;
    - (ii) for “Commission, the Member States”, substitute “appropriate authority”;
  - (f) in paragraph 6, for “Authority”, substitute “Food Safety Authority”.
- 20. In Article 11—**
- (a) in the heading, omit “Community”;
  - (b) for paragraph 1, substitute—

“1. The authorisation of a substance must be prescribed by the appropriate authority and may contain such restrictions or conditions as the appropriate authority may specify in light of the opinion of the Food Safety Authority.”;
  - (c) for paragraph 2, substitute—

“2. In determining whether to authorise a substance, and what restrictions or conditions, if any, to specify, the appropriate authority must take account of relevant provisions of retained EU law and other legitimate factors relevant to the matter under consideration. Where the determination is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide without delay an explanation of the reasons for the differences. If the appropriate authority does not intend to authorise a substance after a favourable opinion by the Food Safety Authority, it must inform the applicant without delay and provide the applicant with an explanation.”;
  - (d) omit paragraph 3;
  - (e) for paragraph 4, substitute—

“4. After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the authorised substance must comply with any condition or restriction attached to such authorisation.”;
  - (f) for paragraphs 5, substitute—

“5. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance must immediately inform the Food Safety Authority of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Food Safety Authority must then review the assessment.”;
  - (g) omit paragraph 6.
- 21. In Article 12—**
- (a) in paragraph 3—
    - (i) for “a Member State or the Commission” substitute “the appropriate authority”;
    - (ii) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;
  - (b) for paragraph 4, substitute—

“4. The appropriate authority must examine the opinion of the Food Safety Authority without delay and may prescribe amendments to the authorisation, including without limitation changes in the conditions of use and, if any, in the restrictions specified in the authorisation.”;
  - (c) omit paragraphs 5 and 6.
- 22. Omit Article 13.**

**23.** For Article 14, substitute—

*“Administrative review*

**1.** Any act or omission of the Food Safety Authority relating to this Regulation may be reviewed by the appropriate authority on its own initiative or in response to a request from any person directly and individually concerned.

**2.** A person requesting such a review must submit a request in writing to the appropriate authority within two months from the day on which the person became aware of the act or omission in question.

**3.** The appropriate authority must take a decision within two months of receipt of the request requiring, if appropriate, the Food Safety Authority to undo its act or to remedy its failure to act.”.

**24.** In Article 15—

(a) in paragraph 1—

(i) in point (c), omit “established within the Community”;

(ii) in point (e), for “relevant Community provisions or, in their absence, national provisions”, substitute “retained EU law or other enactments”;

(b) omit paragraphs 5 and 6;

(c) in paragraph 9, at point (c), for “, in their absence, with any national provisions”, substitute “any other enactment”.

**25.** For Article 16, substitute—

*“Declaration of compliance*

The specific measures referred to in Article 5 must require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation must be available to demonstrate such compliance. That documentation must be made available to the competent authorities on demand.”.

**26.** In Article 17, at paragraph 3, omit “in the Community”.

**27.** In Article 18—

(a) in paragraph 1—

(i) in the opening words, for “a Member State”, substitute “the appropriate authority”;

(ii) omit the second paragraph;

(b) for paragraph 2, substitute—

“**2.** The appropriate authority must, having where appropriate obtained the advice of the Food Safety Authority, review the grounds referred to in paragraph 1 as soon as possible. If the appropriate authority considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments must be prescribed by the appropriate authority.”;

(c) omit paragraphs 3 and 4.

**28.** Omit Article 19.

**29.** In Article 20—

- (a) in paragraph 3—
    - (i) for “Commission”, substitute “appropriate authority”;
    - (ii) for “Authority”, substitute “Food Safety Authority”;
  - (b) for paragraph 4, substitute—

“4. The Food Safety Authority must supply the appropriate authority with all information in its possession on request by the appropriate authority.”;
  - (c) in paragraph 5, for “Commission, the Authority and the Member States”, substitute “appropriate authority and the Food Safety Authority”;
  - (d) in paragraph 6—
    - (i) for “Authority, the Commission and the Member States”, substitute “appropriate authority and the Food Safety Authority”;
    - (ii) for “Commission and the applicant”, substitute “appropriate authority, the Food Safety Authority and the applicant”.
- 30.** In Article 21, for “Authority” substitute “Food Safety Authority”.
- 31.** For Article 22, substitute—

*“Amendments to Annexes*

Amendments to Annexes 1 and 2 may be prescribed by the appropriate authority.”.

- 32.** Omit Article 23.
- 33.** Insert a new Article 23A—

*“Article 23A*

*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>(1)</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>(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.

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<sup>(1)</sup> [S.I. 1979/1573](#), N.I. 12.  
<sup>(2)</sup> [2010 asp 10](#).

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(3).

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.”.

34. Omit Articles 24 and 25.

35. After Article 28, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

#### **Amendment of Regulation 1895/2005**

36. Regulation 1895/2005 is amended as follows.

37. After Article 8, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

#### **Amendment of Regulation 2013/2006**

38. Regulation 2013/2006 is amended as follows.

39. After Article 8, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

#### **Amendment of Regulation 282/2008**

40. Regulation 282/2008 is amended as follows.

41. In Article 4, for point (b), substitute—

- “(b) the plastic input must originate from plastic materials and articles that have been manufactured in accordance with legislation on plastic food contact materials and articles, in particular, Council [Directive 78/142/EEC](#) of 30 January 1978 on the approximation of laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs and [Directive 2002/72/EC](#) relating to plastic materials and articles intended to come into contact with foodstuffs;”.

42. In Article 5—

- (a) omit paragraph 2;

- (b) in both places in which it occurs (including the heading), for “Authority”, substitute “Food Safety Authority”.

**43.** For Article 6, substitute—

*“Authorisation of recycling processes*

1. The authorisation of a recycling process must be prescribed by the appropriate authority and must contain—

- (a) the name of the recycling process;
- (b) the name and address of the authorisation holder;
- (c) a short description of the recycling process;
- (d) any conditions or restrictions concerning the plastic input;
- (e) any conditions or restrictions concerning the recycling process;
- (f) any characterisation of the recycled plastic;
- (g) any conditions in the field of application of the recycled plastic that has been manufactured by the recycling process;
- (h) any requirements concerning monitoring of the compliance of the recycling process with the conditions of the authorisation;
- (i) the date from which the authorisation is effective.

2. Any converter using recycled plastic from the authorised recycling process or any business operator using materials or articles containing recycled plastic from the authorised recycling process must comply with any condition or restriction attached to such authorisation.

3. The applicant or any business operator using the recycling process must immediately inform the Food Safety Authority of any new scientific or technical information, which might affect the safety assessment of the recycling process in relation to human health. If necessary, the Food Safety Authority must review the assessment.”.

**44.** Insert a new Article 6A—

*“Article 6A*

*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>(4)</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>(5)</sup> (Scottish statutory instruments).

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<sup>(4)</sup> S.I. 1979/1573, N.I. 12.

<sup>(5)</sup> 2010 asp 10.

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); and
  - (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<sup>(6)</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.”.

45. Article 7 is omitted.

46. For Article 8, substitute—

*“Modification, suspension and revocation of authorisation of a recycling process*

1. The applicant or any business operator using the recycling process may apply for modification of the existing authorisation in accordance with the procedure laid down in Article 5(1).

2. The application must be accompanied by the following:

- (a) a reference to the original application;
- (b) a technical dossier containing the new information;
- (c) a new complete summary of the technical dossier in a standardised form.

3. The Food Safety Authority must evaluate whether the opinion or the authorisation is still in accordance with this Regulation. The Food Safety Authority may, where necessary, consult the applicant.

4. The appropriate authority must examine the opinion of the Food Safety Authority without delay and may prescribe amendments to the authorisation, including without limitation changes in the conditions of use and changes the restrictions attached to that authorisation.”.

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(6) 1954 c. 33.



**47.** In Article 9—

- (a) in the heading, omit “Community”;
- (b) for paragraph 1, substitute—

“1. The Food Safety Authority must establish and maintain a register of authorised recycling processes. The register must be made available to the public. Each entry in the register must include details of the restrictions or conditions prescribed in relation to the authorised recycling process.”;

- (c) omit paragraph 2;
- (d) in paragraph 3, for “6(3)”, substitute “6(1)”.

**48.** For Article 10, substitute—

*“Official control*

1. The official control of a recycling plant and converter must be performed in accordance with the rules laid down in Regulation (EC) No 882/2004 and must include in particular audits as control technique as specified in Article 10 of Regulation (EC) No 882/2004.

2. The official control must verify that the recycling process corresponds to the authorised process and that an effective quality assurance system in accordance with Regulation (EC) No 2023/2006 is in place.

3. The authorisation holder must notify the Food Safety Authority about the recycling or manufacturing site in which the authorised recycling process is being applied.”.

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

**50.** In Annex 1, in both places in which it occurs, for “EC Register”, substitute “register”.

**Amendment of Regulation 450/2009**

**51.** Regulation 450/2009 is amended as follows.

**52.** In Article 1, omit “Community or national”.

**53.** In Article 2, omit “within the Community”.

**54.** In Article 3, after point (f), insert—

“(g) “the list” means the list referred to in Article 5.”.

**55.** In Chapter 2, in Section 1, in the heading, omit “Community”.

**56.** In Article 5—

- (a) in paragraph 1—
  - (i) for “the ‘Community list’”, substitute “the list”;
  - (ii) omit “(hereinafter referred to as the ‘Community list’)”;
- (b) in paragraph 2, in point (b), for “Community or national”, substitute “retained EU law or any other enactment”;
- (c) in both places in which it occurs (including the heading), omit “Community”.

**57.** In Article 6, in both places in which it occurs (including the heading), omit “Community”.

**58.** In Article 7, in both places in which it occurs (including the heading), omit “Community”.

**59.** In Article 8—

- (a) in each place in which it occurs (including the heading), omit “Community”;
- (b) in both places in which it occurs, for “Commission”, substitute “appropriate authority”;
- (c) in paragraph 2—
  - (i) for “European Food Safety Authority (the Authority)”, substitute “Food Safety Authority”;
  - (ii) in the second paragraph, for “Authority” substitute “Food Safety Authority”;
- (d) in paragraph 5, in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;
- (e) in paragraph 6, for “Authority”, substitute “Food Safety Authority”.

**60.** In Section 2, in the heading, omit “Community”.**61.** In Article 9—

- (a) in paragraph 1, for “the relevant Community and national provisions”, substitute “retained EU law and any other enactment”;
- (b) in paragraph 2, omit “Community”;
- (c) in paragraph 3—
  - (i) for “a specific Community or national measure on”, substitute, “retained EU law or any other enactment relating to”;
  - (ii) for “Community provisions”, substitute “retained EU law”.

**62.** In Article 13, omit “national”.

**63.** After Article 14, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**64.** In Annex 2—

- (a) in point 5, omit “Community”;
- (b) in point 6—
  - (i) for “the Community or national provisions”, substitute “retained EU law or any other enactment”;
  - (ii) omit “Community”.

**Amendment of Regulation 10/2011****65.** Regulation 10/2011 is amended as follows.**66.** In Article 2—

- (a) in paragraph 3, omit “EU or national”;
- (b) in both places in which it occurs, omit “EU”.

**67.** In Article 5—

- (a) in each place in which it occurs (including the heading), omit “Union”;
- (b) for paragraph 3, substitute—

“3. The appropriate authority may prescribe amendments to the list.”.

**68.** Insert a new Article 5A—

*“Article 5A*

*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(7) (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(8) (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); and
- (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(9).

**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.”.

**69.** In Article 6—

- (a) in each place in which it appears (including the heading), omit “Union”;
- (b) in paragraph 1, for “national law” substitute “any relevant enactment”;
- (c) for paragraph 2, substitute—

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(7) [S.I. 1979/1573](#), N.I. 12.

(8) [2010 asp 10](#).

(9) [1954 c. 33](#).

“By way of derogation from Article 5, colorants and solvents which were capable of lawful use in the manufacture of plastic layers in plastic materials and articles prior to adoption of the list may continue to be so used subject to any relevant enactment.”.

**70.** For Article 7, substitute—

“**1.** The appropriate authority must regularly prescribe updates to the provisional list of additives that that was published by the European Commission in 2008.

**2.** An additive must be removed from the provisional list—

- (a) when it is included in the list set out in Annex 1;
- (b) when a decision is taken by the appropriate authority not to include it in the list; or
- (c) if during the examination of the data, the appropriate authority calls for supplementary information and that information is not submitted within the time limits specified by the appropriate authority.”.

**71.** In Article 13, in both places in which it appears, omit “Union”.

**72.** In Article 14—

- (a) in each place in which it appears, omit “Union”;
- (b) omit paragraph 6.

**73.** In Article 16, in paragraph 1, omit “national”.

**74.** In Article 19, in the heading, omit “Union”.

**75.** After Article 23, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**76.** In Annex 1, in the opening words of point 1, omit “Union”.

**77.** In Annex 4, at paragraph 7, omit “relevant EU provisions or, in their absence, with national”.

#### **Amendment of Regulation 2018/213**

**78.** Regulation 2018/213 is amended as follows.

**79.** In Article 4(3), omit “national”.

**80.** After Article 7, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.