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STATUTORY INSTRUMENTS

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**2019 No. 860**

**EXITING THE EUROPEAN UNION  
FOOD**

**The Food Additives, Flavourings, Enzymes and Extraction  
Solvents (Amendment etc.) (EU Exit) Regulations 2019**

*Made - - - - 10th April 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<sup>(1)</sup>.

In accordance with paragraph (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 Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 and come into force on the later of exit day or the day after the day on which they are made.

## PART 2

### Amendment of subordinate legislation

#### **Amendment of the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013**

2. The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013(2) are amended as follows.

3. In regulation 10(b) for “European Union” substitute “United Kingdom”.
4. In regulation 14(1)(d) for “territory of the EU” substitute “United Kingdom”.
5. Omit regulation 15.
6. In Schedule 1—
  - (a) in Table 1 in the entry for Article 26.1 in the second column for “Commission” substitute “Authority”;
  - (b) in Table 2—
    - (i) in the entry for Article 21.1 (as read with Article 22) in the second column for “a language easily understandable to purchasers” substitute “English, or in English and Welsh”;
    - (ii) entry for Article 26.2 in the second column for “Commission” substitute “Authority”.
7. In Schedule 2 in Table 1—
  - (a) in the entry for Article 10 in the second column for “Union” substitute “domestic”;
  - (b) in the entry for Article 19.2 in the second column for “Commission” substitute “Authority”;
  - (c) in the entry for Article 19.3 in the second column for “Commission” substitute “Authority”.
8. In Schedule 3 in Table 1 in the entry for Article 9.5 in the second column for “Commission” substitute “Authority”.
9. In Schedule 4 in Table 1—
  - (a) in the entry for Article 4 in the second column for “Union” substitute “domestic”;
  - (b) in the entry for Article 14.1 in the second column for “Commission” substitute “Authority”;
  - (c) in the entry for Article 14.2 in the second column for “Commission” substitute “Authority”.

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(2) [S.I. 2013/2210](#), to which there is an amendment not relevant to these Regulations.

## PART 3

### Amendment of retained direct EU legislation

#### **Amendment of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods**

10. Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods is amended as follows.

11. In Article 1—

- (a) in paragraph 1 omit “internal”;
- (b) in paragraph 2—
  - (i) in point (a) omit “Community”;
  - (ii) for point (b) substitute—

“(b) a procedure for the establishment of a list of authorised primary smoke condensates and primary tar fractions and their conditions of use in or on foods.”.

12. In Article 3 at the end insert—

“5. “Authority” means—

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

6. “prescribe”, means prescribe by regulations;

7. “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;

8. “Regulation 1321/2013” means [Commission Implementing Regulation \(EU\) No. 1321/2013](#) establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings;

9. “Northern Ireland devolved authority” means the Department of Health.”.

13. In Article 5(3)—

- (a) for “Community legislation” substitute “retained EU law”;
- (b) omit the second sentence.

14. In the heading to Article 6 omit “Community”.

15. In Article 6—

- (a) in paragraph 1—
  - (i) omit “in the Community”;
  - (ii) omit “in accordance with the procedure referred to in Article 19(2)”;
- (b) for paragraph 3 substitute—

“3. “Following the establishment of the list referred to in paragraph 1, the appropriate authority may prescribe the addition of primary products to that list.”.

- 16.** In Article 7(2)—
- (a) in point (a) for “competent authority of a Member State” substitute “appropriate authority”;
  - (b) for point (b) substitute—
    - “(b) The appropriate authority must 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;”;
  - (c) omit point (c).
- 17.** In Article 8—
- (a) in paragraph 1 in the third sentence omit “, the Commission and the Member States”;
  - (b) in paragraph 3 in point (b) omit “the Commission and the Member States”;
  - (c) in paragraph 5 for “Commission, the Member States” substitute “appropriate authority”.
- 18.** In the heading to Article 9 omit “Community”.
- 19.** In Article 9—
- (a) for paragraphs 1 and 2 substitute—
    - “**1.** Within three months of receiving the opinion of the Authority, the appropriate authority must take the decision whether to include a primary product in the list referred to in Article 6(1), taking account of the opinion of the Authority, the requirements of Article 4(1), any relevant provisions of retained EU law and other legitimate factors relevant to the matter under consideration. The appropriate authority must inform the applicant of its decision without delay. Where the decision is not in accordance with the opinion of the Authority, the appropriate authority must provide an explanation for the differences to the Authority and to the applicant.
    - “**2.** Where the appropriate authority decides to include a primary product in the list referred to in Article 6(1) it must prescribe the addition of that product to the list together with the details referred to in Article 6(2) and amend Regulation 1321/2013.”;
  - (b) in paragraph 3 omit “throughout the Community”;
  - (c) in paragraph 5 for “Commission” substitute “Authority”.
- 20.** Omit Article 10.
- 21.** In Article 11—
- (a) in paragraph 2 omit “On its own initiative or following a request from a Member State or the Commission,”;
  - (b) for paragraph 3 substitute—
    - “**3.** The appropriate authority must examine the opinion of the Authority without delay and take the decision whether to modify the entry for that authorisation.”;
  - (c) for paragraph 4 substitute—
    - “**4.** Where the appropriate authority decides to modify the entry for that authorisation it must prescribe the modification of the entry for that product on the list and amend Regulation 1321/2013.”;
  - (d) omit paragraph 5;
  - (e) in paragraph 6 for “Commission” substitute “Authority”.
- 22.** In Article 12—

- (a) in paragraph 1 for “Commission” substitute “Authority”;
  - (b) in paragraph 2(b) after “Authority” insert “, or provided to the European Food Safety Authority, if provided before exit day,”;
  - (c) in paragraph 4—
    - (i) for “Commission” substitute “Authority”;
    - (ii) omit “and the Member States”.
- 23.** In Article 13 (4) for “Community legislation” substitute “retained EU law”.
- 24.** Omit Article 14.
- 25.** In Article 15—
- (a) in paragraph 2—
    - (i) for “Commission” substitute “Authority”;
    - (ii) omit “and the Authority”;
  - (b) in paragraph 4, for “Commission and the Member States” substitute “appropriate authority”;
  - (c) in paragraph 5 for “Commission, the Authority and the Member States” substitute “appropriate authority and the Authority”;
  - (d) in paragraph 6—
    - (i) for “the Commission and the Member States” substitute “and the appropriate authority”;
    - (ii) for “Commission” substitute “Authority”.
- 26.** In Article 17—
- (a) in paragraph 1 for “Member States” substitute “The Authority”;
  - (b) in paragraph 2 for “Commission” substitute “appropriate authority”;
  - (c) in paragraph 3—
    - (i) in the first subparagraph for “Commission” substitute “appropriate authority”;
    - (ii) in the second subparagraph for “adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3)” substitute “prescribed by the appropriate authority”.
- 27.** In Article 18—
- (a) in paragraph 1—
    - (i) for “Commission” substitute “appropriate authority”;
    - (ii) for “adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3)” substitute “prescribed”;
  - (b) in paragraph 2 for “adopted in accordance with the regulatory procedure referred to in Article 19(2)” substitute “prescribed”.
- 28.** Omit Article 19.
- 29.** Insert a new Article 19A—

*“Article 19A*

*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>(3)</sup> (and not by statutory instrument)<sup>(4)</sup>.

2. 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.

3. 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>(5)</sup>.

4. 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.”.

30. After Article 21 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

31. In Annex 1 in paragraph 1 for “Community legislation” substitute “retained EU law”.

32. In Annex 1 in paragraph 2, in the opening words, for “Community legislation” substitute “retained EU law”.

33. In Annex 2 in point 6 for “Scientific Committee on Food given in its report on smoke flavourings of 25 June 1993 or its latest update” substitute “Authority”.

**Amendment of Commission Regulation (EC) No. 627/2006 implementing Regulation (EC) No. 2065/2003 of the European Parliament and of the Council as regards quality criteria for**

(3) S.I. 1979/1573, N.I. 12.

(4) For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (asp 10).

(5) 1954 c. 33.

### **validated analytical methods for sampling, identification and characterisation of primary smoke products**

**34.** [Commission Regulation \(EC\) No. 627/2006](#) implementing Regulation (EC) No. 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products is amended as follows.

**35.** After Article 2 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

### **Amendment of Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings**

**36.** Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings is amended as follows.

**37.** In Article 1—

- (a) in paragraph 1 omit “within the Community”;
- (b) in paragraph 2 omit “in the Community”;
- (c) in paragraph 3 for “Community” substitute “domestic”.

**38.** In the heading to Article 2 for “Community” substitute “domestic”.

**39.** In Article 2—

- (a) in paragraph 1
  - (i) omit “Community” the first time it occurs;
  - (ii) for “Community” substitute “domestic” the second time it occurs;
  - (iii) for the second sentence substitute “The domestic list is to be updated by the appropriate authority.”;
  - (iv) omit the third sentence;
- (b) in paragraph 2 for “Community” substitute “domestic” each place it occurs;
- (c) after paragraph 2 add—

“**3.** “Authority” means—

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

**4.** “prescribe”, means prescribe by regulations;

**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.** “[Regulation 234/2011](#)” means [Commission Implementing Regulation \(EU\) No. 234/2011](#) implementing Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings;

7. “Northern Ireland devolved authority” means the Department of Health.”.

**40.** In Article 3—

- (a) in paragraph 1—
  - (i) for “Community” substitute “domestic”;
  - (ii) for “Commission” substitute “Authority” the first time it occurs;
  - (iii) omit “by a Member State or”;
  - (iv) for “the implementing measures referred to in Article 9(1)(a) (hereinafter referred to as the applicant)” substitute “Regulation 234/2011”;
  - (v) for “Commission” substitute “appropriate authority” the second time it occurs;
- (b) in paragraph 2—
  - (i) for “Commission” substitute “appropriate authority” both places it occurs;
  - (ii) for “European Food Safety Authority (hereinafter referred to as the Authority)” substitute “Authority”;
- (c) for paragraph 3 substitute—
 

“3. The common procedure is to end with the appropriate authority prescribing the update, in accordance with Article 7.”;
- (d) in paragraph 4 in the first subparagraph—
  - (i) for “Commission” substitute “appropriate authority”;
  - (ii) omit “the views of Member States”;
  - (iii) for “Community” substitute “retained EU”;
- (e) in paragraph 4 in the second subparagraph—
  - (i) for “Commission” substitute “appropriate authority”;
  - (ii) omit “and the Member States”.

**41.** In Article 4—

- (a) in paragraph 1—
  - (i) in the opening words, for “Community” substitute “domestic”;
  - (ii) in the opening words, for “Commission” substitute “appropriate authority”;
  - (iii) omit “The application shall be made available to the Member States by the Commission.”;
- (b) omit paragraph 2.

**42.** In Article 5(2) for “Commission, the Member States” substitute “appropriate authority”.

**43.** In Article 6—

- (a) in paragraph 1 omit “and shall inform the Commission” to the end of the paragraph;
- (b) in paragraph 3 omit “and to the Commission”;
- (c) omit paragraph 4.

**44.** In the heading to Article 7 for “Community” substitute “domestic”.

**45.** In Article 7—

- (a) for paragraph 1 substitute—
 

“1. Within nine months of receiving the opinion of the Authority, the appropriate authority must take the decision whether to update the domestic list taking into account



the opinion of the Authority, any relevant provisions of retained EU law and any other legitimate factors relevant to the matter under consideration.

In those cases where the Authority has not given an opinion, the nine month period starts from the date the appropriate authority receives a valid application.”;

(b) omit paragraph 2;

(c) for paragraph 3 substitute—

“3. Where the decision is not in accordance with the opinion of the Authority, the appropriate authority must explain the reasons for its decision.”;

(d) in paragraph 4 for “shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3)” substitute “may be prescribed by the appropriate authority after seeking advice from the Authority”;

(e) in paragraph 5—

(i) for “Community” substitute “domestic” in both places it occurs;

(ii) for “shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4)” substitute “may be prescribed by the appropriate authority after seeking advice from the Authority”;

(f) omit paragraph 6.

**46.** In Article 8—

(a) in paragraph 1—

(i) in the first sentence for “Commission” substitute “Authority”;

(ii) omit the third sentence;

(b) in paragraph 2 for “Commission” substitute “Authority”.

**47.** In Article 9—

(a) in the opening words of paragraph 1—

(i) omit “In accordance with the regulatory procedure referred to in Article 14(2), within a period of no longer than 24 months from the adoption of each sectoral food law,”;

(ii) for “shall be adopted by the Commission” substitute “may be prescribed by the appropriate authority after seeking advice from the Authority”;

(b) omit paragraph 2.

**48.** In Article 10—

(a) for “Commission” substitute “Authority” in both places it occurs;

(b) omit “or, where applicable, at the Authority’s request”;

(c) omit “and the Member States”.

**49.** In Article 11 for “shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002. In particular, it shall” substitute “must”.

**50.** In Article 12—

(a) in paragraph 3—

(i) for “Commission” substitute “Authority”;

(ii) omit “and the Member States”;

(b) in paragraph 4 for “Commission’s” substitute “Authority’s”;

(c) omit paragraph 5;

- (d) in paragraph 6—
  - (i) for “Commission, the Authority and the Member States” substitute “appropriate authority and the Authority”;
  - (ii) for “Commission” substitute “Authority”;
- (e) in paragraph 7 for “Commission, the Authority and the Member States” substitute “appropriate authority and the Authority”.

**51.** Omit Articles 13 and 14.

**52.** Insert a new Article 14A—

*“Article 14A*

*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(6) (and not by statutory instrument)(7).
- 2.** 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.
- 3.** 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(8).
- 4.** 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;

(6) S.I. 1979/1573, N.I. 12.

(7) For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (asp 10).

(8) 1954 c. 33.

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

53. Omit Article 15.

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

**Amendment of Regulation (EC) No. 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No. 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No. 258/97**

55. Regulation (EC) No. 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No. 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No. 258/97 is amended as follows.

56. In Article 1—

- (a) in the first paragraph omit “internal”;
- (b) in the second paragraph at point (a) for “Community” substitute “domestic”.

57. In Article 2(3) omit “Community”.

58. In Article 3(2) at the end insert—

- “(c) “Authority” means—
  - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
  - (ii) as regards Scotland, Food Standards Scotland;”.

59. In the heading to Chapter 2 for “Community” substitute “Domestic”.

60. In the heading to Article 4 for “Community” substitute “Domestic”.

61. In Article 4 for “Community” substitute “domestic”.

62. In the heading to Article 6 for “Community” substitute “domestic”.

63. In Article 6 for “Community” substitute “domestic”.

64. In the heading to Article 7 for “Community” substitute “domestic”.

65. In Article 7 for “Community” substitute “domestic” in each place it occurs.

66. In Article 8 for “Community” substitute “domestic” in both places it occurs.

67. Omit Article 9.

68. In Article 10

- (a) in paragraph 1 in the last sentence for “a language easily understandable to purchasers” substitute “English, or in English and Welsh”;
- (b) omit paragraph 2.

69. In Article 11(1)(g) for “Community” substitute “retained EU”.

70. In Article 14—

- (a) in paragraph 1 for “Commission” substitute “Authority”;
- (b) in paragraph 2—

- (i) for “European Food Safety Authority (hereinafter referred to as the Authority)” substitute “Authority”;
- (ii) for “Commission” substitute “Authority”;
- (c) in paragraph 3—
  - (i) in the first sentence for “Commission” substitute “Authority”.
  - (ii) omit the second sentence.

**71.** Omit Article 15.

**72.** Insert a new Article 15A—

*“Article 15A*

*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>(9)</sup> (and not by statutory instrument)<sup>(10)</sup>.
- 2.** 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.
- 3.** 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>(11)</sup>.
- 4.** 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;

<sup>(9)</sup> S.I. 1979/1573, N.I. 12.

<sup>(10)</sup> For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (asp 10).

<sup>(11)</sup> 1954 c. 33.

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

73. Omit Article 16.

74. In the heading to Article 17 for “Community” substitute “domestic”.

75. In Article 17—

(a) in paragraph 1 for “Community” substitute “domestic”;

(b) in paragraph 2—

(i) in the first subparagraph for “Community” substitute “domestic”;

(ii) for the second subparagraph substitute—

“The deadline for submitting such applications is to be prescribed by the appropriate authority.”;

(c) in paragraph 3—

(i) in the first subparagraph—

(aa) for “Commission” substitute “Authority”;

(bb) for “Community” substitute “domestic”;

(ii) in the second subparagraph for “Commission” substitute “appropriate authority”;

(d) in paragraph 4—

(i) in the first subparagraph—

(aa) for “Community” substitute “domestic”;

(bb) for “Commission” substitute “appropriate authority”;

(ii) in the second subparagraph at point (b)—

(aa) for “Commission” substitute “appropriate authority”;

(bb) for “Community” substitute “domestic”;

(e) in paragraph 5 for “shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3)” substitute “are to be prescribed by the appropriate authority”.

76. In Article 18 for “Community” substitute “domestic”.

77. In Article 24 in the second paragraph—

(i) for “Community” substitute “domestic”;

(ii) omit “in the Member States”.

78. After Article 24 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

### **Amendment of Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives**

79. Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives is amended as follows.

80. In Article 1—

(a) in the first paragraph omit “internal”;

(b) in the second paragraph for “Community” substitute “domestic”.

- 81.** In Article 2—
- (a) in paragraph 2(b) for “Community rules” substitute “retained EU law”;
  - (b) in paragraph 3 for “Community” substitute “domestic”;
  - (c) in paragraph 4, in the opening words, for “Community rules” substitute “retained EU law”.
- 82.** At the end of Article 3 insert—
- “(i) “Authority” means—
    - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (ii) as regards Scotland, Food Standards Scotland;”.
- 83.** In the heading to Chapter 2 for “Community” substitute “Domestic”.
- 84.** In the heading to Article 4 for “Community” substitute “Domestic”.
- 85.** In Article 4 for “Community” substitute “domestic” both places it occurs.
- 86.** In the heading to Article 6 for “Community” substitute “Domestic”.
- 87.** In Article 6 for “Community” substitute “domestic” in each place it occurs.
- 88.** In Article 7 for “Community” substitute “domestic”.
- 89.** In Article 8 for “Community” substitute “domestic”.
- 90.** In Article 9(2) for “shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3)” substitute “are to be prescribed by the appropriate authority”.
- 91.** In the heading to Article 10 for “Community” substitute “domestic”.
- 92.** In Article 10 for “Community” substitute “domestic” in each place it occurs.
- 93.** In the heading to Article 12 for “Community” substitute “domestic”.
- 94.** In Article 12 for “Community” substitute “domestic” both places it occurs.
- 95.** In Article 13 for “Community” substitute “domestic” both places it occurs.
- 96.** In Article 14 for “Community” substitute “domestic”.
- 97.** Omit Article 19.
- 98.** Omit Article 20.
- 99.** In Article 21—
- (a) in paragraph 1 in the last sentence for “a language easily understandable to purchasers” substitute “English, or in English and Welsh”;
  - (b) omit paragraph 2.
- 100.** In Article 22(1)(g) for “Community” substitute “retained EU”.
- 101.** In Article 23(4) omit the second sentence.
- 102.** In Article 24(3)—
- (a) after “measures” insert “prescribed by the appropriate authority”;
  - (b) omit “in accordance with the regulatory procedure with scrutiny referred to in Article 28(4)”.
- 103.** In Article 26—
- (a) in paragraph 1 for “Commission” substitute “Authority”;
  - (b) in paragraph 2—

- (i) for “Commission” substitute “Authority”;
- (ii) omit the second sentence.

**104.** Omit Articles 27 and 28.

**105.** Insert a new Article 28A—

*“Article 28A*

*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>(12)</sup> (and not by statutory instrument)<sup>(13)</sup>.
- 2.** 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.
- 3.** 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>(14)</sup>.
- 4.** 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.”.

**106.** Omit Article 29.

**107.** Omit Article 30(5).

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

<sup>(13)</sup> For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (asp 10).

<sup>(14)</sup> 1954 c. 33.

- 108.** In Article 31 in the first paragraph—
- (a) for “Community” substitute “domestic”;
  - (b) for “Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC” substitute “existing lists”;
  - (c) for “shall be adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 28(4)” substitute “are to be prescribed by the appropriate authority”.
- 109.** Omit Article 32.
- 110.** In Article 34 in the last paragraph for “Community” substitute “domestic”.
- 111.** After Article 35 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.
- 112.** In the heading to Annex 2 for “Union” substitute “Domestic”.
- 113.** In Annex 2—
- (a) in Part A, paragraph 1 for “Union” substitute “domestic”.
  - (b) in Part E point 04.1.1—
    - (i) in the entry for E172 omit “the Union legislation and/or national”;
    - (ii) in the entry for E464 omit “the Union legislation and/or national”.
- 114.** In the heading to Annex 3 for “Union” substitute “Domestic”.
- 115.** Omit Annex 4.

**Amendment to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC**

**116.** Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC is amended as follows.

- 117.** In Article 1—
- (a) in the first paragraph omit “internal”;
  - (b) in the second paragraph for “Community” substitute “domestic” in both places it occurs.
- 118.** At the end of Article 3(2)(k) add—
- “(l) “Authority” means—
    - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (ii) as regards Scotland, Food Standards Scotland.”.
- 119.** For Article 6(3) substitute—
- “3. Detailed rules for the implementation of paragraph 2 may be prescribed by the appropriate authority.”.
- 120.** In Article 8(2)—
- (a) for “Commission, a Member State” substitute “appropriate authority”;
  - (b) for “Commission shall adopt” substitute “appropriate authority is to prescribe”;



- (c) omit “in accordance with the regulatory procedure with scrutiny referred to in Article 21(3)”;
- (d) omit the final sentence.
- 121.** In the heading to Chapter 3 for “Community” substitute “Domestic”.
- 122.** In the heading to Article 10 for “Community” substitute “Domestic”.
- 123.** In Article 10 for “Community” substitute “domestic”.
- 124.** In the heading to Article 11 for “Community” substitute “Domestic”.
- 125.** In Article 11 for “Community” substitute “domestic” in each place it occurs.
- 126.** In Article 12 for “Community” substitute “domestic” in both places it occurs.
- 127.** Omit Article 13.
- 128.** In Article 14—
  - (a) in paragraph 1 in the last sentence for “a language easily understandable to purchasers” substitute “English, or in English and Welsh”;
  - (b) omit paragraph 2.
- 129.** In Article 15(1)(g) for “Community” substitute “retained EU”.
- 130.** In Article 19—
  - (a) in paragraph 1—
    - (i) for “Commission” substitute “Authority”;
    - (ii) for “Community” substitute “United Kingdom”;
    - (iii) omit the second subparagraph;
  - (b) in paragraph 2 for “Commission” substitute “Authority”;
  - (c) in paragraph 3 for “Commission” substitute “Authority”;
  - (d) omit paragraph 4.
- 131.** Omit Articles 20 and 21.
- 132.** Insert a new Article 21A—

*“Article 21A*

*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>(15)</sup> (and not by statutory instrument)<sup>(16)</sup>.
- 2.** Any power to make regulations under this Regulation includes power—

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<sup>(15)</sup> [S.I. 1979/1573, N.I. 12.](#)

<sup>(16)</sup> For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 ([asp 10](#)).

- (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.

3. 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(17).

4. 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.”.

133. In Article 22—

- (a) In the first paragraph for “adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3)” substitute “prescribed by the appropriate authority”;
- (b) omit the second paragraph.

134. Omit Article 23.

135. Omit Article 25.

136. After Article 30 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

137. In the heading to Annex 1 and in the heading to Part A of Annex 1 for “Union” substitute “domestic”.

138. In Annex 1, Part A, Section 1, in the paragraph that begins with the words “Column 8 (Footnotes):” for “Union” substitute “domestic”.

**Amendment to Regulation (EU) No. 234/2011 implementing Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings**

139. Regulation (EU) No. 234/2011 implementing Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings is amended as follows.

140. In Article 3—

- (a) in paragraph 1—

- (i) in the first sentence for “Commission” substitute “appropriate authority”;
    - (ii) for the second sentence substitute “The applicant must take into account any practical guidance on the submission of applications made available by the Authority.”;
  - (b) omit paragraph 2.
- 141.** In Article 4—
- (a) in point (g) for “the Union legislation” substitute “retained EU law”;
  - (b) in point (i) for “the Union legislation” substitute “retained EU law”.
- 142.** In Article 5—
- (a) in paragraph 3 omit “(The EFSA Journal)”;
  - (b) in paragraph 7 in the second subparagraph for “Union” substitute “United Kingdom”.
- 143.** in Article 6(1)(g) for “Union” substitute “domestic”.
- 144.** In Article 7(2)(f) for “Union” substitute “domestic”.
- 145.** In Article 9(2)(f) omit “as described in the Authority’s guidance document on food enzymes”.
- 146.** In Article 10(1)(e) for “Union” substitute “domestic”.
- 147.** In Article 12—
- (a) in paragraph 1 for “Commission” substitute “Authority”;
  - (b) in paragraph 2 for “Commission shall, where necessary, request the Authority” substitute “Authority is”;
  - (c) in paragraph 3—
    - (i) in the first subparagraph—
      - (aa) omit the first sentence;
      - (bb) in the second sentence for “Authority’s letter is received by the Commission” substitute “application is received by the Authority”;
    - (ii) in the second subparagraph for “Union” substitute “domestic”;
  - (d) in paragraph 4—
    - (i) for “Union” substitute “domestic”;
    - (ii) for “Commission” substitute “Authority” in both places it occurs;
  - (e) in paragraph 5 in the second sentence—
    - (i) for “Commission” substitute “Authority”;
    - (ii) omit “the Member States and the Authority”.
- 148.** In Article 13(1)(c) omit “European”.
- 149.** Omit Article 13(2).
- 150.** After Article 14 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.
- 151.** In the Annex in the Model Letter accompanying an application for Food Additives—
- (a) for “European Commission Directorate General Directorate Unit” substitute “appropriate authority”;
  - (b) for “in the European Union” substitute “in the United Kingdom”;
  - (c) for “EU list” substitute “domestic list”.

- 152.** In the Annex in the Model Letter accompanying an application for Food Enzymes—
- (a) for “European Commission Directorate General Directorate Unit” substitute “appropriate authority”;
  - (b) for “in the European Union” substitute “in the United Kingdom”;
  - (c) for “EU list” substitute “domestic list”.
- 153.** In the Annex in the Model Letter accompanying an application for Flavourings—
- (a) for “European Commission Directorate General Directorate Unit” substitute “appropriate authority”;
  - (b) for “in the European Union” substitute “in the United Kingdom”;
  - (c) for “EU list” substitute “domestic list”.

**Amendment to Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes 2 and 3 to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council**

**154.** Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes 2 and 3 to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council is amended as follows.

**155.** After Article 4 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**Amendment to Commission Implementing Regulation (EU) No. 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No. 2232/96 of the European Parliament and of the Council introducing it in Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No.1565/2000 and Commission Decision 1999/217/EC**

**156.** Commission Implementing Regulation (EU) No. 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No. 2232/96 of the European Parliament and of the Council introducing it in Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No.1565/2000 and Commission Decision 1999/217/EC is amended as follows.

- 157.** In Article 1—
- (a) in point (a) for “Union” substitute “domestic”;
  - (b) in point (b) —
    - (i) in the first sentence omit “at Union level”;
    - (ii) in the second sentence for “Union” substitute “domestic”;
  - (c) in point (c) —
    - (i) in the first sentence omit “at Union level”;
    - (ii) in the second sentence for “Union” substitute “domestic”.
- 158.** In Article 4 for “Union” substitute “domestic”.
- 159.** In Article 5 for “Union” substitute “domestic”.
- 160.** Omit Article 6(2).
- 161.** In Article 7 omit the second sentence.
- 162.** Omit Article 9.

163. After Article 10 omit the words “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**Amendment to Commission Regulation (EU) No. 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council**

164. Commission Regulation (EU) No. 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council is amended as follows.

165. After Article 6 omit the words “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**Amendment to Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings**

166. Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings is amended as follows.

167. In Article 1 omit “in the Union”.

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

169. In the heading to the Annex for “Union” substitute “domestic”.

## PART 4

### Revocation of retained direct EU legislation

**Revocation of Commission Regulation (EU) No. 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives**

170. Commission Regulation (EU) No.257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives is revoked.

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

10th April 2019

*Seema Kennedy*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

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## EXPLANATORY NOTE

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

These Regulations are made in exercise of the powers conferred by 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 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.

These Regulations make amendments to legislation relating to food additives. Part 2 amends subordinate legislation in England. Part 3 amends retained direct EU legislation for the whole of the United Kingdom, and Part 4 revokes certain 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.