

STATUTORY INSTRUMENTS

2020 No. 0000

EXITING THE EUROPEAN UNION

FOOD

The Nutrition (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - *****

Coming into force in accordance with regulation 1

The Secretary of State, makes these Regulations in exercise of the powers conferred by sections 8(1), 8C(1)(c) and 23 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(a) and section 41(1) of the European Union (Withdrawal Agreement) Act 2020(b).

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraph 1 of Schedule 7 to the European Union (Withdrawal) Act 2018.

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c).

PART 1

Preliminary

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 and come into force in accordance with paragraphs (2) and (3).

(2) This Part, Part 2 and Part 4 come into force immediately before IP completion day.

(3) Part 3 comes into force on IP completion day.

(4) This regulation and regulation 2 apply to the United Kingdom.

(5) Regulations 3, 5 and 6 and Part 3 apply to England and Wales and Scotland only.

(a) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1). Section 8C was inserted by section 21 of that Act.

(b) 2020 c. 1.

(c) OJ No. L 31, 1.2.2002, p. 1, last amended by Commission Regulation (EC) No 596/2009 (OJ No. L 188, 18.7.2009, p. 14).

- (6) Regulation 4 applies to England only.
- (7) Part 4 applies to Northern Ireland only.
- (8) In these Regulations “the 2019 Regulations” means the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(a).

PART 2

Amendment of the 2019 Regulations

Amendment of Part 1 of the 2019 Regulations

- 2.**—(1) Part 1 of the 2019 Regulations (preliminary) is amended as follows.
- (2) In regulation 1(2) (application), for “the United Kingdom” substitute “England and Wales and Scotland”.

Amendment of Part 2 of the 2019 Regulations

- 3.**—(1) Part 2 of the 2019 Regulations (provision about food supplements) is amended as follows.
- (2) In regulation 5 (regulations: general)—
 - (a) in paragraph (2)—
 - (i) for “United Kingdom” substitute “Great Britain”;
 - (ii) omit sub-paragraph (c);
 - (b) in paragraph (4), omit sub-paragraph (d).
 - (3) Omit regulation 9 (regulations: Northern Ireland).

Amendment of Part 3 of the 2019 Regulations

- 4.**—(1) Part 3 of the 2019 Regulations (amendment of subordinate legislation) is amended as follows.
- (2) In regulation 15 (amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009(b)), in paragraph (2)(b), for “, Food Standards Scotland or the Food Standards Agency in Northern Ireland” substitute “or Food Standards Scotland”.
 - (3) In regulation 16 (amendment of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016(c))—
 - (a) omit paragraph (2);
 - (b) in paragraph (4), in the substituted words, for “UK” substitute “GB”.

Amendment of Part 4 of the 2019 Regulations

- 5.**—(1) Part 4 of the 2019 Regulations (amendment of EU Regulations) is amended as follows.
- (2) In regulation 17 (amendment of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods)—
 - (a) in paragraph (2)(c)(iv), in the substituted words, for “regulations” substitute “guidelines”;
 - (b) in paragraph (3)(b)(iv)—

(a) S.I. 2019/651.
(b) S.I. 2009/3051, amended by S.I. 2019/651.
(c) S.I. 2016/688, amended by S.I. 2017/62, 2019/44, 651 and 2020/43.

- (i) in inserted point (8), omit paragraph (d);
- (ii) for inserted point (9), substitute—
 - “(9) The appropriate authority is the Secretary of State if consent is given by:
 - (a) for regulations, guidelines, applications or the register of claims in relation to Scotland, the Scottish Ministers;
 - (b) for regulations, guidelines, applications or the register of claims in relation to Wales, the Welsh Ministers;”;
 - (iii) in inserted point (10), for “, the Welsh Ministers” to the end of that point, substitute “and the Welsh Ministers”;
- (c) in paragraph (4)(b)(ii), in the substituted words, for “the United Kingdom” substitute “Great Britain”;
- (d) in paragraph (15)(d), in the inserted words—
 - (i) for “exit day” in both places, substitute “IP completion day”;
 - (ii) for “the United Kingdom” substitute “Great Britain”;
- (e) in paragraph (16)—
 - (i) in sub-paragraph (a), in the inserted words—
 - (aa) for “the United Kingdom” in both places substitute “Great Britain”;
 - (bb) for “, Wales or Northern Ireland” (in inserted paragraph 1A(b)) substitute “or Wales”;
 - (cc) omit sub-paragraph (d) (in inserted paragraph 1B);
 - (dd) re-letter sub-paragraph (e) (in inserted paragraph 1B) as sub-paragraph (d);
 - (ii) in sub-paragraph (c), in the inserted words—
 - (aa) for “the United Kingdom” substitute “Great Britain”;
 - (bb) for “, Wales or Northern Ireland” substitute “or Wales”;
- (f) in paragraph (18)(c)—
 - (i) in paragraph (i), in the substituted words—
 - (aa) for “UK-wide” substitute “Great Britain-wide”;
 - (bb) at the end of substituted paragraph (b), insert “and”;
 - (cc) omit substituted paragraph (d) and the “and” immediately preceding it;
 - (dd) for “, Wales and Northern Ireland” substitute “and Wales”;
 - (ii) in paragraph (ii), in the inserted words, for “, Wales or Northern Ireland” substitute “or Wales”;
- (g) in paragraph (19)—
 - (i) in sub-paragraph (b), in the inserted words—
 - (aa) for “the United Kingdom” in both places substitute “Great Britain”;
 - (bb) for “, Wales or Northern Ireland” (in inserted paragraph 1A(b)) substitute “or Wales”;
 - (cc) omit substituted paragraph (d) (in inserted paragraph 1B);
 - (dd) re-letter sub-paragraph (e) (in inserted paragraph 1B) as sub-paragraph (d);
 - (ii) in sub-paragraph (e), in the substituted words—
 - (aa) for “the United Kingdom” substitute “Great Britain”;
 - (bb) at the end of substituted paragraph (b), insert “and”;
 - (cc) omit substituted paragraph (d) and the “and” immediately preceding it;
 - (dd) for “, Wales and Northern Ireland” substitute “and Wales”;

- (iii) in sub-paragraph (f), in the inserted words, for “, Wales or Northern Ireland” substitute “or Wales”;
- (h) in paragraph (23)—
 - (i) in the inserted Article 21B (regulations: Secretary of State), in paragraph 4—
 - (aa) for “, Wales or Northern Ireland” substitute “or Wales”;
 - (bb) omit sub-paragraph (c);
 - (ii) omit the inserted Article 21E.
- (3) In regulation 18 (amendment of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to food)—
 - (a) in paragraph (3)(b), in the inserted words—
 - (i) omit inserted point (3)(d);
 - (ii) omit inserted point (4)(c);
 - (iii) in inserted point (5), for “, the Welsh Ministers and in relation to Northern Ireland, the Department of Health” substitute “or the Welsh Ministers”;
 - (b) in paragraph (10)(c), in the substituted words, for “the United Kingdom” substitute “Great Britain”;
 - (c) in paragraph (11)—
 - (i) in the inserted Article 9B (regulations: Secretary of State), in paragraph 3—
 - (aa) for “, Wales or Northern Ireland” substitute “or Wales”;
 - (bb) at the end of sub-paragraph (a) insert “and”;
 - (cc) omit sub-paragraph (c) and the “and” immediately preceding it;
 - (ii) omit the inserted Article 9E.
 - (4) In regulation 19 (amendment of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009)—
 - (a) for “UK” in each place where those letters appear, substitute “GB”;
 - (b) for “the United Kingdom” in each place where those words appear, substitute “Great Britain”;
 - (c) in paragraph (11)(a), in the substituted words, for “, the Welsh Ministers and in relation to Northern Ireland, the Department of Health” substitute “and the Welsh Ministers”;
 - (d) in paragraph (15)—
 - (i) in the inserted Article 16A—
 - (aa) in paragraph 1, omit sub-paragraph (c);
 - (bb) in paragraph 3, omit sub-paragraph (d);
 - (ii) omit the inserted Article 16E.

Amendment of Part 5 of the 2019 Regulations

6.—(1) Part 5 of the 2019 Regulations (amendment of EU tertiary legislation) is amended as follows.

(2) In regulation 21 (amendment of Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses)—

- (a) in paragraph (2), in the inserted words, for “the United Kingdom” substitute “Great Britain”;
 - (b) in paragraph (4), in the substituted words, for “, Food Standards Scotland or the Food Standards Agency” substitute “or Food Standards Scotland”.
- (3) In the regulations listed in paragraph (4), for “United Kingdom” in each place where those words appear, substitute “Great Britain”.
- (4) The regulations listed in this paragraph are —
- (a) regulation 22 (amendment of Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children’s development and health);
 - (b) regulation 23 (amendment of Commission Regulation (EC) No 984/2009 of 21 October 2009 refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children’s development and health);
 - (c) regulation 24 (amendment of Commission Regulation (EC) No 1024/2009 of 29 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children’s development and health);
 - (d) regulation 26 (amendment of Commission Regulation (EC) No 1167/2009 of 30 November 2009 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health);
 - (e) regulation 31 (amendment of Commission Regulation (EU) No 384/2010 of 5 May 2010 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children’s development and health);
 - (f) regulation 32 (amendment of Commission Regulation (EU) No 957/2010 of 22 October 2010 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children’s development and health);
 - (g) regulation 35 (amendment of Commission Regulation (EU) No 1162/2010 of 9 December 2010 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children’s development and health);
 - (h) regulation 37 (amendment of Commission Regulation (EU) No 440/2011 of 6 May 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children’s development and health);
 - (i) regulation 38 (amendment of Commission Regulation (EU) 665/2011 of 11 July 2011 on the authorisation of certain health claims made on foods and referring to the reduction of disease risk);
 - (j) regulation 40 (amendment of Commission Regulation (EU) No 1160/2011 of 14 November 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk);
 - (k) regulation 41 (amendment of Commission Regulation (EU) No 1170/2011 of 16 November 2011 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk);
 - (l) regulation 44 (amendment of Commission Regulation (EU) No 378/2012 of 3 May 2012 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children’s development and health);
 - (m) regulation 48 (amendment of Commission Regulation (EU) No 1048/2012 of 8 November 2012 on the authorisation of a health claim made on foods and referring to the reduction of disease risk);
 - (n) regulation 57 (amendment of Commission Regulation (EU) No 1135/2014 of 24 October 2014 on the authorisation of a health claim made on foods and referring to the reduction of disease risk);

- (o) regulation 59 (amendment of Commission Regulation (EU) No 1226/2014 of 17 November 2014 on the authorisation of a health claim made on foods and referring to the reduction of disease risk);
- (p) regulation 60 (amendment of Commission Regulation (EU) No 1228/2014 of 17 November 2014 authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk);
- (q) regulation 64 (amendment of Commission Regulation (EU) 2015/391 of 9 March 2015 refusing to authorise certain health claims made on foods and referring to children’s development and health);
- (r) regulation 68 (amendment of Commission Regulation (EU) 2015/1052 of 1 July 2015 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk);
- (s) regulation 69 (amendment of Commission Regulation (EU) 2015/1886 of 20 October 2015 refusing to authorise certain health claims made on foods and referring to children’s development and health);
- (t) regulation 74 (amendment of Commission Regulation (EU) 2016/372 of 15 March 2016 refusing to authorise a health claim made on foods and referring to the reduction of disease risk);
- (u) regulation 78 (amendment of Commission Regulation (EU) 2016/1381 of 16 August 2016 refusing to authorise a health claim made on foods and referring to children’s development and health);
- (v) regulation 79 (amendment of Commission Regulation (EU) 2016/1389 of 17 August 2016 authorising a health claim made on foods and referring to children’s development and health);
- (w) regulation 80 (amendment of Commission Regulation (EU) 2016/1390 of 17 August 2016 refusing to authorise a health claim made on foods and referring to children’s development and health);
- (x) regulation 82 (amendment of Commission Regulation (EU) 2016/1412 of 24 August 2016 refusing to authorise a health claim made on foods and referring to the reduction of disease risk);
- (y) regulation 83 (amendment of Commission Regulation (EU) 2017/236 of 10 February 2017 refusing to authorise a health claim made on foods and referring to the reduction of disease risk);
- (z) regulation 90 (amendment of Commission Regulation (EU) 2018/1555 of 17 October 2018 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk).

(5) In regulation 43 (amendment of Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods), in paragraph (3)(a)(ii), in the substituted words, for “the United Kingdom” substitute “Great Britain”.

(6) In regulation 72 (amendment of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) no 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes)—

- (a) omit paragraphs (2) to (4);
- (b) for paragraph (5) substitute—

“(5) In Article 8 (specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants)—

- (a) in paragraph 1, for “a language easily understood by the consumers”, substitute “English”;

- (b) in paragraph 4, for “Member States”, substitute “The appropriate authority”;
- (c) after paragraph 6, insert—

“7. In this Article “appropriate authority” means—

- (a) in respect of food developed in England, the Secretary of State;
- (b) in respect of food developed in Wales, the Welsh Ministers;
- (c) in respect of food developed in Scotland, the Scottish Ministers.”;

- (c) in paragraph (6), in the substituted Article 9—

- (i) in paragraph 1, for “the United Kingdom” substitute “Great Britain”;
- (ii) in paragraph 2, omit sub-paragraph (d) and the comma immediately preceding it;

- (d) after paragraph (7), insert—

“(8) In Annex IV (name referred to in Article 4), for “respectively:” to the end of that Annex, substitute ““Food for special medical purposes”.”.

PART 3

Amendment of EU Tertiary Legislation

Amendment of 2009/980/EU: Commission Decision

7.—(1) 2009/980/EU: Commission Decision of 17 December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granting the protection of proprietary data under Regulation (EC) No 1924/2006 of the European Parliament and of the Council is amended as follows.

(2) In Article 1, for “the Community list” to the end of that Article, substitute “the Annex to Commission Regulation (EU) 432/2012”.

(3) Omit Article 2.

Amendment of Commission Delegated Regulation (EU) 2016/127

8.—(1) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding is—

- (a) modified so that from 22nd February 2021 it applies to infant formula and follow-on formula manufactured from protein hydrolysates; and
- (b) amended as follows.

(2) In Article 10 (requirements for promotional and commercial practices for infant formula)—

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

“5. In this Article, “appropriate authority” means—

- (a) in respect of advertising in England, the Secretary of State;
- (b) in respect of advertising in Wales, the Welsh Ministers;
- (c) in respect of advertising in Scotland, the Scottish Ministers.”.

(3) In Article 11 (requirements on information relating to infant and young child feeding)—

- (a) in paragraph 1, for “Member States” substitute “The appropriate authority”;
- (b) in paragraph 3, for “appropriate national authority” substitute “appropriate authority”;

(c) after paragraph 3, insert—

“4. In this Article, “appropriate authority” means—

- (a) in respect of information or educational equipment or materials to be provided in England, the Secretary of State;
- (b) in respect of information or educational equipment or materials to be provided in Wales, the Welsh Ministers;
- (c) in respect of information or educational equipment or materials to be provided in Scotland, the Scottish Ministers.”.

(4) For Article 12 (notification), substitute—

“1. When infant formula is placed on the market, the food business operator shall notify the competent authority of each part of Great Britain where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation.

2. When follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II are placed on the market, the food business operator shall notify the competent authority of each part of Great Britain where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation.

3. In this Article, “competent authority” means—

- (a) in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in England, the Secretary of State;
- (b) in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in Wales, the Welsh Ministers;
- (c) in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in Scotland, Food Standards Scotland.”.

(5) Omit Articles 13 and 14.

(6) In Annex VI—

- (a) in Part A (name referred to in Article 5(1)), for “:” to the end of that Part, substitute ““Infant formula” and “Follow-on formula”.”;
- (b) in Part B (name referred to in Article 5(2)), for “:” to the end of that Part, substitute ““Infant milk” and “Follow-on milk”.”.

Amendment of Commission Delegated Regulation (EU) 2019/343

9.—(1) Commission Delegated Regulation (EU) 2019/343 of 28 February 2019 providing derogations from Article 1(3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors is amended as follows.

(2) After Article 3 omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

(3) For the table in the Annex substitute—

<i>“Class of food</i>	<i>Generic descriptor</i>
Hard and soft sweets based on sugars as well as sugar-free and calorie-reduced	Cough drops

variants based on sweeteners (polyols and/or intense sweeteners) containing extracts of herbs, fruit or other plant substances, honey or malt
Non-alcoholic carbonated beverage Tonic”
containing the bittering agent quinine in the form of the flavourings FL 14.011, FL 14.152 or FL 14.155 as referred to in the domestic list of flavourings as laid down in Annex I to Regulation (EC) No 1334/2008

Amendment of Commission Regulation (EU) No 2019/651

10.—(1) Commission Regulation (EU) No 2019/651 of 24 April 2019 refusing to authorise a health claim made on foods and referring to children’s development and health is amended as follows.

(2) In Article 1, for “shall not” to the end of that Article, substitute “may not be made on foods on the Great Britain market.”.

(3) After Article 2, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

PART 4

Revocation

Revocation of the Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019

11. The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019(a) are revoked.

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

Address	Parliamentary Under Secretary of State	<i>Name</i>
Date		Department

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by sections 8(1) and 23 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) (“the 2018 Act”) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under paragraphs (a) to (d), (f) and (g) of section 8(2) of that Act), and to make consequential and supplementary provision arising from the withdrawal of the UK from the European Union, and make consequential and supplementary provision relating to the withdrawal.

Part 2 amends the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651) to ensure that those Regulations do not apply to Northern Ireland, that the amendments made by those Regulations do not relate to Northern Ireland and to ensure that certain amendments made by those Regulations of retained EU law in the field of nutrition and health claims operate effectively. Section 41(1) of the European Union (Withdrawal Agreement) Act 2020 (c. 1) is relied upon in regulation 5(2)(d) to substitute “IP completion day” for references to “exit day” in S.I. 2019/651.

(a) S.I. 2019/650.

Part 3 amends and in some cases revokes retained EU law in the field of nutrition and health claims.

Section 8C(1)(c) of the 2018 Act is relied upon in Part 4 in order to revoke the Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 (S.I. 2019/650). Those Regulations amended EU-derived domestic legislation. As a consequence of the Protocol on Ireland / Northern Ireland in the EU withdrawal agreement, those amendments are no longer required.

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

DRAFT 02/07/20