DRAFT STATUTORY INSTRUMENTS

2019 No.

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019

PART 4

AMENDMENT OF EU REGULATIONS

Amendment of Regulation (EC) No 1924/2006

17.—(1) 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 is amended as follows.

(2) In Article 1 (subject matter and scope)—

(a) omit paragraph 1;

(b) in paragraph 2, in the second sub-paragraph—

(i) after "shall not apply" insert ", unless the appropriate authority by regulations prescribes that those provisions shall apply.";

(ii) omit the words from "National provisions" to the end of that sub-paragraph;

(c) in paragraph 4—

(i) for the words from "a derogation" to "Article 25(3)" substitute "the appropriate authority may by regulations grant a derogation from paragraph 3";

(ii) for "national competent authority of a Member State" substitute "competent authority";

(iii) for "Commission", in the first place it appears, substitute "relevant authorities";

(iv) for the final sentence substitute "The appropriate authority may by regulations prescribe the procedure and requirements for applications made by food business operators under this paragraph.";

(d) in paragraph 5—

(i) omit "the following Community provisions";

(ii) in point (a), for "Directive 89/398/EEC and Directives adopted" substitute "Regulation (EU) No 609/2013 and other relevant enactments";

(iii) in point (b)—

(aa) before "Council" insert "enactments implementing";

(bb) after "natural mineral waters" insert "and Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral water (Recast)(**1**);"

(iv) in point (c), before "Council", insert "enactments implementing";

(v) in point (d), before "Directive", insert "enactments implementing".

(**1**) OJ L 164, 26.6.2009, p. 45–58.

(3) In Article 2 (definitions)—

(a) in paragraph 1—

(i) in point (c), for "Directive 90/496/EEC" substitute "Annex I to Regulation (EU) 1169/2011";

(ii) in point (d), for "Article 1(3)(a) of Directive 2001/13/EC" substitute "Article 2(1)(j) of Regulation (EU) 1169/2011";

(b) in paragraph 2—

(i) in point (1), for "Community or national legislation" substitute "any enactment";

(ii) in point (2), for "the Annex to Directive 90/496/EEC" substitute "Annex I to Regulation (EU) 1169/2011";

(iii) for point (7) substitute—

"(7) 'expert committee' means a committee with appropriate expertise in the matter to be considered, approved by an appropriate authority to give advice for the purposes of this Regulation;";

(iv) after point (7) insert—

"(8) 'appropriate authority', subject to point 9, means:

(a) for regulations, guidelines, applications or the register of claims in relation to England, the Secretary of State;

(b) for regulations, guidelines, applications or the register of claims in relation to Scotland, the Scottish Ministers;

(c) for regulations, guidelines, applications or the register of claims in relation to Wales, the Welsh Ministers;

(d) for regulations, guidelines, applications or the register of claims in relation to Northern Ireland, the Department of Health;

(9) The appropriate authority is the Secretary of State if consent is given by:

(a) for regulations, guidelines, applications or the register or claims in relation to Scotland, the Scottish Ministers;

(b) for regulations, guidelines, applications or the register or claims in relation to Wales, the Welsh Ministers;

(c) for regulations, guidelines, applications or the register or claims in relation to Northern Ireland, the Department of Health;

(10) 'relevant authorities' means the Secretary of State, the Scottish Ministers, the Welsh Ministers and in relation to Northern Ireland, the Department of Health;

(11) 'enactment' includes any enactment of the types specified in the definition of 'enactment' in section 20(1) of the European Union (Withdrawal) Act 2018.".

(4) In Article 3 (general principles for all claims)—

(a) omit "in the Community";

(b) in the second paragraph—

(i) for "Directives 2000/13/EC and 84/450/EEC" substitute "Regulation (EU) No 1169/2011 and the Business Protection from Misleading Marketing Regulations 2008(**2**)";

(ii) in point (d), for the words from "Derogations" to the end of that point, substitute—

(**2**) S.I. 2008/1276, as amended by S.I. 2013/783 and 2701, 2014/549 and 2015/1630.

"The appropriate authority may by regulations adopt derogations in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet, including the conditions for their application, taking into account the special conditions present in the parts of the United Kingdom in relation to which the regulations are to be made.".

(5) In Article 4 (conditions for the use of nutrition and health claims)—

(a) in paragraph 1—

(i) for the first sub-paragraph substitute—

"The appropriate authority may by regulations establish specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles.";

(ii) in the fourth sub-paragraph, for "In setting the nutrient profiles, the Commission shall request the Authority", substitute "Before making regulations to establish the nutrient profiles, the appropriate authority must request an expert committee";

(iii) in the fifth sub-paragraph, for "In setting the nutrient profiles, the Commission shall carry out consultations with", substitute "Before making regulations to establish the nutrient profiles, the appropriate authority must carry out consultations with the other relevant authorities and ";

(iv) for the final sub-paragraph substitute—

"The appropriate authority may by regulations amend the nutrient profiles and their conditions of use to take into account relevant scientific developments, after consulting the other relevant authorities and interested parties, in particular food business operators and consumer groups.".

(b) omit paragraph 4;

(c) in paragraph 5—

(i) for "Measures determining" substitute "The appropriate authority may by regulations specify";

(ii) for the words from "and designed" to the end of the paragraph, substitute ", in the light of scientific evidence.".

(6) In Article 5 (general conditions), in paragraph 1, in points (b)(i) and (d), for "Community legislation" substitute "applicable enactments".

(7) In Article 6 (scientific substantiation for claims), in paragraph 3, for "competent authorities of the Member States", substitute "competent authority".

(8) In Article 7 (nutrition information), in the third paragraph, after "Directive 2002/46/EC." insert "For the purposes of this Article, Article 8 of Directive 2002/46/EC is to be read as if for "the Annex to Directive 90/496/EEC" there were substituted "Annex I to Regulation (EU) 1169/2011".

(9) In Article 8 (nutrition claims: specific conditions), in paragraph 2—

(a) for the words from the beginning to "the Authority", substitute "The appropriate authority may by regulations amend the Annex, after consulting an expert committee";

(b) for "Commission" substitute "appropriate authority".

(10) In Article 9 (comparative claims), in paragraph 1, for "Directive 84/450/EEC" substitute "the Business Protection from Misleading Marketing Regulations 2008".

(11) In Article 10 (health claims: specific conditions)—

(a) in paragraph 1, for the words from "included in" to the end of that paragraph substitute "are included in the list of authorised claims in the Annex to Commission Regulation (EU) 432/2012 or are authorised for the purposes of Article 14";

(b) in paragraph 3, for the words "included in the lists provided for in Article 13 or 14" substitute "authorised for the purposes of Article 13 or 14";

(c) in paragraph 4, for the words from "guidelines" to the end of that paragraph substitute "the appropriate authority may, after consultation with interested parties, in particular food business operators and consumer groups, publish guidelines on the implementation of this Article.".

(12) Omit Article 11.

(13) In Article 12 (restrictions on the use of certain health claims), in point (c), for "other associations not referred to in Article 11." substitute "associations other than national associations of medical, nutrition or dietetic professionals and health-related charities.".

(14) In Article 13 (health claims other than those referring to the reduction of disease risk and to children's development and health)—

(a) in paragraph 1—

(i) in point (c), before "Directive 96/8/EC", insert "any enactment implementing";

(ii) for "provided for in paragraph 3" substitute "in the Annex to Commission Regulation (EU) 432/2012";

(b) omit paragraphs 2 and 3;

(c) for paragraphs 4 and 5 substitute—

"**4.** The appropriate authority may, by regulations and after consulting an expert committee, make changes to the list in the Annex to Commission Regulation (EU) 432/2012, if such changes are based on generally accepted scientific evidence.

5. The appropriate authority may make regulations adding a claim to the list in the Annex to Commission Regulation (EU) 432/2012 which:

(a) is based on newly developed scientific evidence; or

(b) includes a request for the protection of proprietary data,

after making a decision under the procedure laid down in Article 18 or, where the claim relates to children's development and health, the procedure laid down in Articles 15, 16, 17, and 19.".

(15) In Article 14 (reduction of disease risk claims and claims referring to children's development and health), in paragraph 1—

(a) for "Article 2(1)(b) of Directive 2000/13/EC" substitute "Article 7(3) of Regulation (EU) 1169/2011";

(b) for the words from "the following" to "authorised", substitute "the appropriate authority may by regulations authorise the use of the following claims, together with all the necessary conditions for the use of such claims,";

(c) omit the words from "for inclusion" to "these claims";

(d) after paragraph 1, insert—

"**1A.** Claims which have been authorised for the purposes of Article 14 before exit day are to be treated as authorised for use in the United Kingdom on and after exit day, provided that they continue to meet the general requirements of this Regulation, the specific requirements of Article 14 and any other relevant legislative requirements.".

(16) In Article 15 (application for authorisation)—

(a) after paragraph 1, insert—

"**1A.** An application may be made either:

(a) for authorisation in the United Kingdom; or

(b) for authorisation in one of England, Scotland, Wales or Northern Ireland only.

1B. The application must be sent to:

(a) for authorisation in England, the competent authority in England;

(b) for authorisation in Scotland, the competent authority in Scotland;

(c) for authorisation in Wales, the competent authority in Wales;

(d) for authorisation in Northern Ireland, the competent authority in Northern Ireland;

(e) for authorisation in the United Kingdom, any competent authority.";

(b) in paragraph 2—

(i) omit "The application shall be sent to the national competent authority of a Member State";

(ii) in point (a)—

(aa) omit "national";

(bb) in point (ii), for "the Authority" substitute "an expert committee and the relevant authorities";

(cc) in point (iii), for "Authority" substitute "expert committee and the relevant authorities";

(iii) in point (b)—

(aa) for "Authority" substitute "expert committee";

(bb) omit point (i);

(c) in paragraph 3, after point (a), insert—

"(aa) a statement confirming whether the application is for authorisation of the claim for use–

(i) in the United Kingdom; or

(ii) in one of England, Scotland, Wales or Northern Ireland only;";

(d) for paragraph 4 substitute—

"**4.** The appropriate authority may by regulations, having first consulted the other relevant authorities, amend Commission Regulation (EC) 353/2008 to modify the procedure and requirements for applications made under this Article.";

(e) in paragraph 5, for the words from "The Commission" to "make available" substitute "The appropriate authority, in close cooperation with an expert committee and the other relevant authorities, may issue".

(17) In Article 16 (opinion of the Authority)—

(a) in the heading, for "Authority" substitute "expert committee";

(b) in paragraph 1, for "Authority", in both places, substitute "expert committee";

(c) in paragraph 2, for "The Authority or a national competent authority, through the Authority" substitute "The expert committee or the competent authority through the expert committee";

(d) in paragraphs 3 and 5, for "Authority" substitute "expert committee";

(e) in paragraph 5, for "Commission, the Member States" substitute "relevant authorities";

(f) for paragraph 6 substitute—

"**6.** The expert committee shall make its opinion public. The applicant or members of the public may make comments to the competent authority which received the application within 30 days from publication of the opinion of the expert committee.".

(18) In Article 17 (Community authorisation)—

(a) for the heading substitute "Authorisation by the appropriate authority";

(b) omit paragraphs 1 and 2;

(c) in paragraph 3—

(i) for the first sub-paragraph substitute—

"Where the application is made on a UK-wide basis, a decision must be made by:

(a) the appropriate authority for applications in relation to England, in relation to authorisation of the claim in England;

(b) the appropriate authority for applications in relation to Scotland, in relation to authorisation of the claim in Scotland;

(c) the appropriate authority for applications in relation to Wales, in relation to authorisation of the claim in Wales; and

(d) the appropriate authority for applications in relation to Northern Ireland, in relation to authorisation of the claim in Northern Ireland.

The appropriate authority for each of England, Scotland, Wales and Northern Ireland must consult each other appropriate authority prior to making a decision on the application.";

(ii) after the first sub-paragraph insert—

"Where the application is made for authorisation in one of England, Scotland, Wales or Northern Ireland only, the appropriate authority shall make a decision on the application, having consulted the other relevant authorities.";

(iii) in the second sub-paragraph—

(aa) for "the Commission" substitute "the appropriate authority";

(bb) for points (a) and (b) substitute—

"(a) the appropriate authority may by regulations made under the powers in Articles 13 or 14 authorise the claim for sole use by the applicant. In such case, the authorisation for restricted use shall expire at the end of the period of five years after the date on which the regulations are made;

(b) before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the appropriate authority must consider, in consultation with an expert committee and the other relevant authorities, whether to authorise the claim without restriction for use under the powers in Articles 13 or 14.";

(d) omit paragraph 4;

(e) in paragraph 5, for "included in the lists provided for in Articles 13 and 14" substitute "authorised for the purposes of Articles 13 and 14".

(19) In Article 18 (claims referred to in Article 13(5))—

(a) in paragraph 1, for "provided for in Article 13(3)" substitute "in the Annex to Commission Regulation (EU) 432/2012";

(b) after paragraph 1, insert—

"**1A.** The application for this inclusion may be made either:

(a) for use of the health claim in the United Kingdom; or

(b) for use of the health claim in one of England, Scotland, Wales or Northern Ireland only.

1B. The application must be sent to:

(a) for use of the health claim in England, the competent authority in England;

(b) for use of the health claim in Scotland, the competent authority in Scotland;

(c) for use of the health claim in Wales, the competent authority in Wales;

(d) for use of the health claim in Northern Ireland, the competent authority in Northern Ireland;

(e) for use of the health claim in the United Kingdom, any competent authority.";

(c) in paragraph 2, for the words from "The application" to "Member State which" substitute "The competent authority";

(d) in paragraph 3—

(i) for "the Authority", in the first place it appears, substitute "an expert committee";

(ii) for "the Commission and the Member States" substitute "the relevant authorities";

(iii) for "Authority", in the second and third places that it appears, substitute "expert committee";

(iv) for "Authority's" substitute "expert committee's";

(e) for paragraph 4, substitute—

"**4.** Where the application is for the use of the health claim in the United Kingdom, within two months of receiving the opinion of the expert committee, a decision must be made by:

(a) the appropriate authority for applications in relation to England, in relation to authorisation of the claim in England;

(b) the appropriate authority for applications in relation to Scotland, in relation to authorisation of the claim in Scotland;

(c) the appropriate authority for applications in relation to Wales, in relation to authorisation of the claim in Wales; and

(d) the appropriate authority for applications in relation to Northern Ireland, in relation to authorisation of the claim in Northern Ireland.

The appropriate authorities for each of England, Scotland, Wales and Northern Ireland must consult each other prior to making a decision on the application and must take into account the opinion of the expert committee, any relevant enactments and other factors relevant to the matter under consideration.";

(f) after paragraph 4, insert—

"**4A.** Where the application is for the use of the health claim in one of England, Scotland, Wales or Northern Ireland only, the appropriate authority must make a decision on the application within two months of receiving the opinion of the expert committee. The appropriate authority must consult the other relevant authorities prior to making such

a decision and must take into account the opinion of the expert committee, any relevant enactments and other factors relevant to the matter under consideration.";

(g) in paragraph 5—

(i) omit the first sub-paragraph;

(ii) in the second sub-paragraph—

(aa) omit "However,";

(bb) for "the Commission" substitute "the appropriate authority";

(cc) for points (a) and (b) substitute—

"(a) the appropriate authority may by regulations made under the powers in Articles 13 or 14 authorise the claim for sole use by the applicant. In such case, the authorisation for restricted use shall expire at the end of the period of five years after the date on which the regulations are made;

(b) before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the appropriate authority must consider, in consultation with an expert committee and the other relevant authorities, whether to authorise the claim without restriction for use under the powers in Articles 13 or 14.".

(20) In Article 19 (modification, suspension and revocation of authorisations)—

(a) for the first sentence of paragraph 1, substitute "The applicant/user of a claim authorised for the purposes of Articles 13 and 14 may apply for a modification of that health claim to be authorised.";

(b) in paragraph 2,

(i) in the first sub-paragraph, omit "On its own initiative or";

(ii) for "a Member State or from the Commission, the Authority" substitute "an appropriate authority, an expert committee";

(iii) for "included in the lists provided for in Articles 13 and 14" substitute "authorised for the purposes of Article 13 or 14";

(iv) in the second sub-paragraph, for "Commission, the Member States" substitute "relevant authorities";

(v) for "Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002," substitute "expert committee";

(vi) in the third sub-paragraph, for "Commission", substitute "appropriate authority";

(vii) for "The Commission shall examine the opinion of the Authority" substitute "The appropriate authority shall examine the opinion of the expert committee";

(viii) for the final sentence, substitute "Having regard to the opinion of the expert committee, the appropriate authority may by regulations modify or revoke the relevant authorisation by amending as appropriate the list in the Annex to Commission Regulation (EU) 432/2012 or the regulations or retained direct EU legislation authorising a claim for the purposes of Article 14".

(c) after paragraph 2, insert—

"**3.** On imperative grounds of urgency, the appropriate authority may exercise the power to make regulations under paragraph 2 without allowing for the 30 day comment period in the third paragraph of paragraph 2.".

(21) In Article 20 (Community register)—

(a) in the heading, omit "Community";

(b) in paragraph 1—

(i) for "The Commission shall" substitute "The appropriate authority must";

(ii) omit "Community";

(c) in paragraph 2—

(i) in point (c)—

(aa) for "13(3) and (5)" substitute "the list in the Annex to Commission Regulation (EU) 432/2012, as amended from time to time";

(bb) omit from ", 24(2)" to the end of that point;

(ii) in both points (1) and (2), for "the Commission authorised the health claim" substitute "the health claim was authorised".

(22) In Article 21 (data protection), in paragraph 2—

(a) for "Commission" substitute "appropriate authority";

(b) for "included in the list provided for in" substitute "authorised under".

(23) After Article 21, insert—

"Article 21A

Regulations: general

Regulations made under this Regulation may:

(a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);

(b) make different provision for different cases or descriptions of case, different circumstances, different purposes or different areas.

Article 21B

Regulations: Secretary of State

1. Any power of the Secretary of State to make regulations under this Regulation is exercisable by statutory instrument.

2. Except as specified in paragraph 3, a statutory instrument made under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

3. A statutory instrument containing (whether alone or with other provision) regulations made under Article 4(1) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

4. The Secretary of State must not make regulations under this Regulation which will apply in Scotland, Wales or Northern Ireland without the consent of:

(a) the Scottish Ministers, in respect of any proposed application in Scotland;

(b) the Welsh Ministers, in respect of any proposed application in Wales;

(c) the Department of Health, in respect of any proposed application in Northern Ireland.

Article 21C

Regulations: Scottish Ministers

1. For regulations made by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

2. Except as specified in paragraph 3, regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

3. Regulations made by the Scottish Ministers under Article 4(1) are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

Article 21D

Regulations: Welsh Ministers

1. Any power of the Welsh Ministers to make regulations under this Regulation is exercisable by statutory instrument.

2. Regulations made by the Welsh Ministers under this Regulation are subject to annulment in pursuance of a resolution of the National Assembly for Wales.

3. A statutory instrument containing (whether alone or with other provision) regulations made under Article 4(1) may not be made unless a draft of the instrument has been laid before, and approved by, a resolution of, the National Assembly for Wales.

Article 21E

Regulations: Department of Health

1. Any power of the Department of Health to make regulations under this Regulation is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979.

2. Except as specified in paragraph 3, regulations made by the Department of Health are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954 as if they were a statutory instrument within the meaning of that Act.

3. A statutory rule containing regulations made under Article 4(1) may not be made unless a draft of the regulations has been laid before, and approved by, a resolution of, the Northern Ireland Assembly.".

(24) Omit Articles 22 to 27.

(25) In Article 28 (transitional measures)—

(a) in paragraph (1), omit the words from the beginning to "2009";

(b) omit paragraphs (3) to (6).

(26) Omit Article 29.

Amendment of Regulation (EC) No 1925/2006

18.—(1) 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 is amended as follows.

(2) In Article 1 (subject matter and scope)—

(a) omit paragraph 1;

(b) in paragraph 3, for "Community legislation" substitute "other relevant enactments".

(3) In Article 2 (definitions)—

(a) for point (1), substitute—

"(1) 'expert committee' means a committee with appropriate expertise in the matter to be considered, approved by an appropriate authority to give advice for the purposes of this Regulation";

(b) after point (2), insert—

"(3) 'appropriate authority' means:

(a) for regulations applying in relation to England and for the establishment and maintenance of a register in relation to England, the Secretary of State;

(b) for regulations applying in relation to Scotland and for the establishment and maintenance of a register in relation to Scotland, the Scottish Ministers;

(c) for regulations applying in relation to Wales and for the establishment and maintenance of a register in relation to Wales, the Welsh Ministers;

(d) for regulations applying in relation to Northern Ireland and for the establishment and maintenance of a register in relation to Northern Ireland, the Department of Health;

(4) But the appropriate authority is the Secretary of State if consent is given by:

(a) for regulations applying in relation to Scotland and for the establishment and maintenance of a register in relation to Scotland, the Scottish Ministers;

(b) for regulations applying in relation to Wales and for the establishment and maintenance of a register in relation to Wales, the Welsh Ministers;

(c) for regulations applying in relation to Northern Ireland and for the establishment and maintenance of a register in relation to Northern Ireland, the Department of Health;

(5) 'relevant authorities' means the Secretary of State, the Scottish Ministers, the Welsh Ministers and in relation to Northern Ireland, the Department of Health.".

(4) In Article 3 (requirements for the addition of vitamins and minerals), in paragraph 3—

(a) for the first sub-paragraph substitute—

"The appropriate authority may by regulations, after taking into account the opinion of an expert committee, specify modifications to the lists referred to in paragraph 1 of this Article.";

(b) omit the second sub-paragraph;

(c) in the third sub-paragraph for "these modifications, the Commission" substitute "regulations under this paragraph, the appropriate authority".

(5) In Article 4 (restrictions on the addition of vitamins and minerals)—

(a) for point (b)(i) substitute—

"(i) referred to in paragraph B3 of Annex VIII to Regulation (EU) No 1308/2013; and";

(b) in point (b)(ii), after "Regulation;" omit "and";

(c) omit point (b)(iii);

(d) for the final sub-paragraph, substitute—

"The appropriate authority may by regulations determine the additional foods or categories of foods to which particular vitamins and minerals may not be added, in the light of scientific evidence and taking into account their nutritional value.".

(6) In Article 5 (purity criteria)—

(a) in paragraph 1—

(i) for "Measures determining" substitute "The appropriate authority may by regulations determine";

(ii) omit the words from "and designed" to "Article 14(3)";

(b) in paragraph 2, for "Community legislation" substitute "other relevant enactments";

(c) in paragraph 3—

(i) for "Community legislation" substitute "other relevant enactments";

(ii) for "such specifications are adopted" substitute "the appropriate authority makes regulations under paragraph 1";

(iii) omit the words from "national" to the end of that paragraph.

(7) In Article 6 (conditions for the addition of vitamins and minerals)—

(a) in paragraph 1, for the words from "and designed" to "2009" substitute "may be adopted by regulations made by the appropriate authority";

(b) in paragraph 2—

(i) for "Any" substitute "The appropriate authority may by regulations specify";

(ii) omit the words from "and designed" to the end of that paragraph;

(c) in paragraph 6—

(i) for "Annex to Directive 90/496/EEC" substitute "Annex XIII to Regulation (EU) No 1169/2011";

(ii) for the words from "and designed" to the end of the paragraph substitute "may be adopted by regulations made by the appropriate authority.".

(8) In Article 7 (labelling, presentation and advertising)—

(a) in paragraph 1, for the words from "and designed" to the end of the paragraph substitute "may be adopted by regulations made by the appropriate authority.";

(b) in paragraph 6, for "accordance with the procedure referred to in Article 14(2)" substitute "regulations made by the appropriate authority".

(9) In Article 8 (restricted or prohibited substances)—

(a) in the heading, omit "Community";

(b) in paragraph 2—

(i) for the words from the beginning to "Article 14(3)" substitute "Following an assessment of available evidence by an expert committee, the appropriate authority may make regulations";

(ii) omit the words from "On imperative grounds" to the end of that paragraph;

(c) in paragraph 3, for "Community provisions" substitute "Enactments";

(d) for paragraph 4, substitute—

"**4.** Food business operators, or any other interested parties, may at any time submit to the appropriate authority a file containing the scientific data demonstrating the safety of a substance listed in Annex III, Part C, under the conditions of its use in a food or in a category of foods and explaining the purpose of that use. The appropriate authority shall

submit the file to an expert committee for evaluation and shall inform the other relevant authorities of the submission and shall make the file available to them.";

(e) for paragraph 5, substitute—

"**5.** Within four years from the date a substance has been listed in Annex III, Part C, the appropriate authority must consider, in consultation with the other relevant authorities and taking into account the opinion of the expert committee on any files submitted for evaluation as mentioned in paragraph 4 of this Article, whether to make regulations to generally allow the use of a substance listed in Annex III, Part C, or to list it in Annex III, Part A or B, as appropriate.";

(f) for paragraph 6, substitute—

"**6.** The appropriate authority may by regulations amend Commission Implementing Regulation (EU) No 307/2012 in order to modify the implementing rules for the application of this Article.".

(10) In Article 9—

(a) in the heading, omit "Community";

(b) in paragraph 1, for the words from the beginning to "Community" substitute "The appropriate authority must establish and maintain a";

(c) for point 2(d) substitute—

"(d) information regarding enactments applicable in any part of the United Kingdom on:

(i) the mandatory addition of vitamins and minerals to specified foods or categories of foods; or

(ii) the prohibition or restriction on the use of certain other substances in the manufacture of specified foods;";

(d) omit point 2(f).

(11) After Article 9 insert—

"Article 9A

Regulations: general

1. Regulations made under this Regulation may:

(a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);

(b) make different provision for different purposes.

Article 9B

Regulations: Secretary of State

1. Any power of the Secretary of State to make regulations under this Regulation is exercisable by statutory instrument.

2. A statutory instrument made under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

3. The Secretary of State may not make regulations under this Regulation which will apply in Scotland, Wales or Northern Ireland without the consent of:

(a) the Scottish Ministers, in respect of any proposed application in Scotland;

(b) the Welsh Ministers, in respect of any proposed application in Wales; and

(c) the Department of Health, in respect of any proposed application in Northern Ireland.

Article 9C

Regulations: Scotland

1. For regulations made by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

2. Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

Article 9D

Regulations: Wales

1. Any power of the Welsh Ministers to make regulations under this Regulation is exercisable by statutory instrument.

2. Regulations made by the Welsh Ministers under this Regulation are subject to annulment in pursuance of a resolution of the National Assembly for Wales.

Article 9E

Regulations: Northern Ireland

1. Any power of the Department of Health to make regulations under this Regulation is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979.

2. Regulations made by the Department of Health are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954 as if they were a statutory instrument within the meaning of that Act.".

(12) Omit Articles 10 to 18.

Amendment of Regulation (EU) No 609/2013

19.—(1) 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 is amended as follows.

(2) In Article 1 (subject matter), in paragraph 2, for "Union" substitute "UK".

(3) In Article 2 (definitions), after paragraph (h) insert—

"(i) 'UK list' means the list set out in the Annex.".

(4) In Article 3 (interpretation decisions)—

(a) for the first paragraph, substitute "The appropriate authority may make regulations specifying:";

(b) omit the final paragraph.

(5) In Article 4 (placing on the market), omit paragraph 3.

(6) In Article 6 (general provisions), for "Union law" in each place where those words appear substitute "retained EU law".

(7) Omit Articles 7 and 8.

(8) In Article 9 (general compositional and information requirements), in paragraph 4, for "Article 1 of Regulation (EC) No 258/97" substitute "Regulation (EU) 2015/2283".

(9) In Article 11 (specific compositional and information requirements)—

(a) in paragraph 1—

(i) omit the words from "Subject to the general requirements" to "article 10, and";

(ii) for the words from "the Commission" to "Article 18" substitute "and having regard to such scientific opinion as an appropriate authority considers appropriate, the appropriate authority may make regulations";

(iii) in sub-paragraph (b) omit the words from "The specific requirements" in the second place they appear to the end of that sub-paragraph;

(iv) in sub-paragraph (d) omit the words from "and on the basis" until the end of that sub-paragraph;

(v) omit the words "Those delegated acts shall be adopted by 20 July 2015.".

(b) omit paragraph 2.

(10) Omit Articles 12 and 13.

(11) In Article 14 (technical guidelines)—

(a) for "The Commission" substitute "The Secretary of State, the Scottish Ministers, the Welsh Ministers and in relation to Northern Ireland, the Department of Health";

(b) for "SMEs" substitute "small or medium sized enterprises as defined in the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises";

(c) after "Chapter III", insert—

", as it applies in their territory.

For the purposes of this Article, the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises(**3**) is to be read as if—

(a) in Article 2—

(i) in paragraph 1, for "EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million" there were substituted "£44,000,000, and/or an annual balance sheet total not exceeding £38,000,000";

(ii) in paragraph 2, for "EUR 10 million" there were substituted "£8,800,000";

(iii) in paragraph 3, for "EUR 2 million" there were substituted "£1,750,000";

(b) in Article 3—

(i) in paragraph 2(a), for "EUR 1 250 000" there were substituted "£1,100,000";

(ii) in paragraph 2(d), for "EUR 10 million" there were substituted "£8,800,000";

(iii) in paragraph 5, for "by national or Community rules" there were substituted "under the law of the United Kingdom (or any part of it)";

(**3**) OJ L 124, 20.5.2003, p. 36.

(c) in Article 5, in paragraph (b), for "national law" there were substituted "the law of the United Kingdom (or any part of it).".

(12) In the heading to Chapter III, substitute "UK list".

(13) In Article 15—

(a) for "Union list" in the heading and in each place where those words appear substitute "UK list";

(b) in paragraphs 4 and 5, for "Union law" substitute "retained EU law and any other legislation applying in any part of the United Kingdom";

(c) in paragraph 5, omit "Member States may maintain national rules setting stricter purity criteria.";

(d) in paragraph 6, for the words from "the Commission" to "Article 18" substitute "an appropriate authority may make regulations in relation to the categories of substances listed in paragraph 1 of this Article".

(14) In Article 16 (updating the union list)—

(a) for "Union list" in the heading and in each place where those words appear, substitute "UK list";

(b) in paragraph 1—

(i) omit the words from "Subject to the general requirements" to "article 11, and";

(ii) for the words from "the Commission" to "Article 18 to" substitute "the appropriate authority may by regulations";

(c) omit paragraph 2.

(15) After Article 16, in Chapter IV (procedural provisions) insert—

"Article 16A

Regulations

1. Any power to make regulations under this Regulation may be exercised by the Secretary of State for the whole or part of the United Kingdom if consent is given by—

(a) for regulations applying in relation to Scotland, the Scottish Ministers;

(b) for regulations applying in relation to Wales, the Welsh Ministers;

(c) for regulations applying in relation to Northern Ireland, the Department of Health.

2. Regulations made under this Regulation may–

(a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);

(b) make different provision for different purposes.

3. In this Regulation–

"appropriate authority" means:

(a) for regulations applying in relation to England, the Secretary of State;

(b) for regulations applying in relation to Scotland, the Scottish Ministers;

(c) for regulations applying in relation to Wales, the Welsh Ministers;

(d) for regulations applying in relation to Northern Ireland, the Department of Health;

"enactment" includes any enactment of the types specified in the definition of 'enactment' in section 20(1) of the European Union (Withdrawal) Act 2018.

Article 16B

Regulations: Secretary of State

1. Any power of the Secretary of State to make regulations under this Regulation is exercisable by statutory instrument.

2. A statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

Article 16C

Regulations: The Scottish Ministers

1. For regulations made by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

2. Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

Article 16D

Regulations: The Welsh Ministers

1. Any power of the Welsh Ministers to make regulations under this Regulation is exercisable by statutory instrument.

2. A statutory instrument containing regulations made under regulation 2 by the Welsh Ministers is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

Article 16E

Regulations: Northern Ireland

1. Any power of the Department of Health to make regulations under this Regulation is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979.

2. Regulations made under this Regulation by the Department of Health are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954 as if they were a statutory instrument within the meaning of that Act.".

(16) Omit Articles 17 to 20.

(17) In Article 21—

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

(b) after paragraph 2, insert—

"**3.** In this Article, any reference to compliance with a provision of the Directive is to be read as a reference to complying with that provision as would be required if the provision formed part of domestic law.".

(18) Omit Article 22.

(19) In the heading to the Annex, for "Union list" substitute "UK list".