This draft Statutory Instrument supersedes the draft of the same title which was laid before Parliament on 16th January and published on 16th January ISBN 9780111178508. It is being issued free of charge to all known recipients of that draft Statutory Instrument.

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2019 No. 0000

EXITING THE EUROPEAN UNION

FOOD

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

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) and 23 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

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(**b**).

PART 1

PRELIMINARY

Citation, commencement and application

1.—(1) These Regulations may be cited as the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

(2) These Regulations apply to the United Kingdom, except for Part 3 which applies to England only.

(**a**) 2018 c. 16.
(**b**) 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).

PART 2

PROVISION ABOUT FOOD SUPPLEMENTS

Food supplements

2.—(1) The following Schedules take effect—

(a) Schedule 1: Vitamins and minerals which may be used in the manufacture of food supplements;

(b) Schedule 2: Vitamin and mineral substances which may be used in the manufacture of food supplements.

(2) Regulations may be made to amend Schedule 1 or 2.

Purity criteria for substances listed in Schedule 2

3. Regulations may be made to set purity criteria for any vitamin and mineral substance listed in Schedule 2.

Amounts of vitamins and minerals

4.—(1) Regulations may be made to set the maximum amounts of vitamins and minerals that may be present in food supplements per daily portion of consumption as recommended by the manufacturer, taking into account—

(a) the upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the intake of vitamins and minerals from other dietary sources.

(2) Regulations may be made to set minimum amounts of vitamins and minerals required to be present in food supplements per daily portion of consumption as recommended by the manufacturer.

(3) When setting the maximum amounts referred to in paragraph (1), the appropriate authority must take into account reference intakes of vitamins and minerals for the population.

Regulations: general

5.—(1) Any power to make regulations under this Part is exercisable by the appropriate authority.

(2) But the power to make regulations under this Part 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.

(3) Regulations made under this Part may—

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

(b) make different provision for different purposes.

(4) In this Part—

"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.

Regulations: Secretary of State

6.—(1) Any power of the Secretary of State to make regulations under this Part is exercisable by statutory instrument.

(2) A statutory instrument containing regulations made under regulation 2 (food supplements) is subject to annulment in pursuance of a resolution of either House of Parliament.

(3) A statutory instrument containing regulations made under regulation 3 (purity criteria for substances listed in Schedule 2) or 4 (amounts of vitamins and minerals) may not be made unless a draft of the instrument has been laid before, and approved by, a resolution of, each House of Parliament.

Regulations: The Scottish Ministers

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

(2) Regulations made by the Scottish Ministers under regulation 2 (food supplements) 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 regulation 3 (purity criteria for substances listed in Schedule 2) or 4 (amounts of vitamins and minerals) are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

Regulations: The Welsh Ministers

8.—(1) Any power of the Welsh Ministers to make regulations under this Part is exercisable by statutory instrument.

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

(3) A statutory instrument containing regulations made under regulation 3 (purity criteria for substances listed in Schedule 2) or 4 (amounts of vitamins and minerals) 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.

Regulations: Northern Ireland

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

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

(3) A statutory rule containing regulations made under regulation 3 (purity criteria for substances listed in Schedule 2) or 4 (amounts of vitamins and minerals) may not be made unless a draft of the regulations has been laid before, and approved by, a resolution of, the Northern Ireland Assembly.

(**a**) 2010 asp 10.
(**b**) S.I. 1979/1573 (N.I. 12), to which there are amendments not relevant to these Regulations.
(**c**) 1954 c.33, as amended by S.I. 1999/663.

PART 3

AMENDMENT OF SUBORDINATE LEGISLATION

Amendment of the Medical Food (England) Regulations 2000

10.—(1) The Medical Food (England) Regulations 2000(**a**) are amended as follows.

(2) Regulation 2 (interpretation)(**b**) is renumbered as paragraph (1) of that regulation.

(3) After paragraph (1) as so renumbered, insert—

"(2) In these Regulations, 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.

(3) For the purposes of these Regulations, Articles 4 to 5 of, and the Annex to, the Directive are to be read subject to the modifications set out in Schedule 1.".

(4) In regulation 5A(**c**) (application of the improvement notice provisions of the Act), for "Schedule", in each place where it appears, substitute "Schedule 2".

(5) The Schedule is renumbered as Schedule 2.

(6) Before Schedule 2 as so renumbered, insert—

"SCHEDULE 1

Regulation 2(3)

Modifications to the Directive

1. The Directive is modified as follows.

2. Article 4(2) is to be read as if for "Article 3 of Directive 79/112/EEC," there were substituted "Article 9 of Regulation (EU) No 1169/2011".

3. Article 5 is to be read as if—

(a) in paragraph 1—

(i) for "where a product is manufactured in a third country" there were substituted "where a product is manufactured outside of the United Kingdom";

(ii) for the first reference to "Member States" there were substituted "territories within the United Kingdom";

(iii) the words "Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation" were omitted.

(b) in paragraph 2, for "are those referred to in Article 9(4) of Directive 89/398/EEC" there were substituted–

"are–

(a) in respect of England, the Secretary of State,

(b) in respect of Scotland, Food Standards Scotland(**d**),

(c) in respect of Wales, the Welsh Ministers,

(d) in respect of Northern Ireland, the Food Standards Agency(**e**).".

(**a**) S.I. 2000/845, amended by S.I. 2005/2626, 2007/3521, 2008/2445, 2011/3012, 2016/688, 2019/.
(**b**) A relevant amendment to regulation 2 was made by S.I. 2007/3251.
(**c**) Regulation 5A was inserted by S.I. 2016/688.
(**d**) Food Standards Scotland was established by section 1 of the Food (Scotland) Act 2015 (asp 1).
(**e**) The Food Standards Agency was established by section 1 of the Food Standards Act 1999 (c. 28).

4. In the Annex, paragraph 4 is to be read as if for "Directive 91/321/EEC and its subsequent modifications" there were substituted "Directive 2006/141/EC(**a**)".".

Amendment of the Kava-kava in Food (England) Regulations 2002

11.—(1) The Kava-kava in Food (England) Regulations 2002(**b**) are amended as follows.

(2) In regulation 2 (interpretation)(**c**)—

(a) omit the definitions of "EEA Agreement", "EEA State" and "free circulation in member States";

(b) after the definition of port health authority, insert—

""third country" means a country other than the United Kingdom.".

(3) In regulation 3 (prohibition on sale etc of food consisting of or containing Kava-kava)(**d**) for paragraph (2), substitute—

"(2) The prohibition imposed by paragraph (1) shall not apply where the food consisting of or containing Kava-kava is imported from a third country if the food is being, or is to be, exported to a third country.".

Amendment of the Food Supplements (England) Regulations 2003

12.—(1) The Food Supplements (England) Regulations 2003(**e**) are amended as follows.

(2) In regulation 2(**f**) (interpretation) omit—

(a) the definition of "Directive 2001/83";

(b) paragraphs (3) and (4).

(3) In regulation 3 (scope of regulations) in paragraph (2), for "as defined by Directive 2001/83" substitute "as defined by regulation 2(1) of the Human Medicines Regulations 2012(**g**)".

(4) In regulation 5(**h**) (prohibitions on sale relating to composition of food supplements)—

(a) in paragraph (1)—

(i) in sub-paragraph (a) for "Annex I to Directive 2002/46" substitute "Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019";

(ii) in sub-paragraph (b)(i) for "Annex II to Directive 2002/46" substitute "Schedule 2 to the Nutrition (Amendment) (EU Exit) Regulations 2019";

(b) in paragraph (2) for sub-paragraph (a) substitute—

"(a) the purity criteria, if any, specified in EU-derived domestic legislation, retained direct EU legislation or in regulations made by the Secretary of State under regulation 3 of the Nutrition (Amendment) (EU Exit) Regulations 2019; or".

(5) In regulation 6(**i**) (restrictions on sale relating to labelling etc of food supplements) in paragraph (3)(b) for "Annex I to Directive 2002/46" substitute "Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019".

(**a**) OJ No. L 401, 30.12.2006, p. 1, last amended by Commission Delegated Regulation (EU) 2016/127 (OJ No. L 25, 2.2.2016, p. 1).
(**b**) S.I. 2002/3169, amended by S.I. 2004/455, 2012/1809.
(**c**) Regulation 2 was amended by S.I. 2004/455, 2012/1809.
(**d**) Paragraph 2 of regulation 3 was inserted by S.I. 2004/455.
(**e**) S.I. 2003/1387 relevant amending instruments are S.I. 2005/2626, 2009/3251 and 2014/1855.
(**f**) Relevant amendments to regulation 2 were made by S.I. 2009/3251.
(**g**) S.I. 2012/1916.
(**h**) Relevant amendments to regulation 5 were made by S.I. 2009/3251.
(**i**) Regulation 6 was amended by S.I. 2009/3251 and 2014/1855.

Amendment of the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007

13.—(1) The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007(**a**) are amended as follows.

(2) In regulation 4 (offences and penalties)—

(a) in paragraph (1), omit "Subject to the transitional measures contained in Article 18 (relating to foods placed on the market before 1 July 2007),";

(b) in paragraph (2)(a), omit "as read with Article 17(1) (transitional application of national rules)".

Amendment of the Infant Formula and Follow-on Formula (England) Regulations 2007

14.—(1) The Infant Formula and Follow-on Formula (England) Regulations 2007(**b**) are amended as follows.

(2) In regulation 2 (interpretation)(**c**), after paragraph (6) insert—

"(7) In these Regulations, 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.".

(3) In regulation 12 (listed substances and their purity criteria (infant formula and follow-on formula))(**d**), in paragraph (3)(a) for "EU legislation" substitute "retained EU law".

Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

15.—(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009(**e**) are amended as follows.

(2) In Schedule 1 (specified provisions)(**f**), in the "subject matter" column of the table—

(a) in the entry relating to Article 2(1), for "covered by Directive 2009/39 of the European Parliament and the Council on foodstuffs intended for particular nutritional uses" substitute "(foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability);

(b) in the entry relating to Article 3(2), for "competent authority referred to in Article 11 of Directive 2009/39" substitute "Secretary of State, Welsh Ministers, Food Standards Scotland or the Food Standards Agency in Northern Ireland";

(c) in the entries relating to Article 4(2) and (3), for "EU legislation" substitute "retained EU law".

Amendment of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016

16.—(1) The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016(**g**) are amended as follows.

(2) In regulation 2 (interpretation), omit paragraph (5).

(**a**) S.I. 2007/1631, to which there are amendments not relevant to these regulations.
(**b**) S.I. 2007/3521.
(**c**) Regulation 2 was amended by S.I. 2011/3012, 2013/3243.
(**d**) Regulation 12 was amended by S.I. 2011/1043.
(**e**) S.I. 2009/3051.
(**f**) Schedule 1 was amended by S.I. 2011/1043 and 2016/688.
(**g**) S.I. 2016/688 as amended by S.I. 2019/.

(3) In regulation 7 (review), omit paragraph (2).

(4) In Schedule 1 (Specified EU requirements)(**a**) in the entry in column 1, for "Article 15(1) (Union list)" substitute "Article 15(1) (UK list)".

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)(**b**);"

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

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

(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—

(**a**) Schedule 1 was amended by S.I. 2019/.
(**b**) OJ L 164, 26.6.2009, p. 45–58.

(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(**a**)";

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

"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.";

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

(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(**a**) 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)";

(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";

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

(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".

PART 5

AMENDMENT OF EU TERTIARY LEGISLATION

Amendment of Commission Regulation (EC) No 353/2008

20.—(1) Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council is amended as follows.

(2) In paragraph (b) of Article 1 (subject matter), for "Article 13(3)" substitute "Article 13(4)".

(3) Omit Article 8.

(4) In the Annex, in paragraph 5, for "a competent authority of either a Member State or a third country" substitute "another country".

Amendment of Commission Regulation (EC) No 953/2009

21.—(1) 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 is amended as follows.

(2) For Article 1 (scope) substitute—

"1. This Regulation shall apply to foods for particular nutritional uses, excluding foodstuffs for particular nutritional use:

(a) fulfilling the particular requirements of infants and young children in good health in the United Kingdom and intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food;

(b) by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding; and

(c) by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants

2. In this Regulation:

"infants" means children under the age of 12 months;

"young children" means children aged between one and three years.".

(3) In Article 2 (eligible substances)—

(a) in paragraph 1, for "covered by Directive 2009/39/EC" substitute "(foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability)".

(b) in paragraph 2, for "Regulation (EC) No 258/97" substitute "Regulation (EU) 2015/2283".

(4) In Article 3 (general requirements) in paragraph 2, for "competent authorities referred to in Article 11 of Directive 2009/39/EC" substitute "Secretary of State, Welsh Ministers, Food Standards Scotland or the Food Standards Agency".

(5) In Article 4 (specific requirements for substances listed in the Annex)—

(a) omit paragraph 1;

(b) in paragraph 2, for "by Community legislation" substitute "in retained EU law";

(c) in paragraph 3—

(i) omit "by Community legislation" substitute "in retained EU law";

(ii) omit "National rules setting stricter purity criteria may be maintained".

(6) Omit Articles 5 and 6.

(7) In the Annex (Substances that may be added for specific nutritional purposes in foods for particular nutritional uses) for the definition of "foods for special medical purposes" substitute "means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two".

Amendment of Commission Regulation (EC) No 983/2009

22.—(1) 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 is amended as follows.

(2) In Article 1—

(a) for "Community" substitute "United Kingdom";

(b) omit the second sentence.

(3) Omit Articles 3 and 4.

Amendment of Commission Regulation (EC) No 984/2009

23.—(1) 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 is amended as follows.

(2) In Article 1, for "Community" substitute "United Kingdom".

(3) Omit Articles 2 and 3.

Amendment of Commission Regulation (EC) No 1024/2009

24.—(1) 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 is amended as follows.

(2) In Article 1—

(a) for "Community" substitute "United Kingdom";

(b) omit the second sentence.

(3) For Article 2, substitute—

"2. The health claims set out in Annex II to this Regulation may not be made on foods on the United Kingdom market.".

(4) Omit Article 3.

Amendment of Commission Regulation (EC) No 1025/2009

25.—(1) Commission Regulation (EC) No 1025/2009 of 29 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 is amended as follows.

(2) In Article 1—

(a) omit "Community";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EC) No 1167/2009

26.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in the first sentence, for "shall not be included" to the end of that sentence substitute "may not be made on foods on the United Kingdom market";

(b) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EC) No 1168/2009

27.—(1) Commission Regulation (EC) No 1168/2009 of 30 November 2009 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Community";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 375/2010

28.—(1) Commission Regulation (EU) No 375/2010 of 3 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Community";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 382/2010

29.—(1) Commission Regulation (EU) No 382/2010 of 5 May 2010 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 is amended as follows.

(2) In Article 1—

(a) omit "Community";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 383/2010

30.—(1) Commission Regulation (EU) No 383/2010 of 5 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Community";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 384/2010

31.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in the first sentence, for "European Union" substitute "United Kingdom";

(b) omit the second sentence.

(3) In Article 2, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(4) Omit Article 3.

Amendment of Commission Regulation (EU) No 957/2010

32.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in the first sentence, for "European Union" substitute "United Kingdom";

(b) omit the second sentence.

(3) In Article 2—

(a) in the first sentence, for the words from "shall not" to the end of that sentence, substitute "may not be made on foods on the United Kingdom market";

(b) omit the second sentence.

(4) Omit Article 3.

Amendment of Commission Regulation (EU) No 958/2010

33.—(1) Commission Regulation (EU) No 958/2010 of 5 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1161/2010

34.—(1) Commission Regulation (EU) No 1161/2010 of 9 December 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1162/2010

35.—(1) 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 is amended as follows.

(2) In Article 1–

(a) in the first sentence, for the words from "shall not" to the end of that sentence, substitute "may not be made on foods on the United Kingdom market";

(b) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 432/2011

36.—(1) Commission Regulation (EU) No 432/2011 of 4 May 2011 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 440/2011

37.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "European Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) In Article 2—

(a) in paragraph 1, for the words from "shall not" to the end of that paragraph, substitute "may not be made on foods on the United Kingdom market";

(b) omit paragraph 2.

(4) Omit Article 3.

Amendment of Commission Regulation (EU) No 665/2011

38.—(1) Commission Regulation (EU) No 665/2011 of 11 July 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "European Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) In Article 2, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market"

(4) Omit Article 3.

Amendment of Commission Regulation (EU) No 666/2011

39.—(1) Commission Regulation (EU) No 666/2011 of 11 July 2011 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1160/2011

40.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "European Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) In Article 2, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market.".

Amendment of Commission Regulation (EU) No 1170/2011

41.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market.".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1171/2011

42.—(1) Commission Regulation (EU) No 1171/2011 of 16 November 2011 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Implementing Regulation (EU) No 307/2012

43.—(1) 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 is amended as follows.

(2) In Article 2 (definitions)—

(a) omit the definition of "request";

(b) in the definition of "file", for "the Authority", substitute "an expert committee".

(c) after the definition of "placing on the market" insert–

"'appropriate authority' and 'expert committee' have the same meaning as in Regulation (EC) 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.".

(3) In Article 3 (conditions to be met for the request)—

(a) in paragraph 1—

(i) for "the assessment of" substitute "assessing";

(ii) for "Member States" substitute "parts of the United Kingdom";

(b) in paragraph 2, for "Member States may submit a request to the Commission when the assessment referred to in paragraph 1" substitute "The power to make regulations under Article 8 of Regulation (EC) No 1925/2006 may be exercised where the assessment referred to in paragraph 1";

(c) omit paragraph 4.

(4) In Article 4 (content of the Request)—

(a) for the heading substitute "Evidence required for the purposes of advice by an expert committee under Article 8 of Regulation 1925/2006";

(b) in paragraph 1—

(i) for "The request shall contain" substitute "In preparing advice for the purpose of Article 8 of Regulation (EC) No 1925/2006, the Committee shall consider ;

(ii) for "and shall include" substitute ", including";

(iii) omit the final sentence of point (b).

(c) omit paragraph 2;

(d) for paragraph 3 substitute—

"3. Where an expert committee is asked to provide advice for the purposes of Article 8 of Regulation (EC) No 1925/2006, it shall make public the evidence referred to in paragraph 1.";

(e) in paragraph 4—

(i) omit the first sentence;

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

(f) in paragraph 5—

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

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

(iii) after "opinion" insert ", except in cases of urgency".

(5) In Article 5 (substance included in Annex III, Part C)—

(a) for "Authority" in each place it appears substitute "expert committee";

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

(6) In Article 6 (opinion of the Authority)—

(a) for "Authority" in the heading and in each place it appears in paragraphs 1 and 2, substitute "expert committee";

(b) for "Authority's" substitute "expert committee's".

(7) Omit Article 7.

Amendment of Commission Regulation (EU) No 378/2012

44.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for the words from "shall not" to the end of that paragraph, substitute "may not be made on foods on the United Kingdom market";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 379/2012

45.—(1) Commission Regulation (EU) No 379/2012 of 3 May 2012 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 432/2012

46.—(1) Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In paragraph 1 of Article 1 (permitted health claims), for "Article 13(3)" substitute "Article 13(4)".

(3) Omit Article 2.

Amendment of Commission Implementing Regulation (EU) No 489/2012

47. Commission Implementing Regulation (EU) No 489/2012 of 8 June 2012 establishing implementing rules for the application of Article 16 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 is revoked.

Amendment of Commission Regulation (EU) No 1048/2012

48.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "European Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of 2013/63/EU: Commission Implementing Decision

49. 2013/63/EU: Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council is revoked.

Amendment of Commission Regulation (EU) No 851/2013

50.—(1) Commission Regulation (EU) No 851/2013 of 3 September 2013 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) in paragraph 1—

(i) omit "Union";

(ii) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(b) omit paragraph 2.

(3) Omit Articles 2 and 4.

Revocation of Commission Regulation (EU) No 907/2013

51. Commission Regulation (EU) No 907/2013 of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations) is revoked.

Amendment of Commission Regulation (EU) No 1017/2013

52.—(1) Commission Regulation (EU) No 1017/2013 of 23 October 2013 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1066/2013

53.—(1) Commission Regulation (EU) No 1066/2013 of 30 October 2013 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 40/2014

54.—(1) Commission Regulation (EU) No 40/2014 of 17 January 2014 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 3.

Amendment of Commission Regulation (EU) No 155/2014

55.—(1) Commission Regulation (EU) No 155/2014 of 19 February 2014 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 175/2014

56.—(1) Commission Regulation (EU) No 175/2014 of 25 February 2014 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1135/2014

57.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1154/2014

58.—(1) Commission Regulation (EU) No 1154/2014 of 29 October 2014 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Commission Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1226/2014

59.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) No 1228/2014

60.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) In Article 2, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(4) Omit Article 3.

Amendment of Commission Regulation (EU) No 1229/2014

61.—(1) Commission Regulation (EU) No 1229/2014 of 17 November 2014 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/7

62.—(1) Commission Regulation (EU) 2015/7 of 6 January 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 3.

Amendment of Commission Regulation (EU) 2015/8

63.—(1) Commission Regulation (EU) 2015/8 of 6 January 2015 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(c) omit the second sentence.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/391

64.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for the words from "shall not" to the end of that paragraph, substitute "may not be made on foods on the United Kingdom market";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/402

65.—(1) Commission Regulation (EU) 2015/402 of 11 March 2015 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Commission Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/539

66.—(1) Commission Regulation (EU) 2015/539 of 31 March 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) in paragraph 1—

(i) omit "Union";

(ii) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(b) in paragraph 2, for "the date of entry into force of this Regulation" substitute "21 April 2015".

(3) In Article 2, for "the date of entry into force of this Regulation" substitute "21 April 2015".

(4) Omit Article 4.

Amendment of Commission Regulation (EU) 2015/1041

67.—(1) Commission Regulation (EU) 2015/1041 of 30 June 2015 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/1052

68.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/1886

69.—(1) 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for the words from "shall not" to the end of that paragraph, substitute "may not be made on foods on the United Kingdom market".

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/1898

70.—(1) Commission Regulation (EU) 2015/1898 of 21 October 2015 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2015/2314

71.—(1) Commission Regulation (EU) 2015/2314 of 7 December 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) in paragraph 1—

(i) omit "Union";

(ii) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(b) in paragraph 2, for "the date of entry into force of this Regulation" substitute "1 January 2016".

(3) In Article 2, for "the date of entry into force of this Regulation" substitute "1 January 2016".

(4) Omit Article 4.

Amendment of Commission Delegated Regulation (EU) 2016/128

72.—(1) 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 is amended as follows.

(2) In Article 1 (placing on the market), after "food for special medical purposes" insert ", other than food for infants,".

(3) In Article 2 (compositional requirements), in paragraph 3, omit the first sentence.

(4) In Article 3 (requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children)—

(a) in the heading, omit "infants and";

(b) in paragraphs 2 and 4, omit "infants and".

(5) Omit Article 8.

(6) For Article 9 (notifications) substitute—

"1. When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each part of the United Kingdom where the product concerned is being marketed of the information appearing on the label, by sending to the competent authority 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. In this Article, "competent authority" means–

(a) in respect of food being placed on the market in England, the Secretary of State,

(b) in respect of food being placed on the market in Wales, the Welsh Ministers,

(c) in respect of food being placed on the market in Scotland, Food Standards Scotland,

(d) in respect of food being placed on the market in Northern Ireland, the Food Standards Agency.".

(7) Omit Articles 10 and 11.

Amendment of Commission Regulation (EU) 2016/371

73.—(1) Commission Regulation (EU) 2016/371 of 15 March 2016 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/372

74.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Implementing Regulation (EU) 2016/854

75.—(1) Commission Implementing Regulation (EU) 2016/854 of 30 May 2016 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 3.

Amendment of Commission Regulation (EU) 2016/862

76.—(1) Commission Regulation (EU) 2016/862 of 31 May 2016 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1379

77.—(1) Commission Regulation (EU) 2016/1379 of 16 August 2016 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1381

78.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1389

79.—(1) Commission Regulation (EU) 2016/1389 of 17 August 2016 authorising a health claim made on foods and referring to children's development and health is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for "Union" substitute "United Kingdom";

(b) omit paragraph 2.

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1390

80.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1411

81.—(1) Commission Regulation (EU) 2016/1411 of 24 August 2016 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2016/1412

82.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2017/236

83.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Implementing Regulation (EU) 2017/672

84.—(1) Commission Implementing Regulation (EU) 2017/672 of 7 April 2017 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 3.

Amendment of Commission Implementing Regulation (EU) 2017/676

85.—(1) Commission Implementing Regulation (EU) 2017/676 of 10 April 2017 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012".

(3) Omit Article 3.

Amendment of Commission Regulation (EU) 2017/1200

86.—(1) Commission Regulation (EU) 2017/1200 of 5 July 2017 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2017/1201

87.—(1) Commission Regulation (EU) 2017/1201 of 5 July 2017 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2017/1202

88.—(1) Commission Regulation (EU) 2017/1202 of 5 July 2017 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 is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2018/199

89.—(1) Commission Regulation (EU) 2018/199 of 9 February 2018 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health is amended as follows.

(2) In Article 1—

(a) omit "Union";

(b) for "as provided for in Article 13(3) of Regulation (EC) No 1924/2006" substitute "in the Annex to Regulation (EU) 432/2012";

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2018/1555

90.—(1) 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 is amended as follows.

(2) In Article 1, for the words from "shall not" to the end of that Article, substitute "may not be made on foods on the United Kingdom market".

(3) Omit Article 2.

Amendment of Commission Regulation (EU) 2018/1556

91.—(1) Commission Regulation (EU) 2018/1556 of 17 October 2018 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 is amended as follows.

(2) In Article 1—

(a) omit “Union”;

(b) for “as provided for in Article 13(3) of Regulation (EC) No 1924/2006” substitute “in the Annex to Regulation (EU) 432/2012”;

(3) Omit Article 2.

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

Parliamentary Under Secretary of State
Department of Health and Social Care

SCHEDULE 1

Regulation 2(1)(a)

Vitamins and minerals which may be used in the manufacture of food supplements

1. Vitamins	*2. Minerals*
Vitamin A (µg RE)	Calcium (mg)
Vitamin D (µg)	Magnesium (mg)
Vitamin E (mg α-TE)	Iron (mg)
Vitamin K (µg)	Copper (µg)
Vitamin B1 (mg)	Iodine (µg)
Vitamin B2 (mg)	Zinc (µg)
Niacin (mg NE)	Manganese (mg)
Pantothenic acid (mg)	Sodium (mg)
Vitamin B6 (mg)	Potassium (mg)
Folic acid (µg)	Selenium (µg)
Vitamin B12 (µg)	Chromium (µg)
Biotin (µg)	Molybdenum (µg)
Vitamin C (mg)	Fluoride (mg)
	Chloride (mg)
	Phosphorus (mg)
	Boron (mg)
	Silicon (mg)

SCHEDULE 2

Regulation 2(1)(b)

Vitamin and mineral substances which may be used in the manufacture of food supplements

A. Vitamins
1. VITAMIN A
(a) retinol
(b) retinyl acetate
(c) retinyl palmitate
(d) beta-carotene

2. VITAMIN D
(a) cholecalciferol
(b) ergocalciferol
3. VITAMIN E
(a) D-alpha-tocopherol
(b) DL-alpha-tocopherol
(c) D-alpha-tocopheryl acetate
(d) DL-alpha-tocopheryl acetate
(e) D-alpha-tocopheryl acid succinate
(f) mixed tocopherols
(g) tocotrienol tocopherol
4. VITAMIN K
(a) phylloquinone (phytomenadione)
(b) menaquinone
5. VITAMIN B1
(a) thiamin hydrochloride
(b) thiamine mononitrate
(c) thiamine monophosphate chloride
(d) thiamine pyrophosphate chloride
6. VITAMIN B2
(a) riboflavin
(b) riboflavin 5'-phosphate, sodium
7. NIACIN
(a) nicotinic acid
(b) nicotinamide
(c) inositol hexanicotinate (inositol hexaniacinate)
8. PANTOTHENIC ACID
(a) D-pantothenate, calcium
(b) D-pantothenate, sodium
(c) dexpanthenol
(d) pantethine
9. VITAMIN B6
(a) pyridoxine hydrochloride
(b) pyridoxine 5′-phosphate
(c) pyridoxal 5′-phosphate
10. FOLATE
(a) pteroylmonoglutamic acid
(b) calcium-L-methylfolate
(c) (6S)-5-methyltetrahydrofolic acid, glucosamine salt
11. VITAMIN B12
(a) cyanocobalamin
(b) hydroxocobalamin
(c) 5′-deoxyadenosylcobalamin
(d) methylcobalamin
12. BIOTIN
(a) D-biotin
13. VITAMIN C
(a) L-ascorbic acid
(b) sodium-L-ascorbate

(c) calcium-L-ascorbate
(d) potassium-L-ascorbate
(e) L-ascorbyl 6-palmitate
(f) magnesium L-ascorbate
(g) zinc L-ascorbate
B. Minerals
calcium acetate
calcium L-ascorbate
calcium bisglycinate
calcium carbonate
calcium chloride
calcium citrate malate
calcium salts of citric acid
calcium gluconate
calcium glycerophosphate
calcium lactate
calcium pyruvate
calcium salts of orthophosphoric acid
calcium succinate
calcium hydroxide
calcium L-lysinate
calcium malate
calcium oxide
calcium L-pidolate
calcium L-threonate
calcium sulphate
calcium phosphoryl oligosaccharides
magnesium acetate
magnesium L-ascorbate
magnesium bisglycinate
magnesium carbonate
magnesium chloride
magnesium salts of citric acid
magnesium gluconate
magnesium glycerophosphate
magnesium salts of orthophosphoric acid
magnesium lactate
magnesium L-lysinate
magnesium hydroxide
magnesium malate
magnesium oxide
magnesium L-pidolate
magnesium potassium citrate
magnesium pyruvate
magnesium succinate
magnesium sulphate
magnesium taurate
magnesium acetyl taurate
ferrous carbonate
ferrous citrate
ferric ammonium citrate

ferrous gluconate
ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl + electrolytic + hydrogen reduced)
ferrous bisglycinate
ferrous L-pidolate
ferrous phosphate
ferrous ammonium phosphate
ferric sodium EDTA
iron (II) taurate
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper L-aspartate
copper bisglycinate
copper lysine complex
copper (II) oxide
sodium iodide
sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc L-ascorbate
zinc L-aspartate
zinc bisglycinate
zinc chloride
zinc citrate
zinc gluconate
zinc lactate
zinc L-lysinate
zinc malate
zinc mono-L-methionine sulphate
zinc oxide
zinc carbonate
zinc L-pidolate
zinc picolinate
zinc sulphate
manganese ascorbate
manganese L-aspartate
manganese bisglycinate
manganese carbonate
manganese chloride
manganese citrate
manganese gluconate
manganese glycerophosphate

manganese pidolate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium chloride
sodium citrate
sodium gluconate
sodium lactate
sodium hydroxide
sodium salts of orthophosphoric acid
sodium sulphate
potassium sulphate
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium L-pidolate
potassium malate
potassium salts of orthophosphoric acid
L-selenomethionine
selenium enriched yeast
selenious acid
sodium selenate
sodium hydrogen selenite
sodium selenite
chromium (III) chloride
chromium enriched yeast
chromium (III) lactate trihydrate
chromium nitrate
chromium picolinate
chromium (III) sulphate
ammonium molybdate (molybdenum (VI))
potassium molybdate (molybdenum (VI))
sodium molybdate (molybdenum (VI))
calcium fluoride
potassium fluoride
sodium fluoride
sodium monofluorophosphate
boric acid
sodium borate
choline-stabilised orthosilicic acid
silicon dioxide
silicic acid
organic silicon (monomethylsilanetriol)

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) 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 and Schedules 1 and 2 make provision in relation to food supplements, transferring functions to legislate in respect of vitamins and minerals and purity criteria from the Commission to the Secretary of State, Scottish Ministers, Welsh Ministers and in relation to Northern Ireland, the Department of Health. Part 3 amends secondary legislation (for England) and Parts 4 and 5 amend and in some cases, revoke retained EU law in the field of nutrition and health claims.

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

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