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

[[X1]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**]**

[[X1]THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.

(2) Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.

(3) General labelling provisions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(3)]. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications.

This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.

(5) Generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, such as 'digestive' or 'cough drops', should be exempted from the application of this Regulation.

(6) Non-beneficial nutrition claims are not covered by the scope of this Regulation; Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the Commission and to other Member States in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(4)].

(7) At international level the Codex Alimentarius has adopted General Guidelines on Claims in 1991 and Guidelines for the Use of Nutrition Claims in 1997. An amendment to the latter has been adopted by the Codex Alimentarius Commission in 2004. That amendment concerns the inclusion of health claims in the 1997 Guidelines. Due consideration is given to the definitions and conditions set in the Codex Guidelines.

(8) The possibility of using the claim 'low fat' for spreadable fats provided for in Council Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats[(5)] should be adapted to the provisions of this Regulation as soon as possible. In the meantime, Regulation (EC) No 2991/94 applies for the products it covers.

(9) There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino-acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

(10) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances, or the nutrient profile of a product, are appropriate criteria for determining whether the product can bear claims. The use of such criteria at national level, whilst justified for the purpose of allowing consumers to make informed nutritional choices, is likely to result in barriers to intra-Community trade and should therefore be harmonised at Community level. Health information and communication supporting

national authority or Community messages about the dangers of misuse of alcohol should not fall under the scope of this Regulation.

(11) The application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. Nutrient profiles as provided for in this Regulation should be intended for the sole purpose of governing the circumstances in which claims may be made. They should be based on generally accepted scientific evidence relative to the relationship between diet and health. However, profiles should also allow for product innovation and should take into account the variability of dietary habits and traditions, and the fact that individual products may have an important role in the context of an overall diet.

(12) The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet should be taken into account and due regard should be given to the various dietary habits and consumption patterns existing in the Member States. Exemptions from the requirement to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical tasks and the adoption of the relevant measures should be entrusted to the Commission, taking into account the advice of the European Food Safety Authority.

(13) Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[(6)] presented in a liquid form and containing more than 1,2 % by volume of alcohol are not considered as beverages under this Regulation.

(14) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.

(15) In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body. In addition, and where appropriate, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed.

(16) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning

misleading and comparative advertising[7], the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.

(17) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(18) A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice.

(19) Given the positive image conferred on foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.

(20) General nutritional labelling provisions are contained in Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs[8]. According to that Directive, where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling should be compulsory. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given should be that of Group 2 as defined in Article 4(1) of Directive 90/496/EEC. In order to achieve a high level of consumer protection, this obligation to provide the information of Group 2 should apply mutatis mutandis where any health claim is made, with the exception of generic advertising.

(21) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. Any claim considered to have the same meaning for consumers as a nutrition claim included in the abovementioned list should be subject to the same conditions of use indicated therein. For example, claims related to the addition of vitamins and minerals such as ‘with …’, ‘restored …’, ‘added …’, or ‘enriched …’ should be subject to the conditions set for the claim ‘source of …’. The list should be regularly updated in order to take into account

scientific and technological developments. Furthermore, for comparative claims it is necessary that the products being compared be clearly identified to the final consumer.

(22) Conditions for claims such as ‘lactose-free’ or ‘gluten-free’, addressed to a group of consumers with specific disorders, should be dealt with in Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[9]. In addition, that Directive provides the possibility that foodstuffs for normal consumption can indicate their suitability for use by these groups of consumers if they fulfil the conditions for such statement. Until the conditions for such statements are set at Community level, Member States may maintain or adopt relevant national measures.

(23) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments. Upon request the applicant should be able to have access to his file to check the state of the procedure.

(24) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate, when using psychological and behavioural claims, to require scientific substantiation.

(25) In the light of Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[10] which prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, it is considered appropriate to extend this restriction to all foods.

(26) Health claims other than those referring to the reduction of disease risk and to children's development and health, based on generally accepted scientific evidence, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a Community list of such permitted claims after consulting the European Food Safety Authority. Furthermore, in order to stimulate innovation, those health claims which are based on newly developed scientific evidence should undergo an accelerated type of authorisation.

(27) In order to keep up with scientific and technological developments, the list referred to above should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

(28) Diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.

(29) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the European Food Safety Authority and in subsequent procedures.

(30) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.

(31) For the sake of transparency and in order to avoid multiple applications in respect of claims which have already been assessed, a public Register containing the lists of such claims should be established and updated by the Commission.

(32) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials, and to facilitate access to claims by small and medium-sized enterprises (SMEs), which rarely have the financial capacity to carry out research activities.

(33) SMEs represent an important added value to the European food industry in terms of quality and preservation of different dietary habits. In order to facilitate the implementation of this Regulation, the European Food Safety Authority should make available appropriate technical guidance and tools, in due time, especially for SMEs.

(34) Given the particular nature of foods bearing claims, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.

(35) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation.

(36) Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(37) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[11],

HAVE ADOPTED THIS REGULATION:

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 404 of 30 December 2006).

Modifications etc. (not altering text)

C1 Regulation applied (with modifications) (N.I.) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(a), **Sch. 1** (with regs. 7, 8)

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

[F1] 1 . . . . . .

2 This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

[[F2]In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply **[**[F3], unless the appropriate authority by regulations prescribes that those provisions shall apply**]**. [F4]...**]**

This Regulation shall also apply in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

3 A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.

[[F2]4 For generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, **[**[F5]the appropriate authority may by regulations grant a derogation from paragraph 3**]**, on application by the food business operators concerned. The application shall be sent to the **[**[F6]competent authority**]** which will forward it to the **[**[F7]relevant authorities**]** without delay. **[**[F8]The appropriate authority may publish guidelines setting out the procedure and requirements for applications made by food business operators under this paragraph.**]]**

5 This Regulation shall apply without prejudice to [F9]...:

a **[**[F10]Regulation (EU) No 609/2013 and other relevant enactments**]** relating to foodstuffs for particular nutritional uses;

b [F11enactments implementing] Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters [12][F12and 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)];

c [F13enactments implementing] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [13] ;

d [F14enactments implementing] Directive 2002/46/EC.

Textual Amendments

F1 Art. 1(1) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F3 Words in Art. 1(2) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Art. 1(2) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 1(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in Art. 1(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Art. 1(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Art. 1(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(c)(iv)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in Art. 1(5) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Art. 1(5)(a) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 1(5)(b) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in Art. 1(5)(b) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in Art. 1(5)(c) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Art. 1(5)(d) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(2)(d)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Definitions

1 For the purposes of this Regulation:

a the definitions of ‘food’, ‘food business operator’, ‘placing on the market’, and ‘final consumer’ set out in Articles 2, 3(3), 3(8) and 3(18) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 [(14)] shall apply;

b the definition of ‘ food supplement ’ set out in Directive 2002/46/EC shall apply;

c the definitions of ‘nutrition labelling’, ‘protein’, ‘carbohydrate’, ‘sugars’, ‘fat’, ‘saturates’, ‘mono-unsaturates’, ‘poly-unsaturates’, ‘fibre’ set out in **[**[F15]Annex I to Regulation (EU) 1169/2011**]** shall apply;

d the definition of ‘ labelling ’ set out in **[**[F16]Article 2(1)(j) of Regulation (EU) 1169/2011**]** shall apply.

2 The following definitions shall also apply:

1 ‘claim’ means any message or representation, which is not mandatory under **[**[F17]any enactment**]**, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;

2 ‘nutrient’ means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in **[**[F18]Annex I to Regulation (EU) 1169/2011**]**, and substances which belong to or are components of one of those categories;

3 ‘other substance’ means a substance other than a nutrient that has a nutritional or physiological effect;

4 ‘nutrition claim’ means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

a the energy (calorific value) it

i provides;

ii provides at a reduced or increased rate; or

iii does not provide; and/or

b the nutrients or other substances it

i contains;

ii contains in reduced or increased proportions; or

iii does not contain;

5 ‘health claim’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

6 ‘reduction of disease risk claim’ means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

[[F19]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;**]**

[[F20]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;

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

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

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

10 'relevant authorities' means the Secretary of State, the Scottish Ministers and the Welsh Ministers;

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.**]**

Textual Amendments

F15 Words in Art. 2(1)(c) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in Art. 2(1)(d) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in Art. 2.2(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in Art. 2.2(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F19 Art. 2.2(7) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F20 Art. 2.2(8)-(11) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(3)(b)(iv)** (as amended by (S.I. 2020/1476), regs. 1(2), 5(2)(b)); 2020 c. 1, **Sch. 5 para. 1(1)**

CHAPTER II

GENERAL PRINCIPLES

Article 3

General principles for all claims

Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market [F21]... only if they comply with the provisions of this Regulation.

Without prejudice to **[**[F22]Regulation (EU) No 1169/2011 and the Business Protection from Misleading Marketing Regulations 2008**]**, the use of nutrition and health claims shall not:

(a) be false, ambiguous or misleading;

(b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;

(d) **[**[F2]state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. **[**[F23]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 Great Britain in relation to which the regulations are to be made.**]]**

(e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

Textual Amendments

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F21 Words in Art. 3 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in Art. 3 substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in Art. 3(d) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(4)(b)(ii)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 4

Conditions for the use of nutrition and health claims

1 **[**[F24]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.**]**

The nutrient profiles for food and/or certain categories of food shall be established taking into account in particular:

a the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;

b the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;

c the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

The nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.

[[F25]Before making regulations to establish the nutrient profiles, the appropriate authority must request an expert committee**]** to provide within 12 months relevant scientific advice, focusing in particular on:

(i) whether profiles should be set for food in general and/or categories of food;

(ii) the choice and balance of nutrients to be taken into account;

(iii) the choice of reference quantity/basis for profiles;

(iv) the approach to the calculation of the profiles; and

(v) the feasibility and testing of a proposed system.

[[F26]Before making regulations to establish the nutrient profiles, the appropriate authority must carry out consultations with the other relevant authorities and**]** interested parties, in particular food business operators and consumer groups.

[[F27]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.**]**

2 By way of derogation from paragraph 1, nutrition claims:

a referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation;

b shall be allowed, where a single nutrient exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows: 'High [(15)] content'.

3 Beverages containing more than 1,2 % by volume of alcohol shall not bear health claims.

As far as nutrition claims are concerned, only nutrition claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content for beverages containing more than 1,2 % by volume of alcohol, shall be permitted.

[F28] 4 . . . . . .

[[F2]5 **[**[F29]The appropriate authority may by regulations specify**]** the foods or categories of foods other than those referred to in paragraph 3 for which nutrition or health claims are to be restricted or prohibited **[**[F30], in the light of scientific evidence.**]]**

Textual Amendments

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F24 Words in Art. 4(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F25 Words in Art. 4(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F26 Words in Art. 4(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Words in Art. 4(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F28 Art. 4(4) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F29 Words in Art. 4(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F30 Words in Art. 4(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(5)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 5

General conditions

1 The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

a the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;

b the nutrient or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity as defined in **[**F31applicable enactments**]** or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or

(ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;

c where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;

d the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in **[**F32applicable enactments**]** or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;

e compliance with the specific conditions set out in Chapter III or Chapter IV as the case may be.

2 The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

3 Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

Textual Amendments

F31 Words in Art. 5(1)(b)(i) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(6)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Art. 5(1)(d) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(6)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Scientific substantiation for claims

1 Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.

2 A food business operator making a nutrition or health claim shall justify the use of the claim.

3 The **[**F33competent authority**]** may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation.

Textual Amendments

F33 Words in Art. 6(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 7

Nutrition information

[F34Nutrition labelling of products on which a nutrition and/or health claim is made shall be mandatory, with the exception of generic advertising. The information to be provided shall consist of that specified in Article 30(1) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers [(16)] . Where a nutrition and/or health claim is made for a nutrient referred to in Article 30(2) of Regulation (EU) No 1169/2011 the amount of that nutrient shall be declared in accordance with Articles 31 to 34 of that Regulation.

The amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall be stated in the same field of vision as the nutrition labelling and be expressed in accordance with Articles 31, 32 and 33 of Regulation (EU) No 1169/2011. The units of measurement used to express the amount of the substance shall be appropriate for the individual substances concerned.

In the case of food supplements, the nutrition information shall be provided in accordance with Article 8 of Directive 2002/46/EC. **[**F35For 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".**]]**

Textual Amendments

F34 Substituted by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (Text with EEA relevance).

F35 Words in Art. 7 inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(8)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

NUTRITION CLAIMS

Article 8

Specific conditions

1 Nutrition claims shall only be permitted if they are listed in the Annex and are in conformity with the conditions set out in this Regulation.

[[F2]2 **[**[F36]The appropriate authority may by regulations amend the Annex, after consulting an expert committee.**]** Where appropriate, the **[**[F37]appropriate authority**]** shall involve interested parties, in particular food business operators and consumer groups, in order to evaluate the perception and understanding of the claims in question.**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F36 Words in Art. 8(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F37 Words in Art. 8(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 9

Comparative claims

1 Without prejudice to **[**[F38]the Business Protection from Misleading Marketing Regulations 2008**]**, a comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.

2 Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.

Textual Amendments

F38 Words in Art. 9(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(10)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV

HEALTH CLAIMS

Article 10

Specific conditions

1 Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and **[**F39are 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**]**.

2 Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

a a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;

b the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

c where appropriate, a statement addressed to persons who should avoid using the food; and

d an appropriate warning for products that are likely to present a health risk if consumed to excess.

3 Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim **[**F40authorised for the purposes of Article 13 or 14**]**.

4 Where appropriate, **[**F41the appropriate authority may, after consultation with interested parties, in particular food business operators and consumer groups, publish guidelines on the implementation of this Article.**]**

Textual Amendments

F39 Words in Art. 10(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(11)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F40 Words in Art. 10(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(11)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F41 Words in Art. 10(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(11)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F42 Article 11

National associations of medical, nutrition or dietetic professionals and health-related charities

. . . . . .

Textual Amendments

F42 Art. 11 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(12)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 12

Restrictions on the use of certain health claims

The following health claims shall not be allowed:

(a) claims which suggest that health could be affected by not consuming the food;

(b) claims which make reference to the rate or amount of weight loss;

(c) claims which make reference to recommendations of individual doctors or health professionals and **[**[F43]associations other than national associations of medical, nutrition or dietetic professionals and health-related charities.**]**

Textual Amendments

F43 Words in Art. 12(c) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(13)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Health claims other than those referring to the reduction of disease risk and to children's development and health

1 Health claims describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body; or

(b) psychological and behavioural functions; or

(c) without prejudice to **[**[F44]any enactment implementing**]** Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

which are indicated in the list **[**[F45]in the Annex to Commission Regulation (EU) 432/2012**]** may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

[F46] 2 . . . . . .

[F47] 3 . . . . . .

[F48 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.**]**

Textual Amendments

F44 Words in Art. 13(1)(c) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(14)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F45 Words in Art. 13(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(14)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F46 Art. 13(2) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(14)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F47 Art. 13(3) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(14)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F48 Art. 13(4)(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(14)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 14

Reduction of disease risk claims and claims referring to children's development and health

[F49 1 Notwithstanding **[**F50 Article 7(3) of Regulation (EU) 1169/2011**]**, **[**F51 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,**]** in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation F52...:

a reduction of disease risk claims;

b claims referring to children's development and health.**]**

[F53 1A Claims which have been authorised for the purposes of Article 14 before IP completion day are to be treated as authorised for use in Great Britain on and after IP completion 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.**]**

2 In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Textual Amendments

F49 Substituted by Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

F50 Words in Art. 14(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(15)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F51 Words in Art. 14(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(15)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in Art. 14(1) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(15)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Art. 14(1A) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(15)(d)** (as amended by (S.I. 2020/1476), regs. 1(2), 5(2)(d)); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 15

Application for authorisation

1 When reference is made to this Article, an application for authorisation shall be submitted in accordance with the following paragraphs.

[F54 1A An application may be made either:

a for authorisation in Great Britain; or

b for authorisation in one of England, Scotland or Wales 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 Great Britain, any competent authority.**]**

2 F55...

a The F56... competent authority shall:

(i) acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform without delay **[**F57an expert committee and the relevant authorities**]**; and

(iii) make the application and any supplementary information supplied by the applicant available to the **[**F58expert committee and the relevant authorities**]**;

b The **[**F59expert committee**]** shall:

(i) F60...

(ii) make the summary of the application referred to in paragraph 3(g) available to the public.

3 The application shall include the following:

a the name and address of the applicant;

[[F61]aa a statement confirming whether the application is for authorisation of the claim for use–

i in Great Britain; or

ii in one of England, Scotland or Wales only;**]**

b the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;

c a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;

d where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

e a copy of other scientific studies which are relevant to that health claim;

f a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

g a summary of the application.

[[F62]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.**]**

5 **[**[F63]The appropriate authority, in close cooperation with an expert committee and the other relevant authorities, may issue**]** appropriate technical guidance and tools to assist food business operators, in particular SMEs, in the preparation and presentation of the application for scientific assessment.

Textual Amendments

F54 Art. 15(1A)(1B) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(a)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(e)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F55 Words in Art. 15(2) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F56 Word in Art. 15(2)(a) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F57 Words in Art. 15(2)(a)(ii) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F58 Words in Art. 15(2)(a)(iii) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F59 Words in Art. 15(2)(b) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F60 Art. 15(2)(b)(i) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(b)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F61 Art. 15(3)(aa) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(c)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(e)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F62 Art. 15(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F63 Words in Art. 15(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(16)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 16

Opinion of the [F64expert committee]

1 In giving its opinion, the **[**F65expert committee**]** shall respect a time limit of five months from the date of receipt of a valid application. Whenever the **[**F65expert committee**]** seeks supplementary information from the applicant as provided for in paragraph 2, such time limit shall be extended by up to two months following the date of receipt of the requested information submitted by the applicant.

2 **[**F66The expert committee or the competent authority through the expert committee**]** may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

3 In order to prepare its opinion, the **[**F67expert committee**]** shall verify:

a that the health claim is substantiated by scientific evidence;

b that the wording of the health claim complies with the criteria laid down in this Regulation.

4 In the event of an opinion in favour of authorising the health claim, the opinion shall include the following particulars:

a the name and address of the applicant;

b the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;

c a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use;

d where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

5 The **[**F68expert committee**]** shall forward its opinion to the **[**F69relevant authorities**]** and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based.

[F706 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.**]**

Textual Amendments

F64 Words in Art. 16 heading substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F65 Words in Art. 16(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F66 Words in Art. 16(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F67 Words in Art. 16(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F68 Words in Art. 16(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F69 Words in Art. 16(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F70 Art. 16(6) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(17)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 17

[F71Authorisation by the appropriate authority]

F72 1 . . . . . .

F72 2 . . . . . .

[F2 3 [F73Where the application is made on a Great Britain-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; and

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

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

[F74Where the application is made for authorisation in one of England, Scotland or Wales only, the appropriate authority shall make a decision on the application, having consulted the other relevant authorities.]

However, where at the applicant's request for the protection of proprietary data, [F75the appropriate authority] proposes to restrict the use of the claim in favour of the applicant:

[F76a 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.]]

F77 4 . . . . . .

5 Health claims [F78authorised for the purposes of Articles 13 and 14] may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 21.

6 The granting of authorisation shall not lessen the general civil and criminal liability of any food business operator in respect of the food concerned.

Textual Amendments

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F71 Art. 17 heading substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F72 Art. 17(1)(2) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Words in Art. 17(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(c)(i)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(f)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F74 Words in Art. 17(3) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(c)(ii)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(f)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Words in Art. 17(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(c)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F76 Art. 17(3)(a)(b) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(c)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F77 Art. 17(4) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F78 Words in Art. 17(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(18)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 18

Claims referred to in Article 13(5)

1 A food business operator intending to use a health claim not included in the list **[**F79in the Annex to Commission Regulation (EU) 432/2012**]** may apply for the inclusion of the claim in that list.

[F80 1A The application for this inclusion may be made either:

a for use of the health claim in Great Britain; or

b for use of the health claim in one of England, Scotland or Wales 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 Great Britain, any competent authority.**]**

2 **[**F81The competent authority**]** shall acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application. The application shall include the data provided for in Article 15(3) and the reasons for the request.

3 The valid application, in line with the guidance referred to in Article 15(5), and any information supplied by the applicant shall be sent without delay to **[**F82an expert committee**]** for a scientific assessment as well as to **[**F83the relevant authorities**]** for information. The **[**F84expert committee**]** shall issue its opinion within a time limit of five months from the date of receipt of the request. Such time limit may be extended by up to one month if the **[**F84expert committee**]** considers it necessary to seek supplementary information from the applicant. In such a case the applicant shall submit the requested information within 15 days from the date of receipt of the **[**F85expert committee's**]** request.

The procedure laid down in Article 16(3)(a) and (b), (5) and (6) shall apply mutatis mutandis.

[F86 4 Where the application is for the use of the health claim in Great Britain, 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; and

c the appropriate authority for applications in relation to Wales, in relation to authorisation of the claim in Wales.

The appropriate authorities for each of England, Scotland and Wales 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.**]**

[F87 4A Where the application is for the use of the health claim in one of England, Scotland or Wales 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.**]**

[F88 5 F89...

F90... where at the applicant's request for the protection of proprietary data **[**F91 the appropriate authority**]** proposes to restrict the use of the claim in favour of the applicant:

[F92 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.**]]**

Textual Amendments

F79 Words in Art. 18(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Art. 18(1A)(1B) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(b)** (as amended by (S.I. 2020/1476), regs. 1(2), 5(2)(g)(i)); 2020 c. 1, **Sch. 5 para. 1(1)**

F81 Words in Art. 18(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F82 Words in Art. 18(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F83 Words in Art. 18(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F84 Words in Art. 18(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(d)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F85 Words in Art. 18(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(d)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F86 Art. 18(4) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(e)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(g)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F87 Art. 18(4A) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(f)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(g)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F88 Inserted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F89 Words in Art. 18(5) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F90 Word in Art. 18(5) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(g)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F91 Words in Art. 18(5) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(g)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F92 Art. 18(5)(a)(b) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(19)(g)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 19

Modification, suspension and revocation of authorisations

1 **[**F93The 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.**]** The procedures laid down in Articles 15 to 18 shall apply mutatis mutandis.

2 F94... Following a request from **[**F95an appropriate authority, an expert committee**]** shall issue an opinion on whether a health claim **[**F96authorised for the purposes of Article 13 or 14**]** still meets the conditions laid down in this Regulation.

It shall forthwith transmit its opinion to the **[**F97relevant authorities**]** and, where relevant, to the original applicant of the claim in question. The **[**F98expert committee**]** shall make its opinion public.

The applicant/user or a member of the public may make comments to the **[**F99appropriate authority**]** within 30 days of such publication.

[F100The appropriate authority shall examine the opinion of the expert committee**]** and any comments received as soon as possible. **[**F101Having 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.**]**

[F102**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.**]**

Textual Amendments

F93 Words in Art. 19(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F94 Words in Art. 19(2) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F95 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F96 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F98 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F99 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)

F100 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(vii)**; 2020 c. 1, Sch. 5 para. 1(1)

F101 Words in Art. 19(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(b)(viii)**; 2020 c. 1, Sch. 5 para. 1(1)

F102 Art. 19(3) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(20)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER V

GENERAL AND FINAL PROVISIONS

Article 20

[F103]... Register

1 **[**[F104]The appropriate authority must**]** establish and maintain a [F105]... Register of nutrition and health claims made on food, hereinafter referred to as ‘the Register’ .

2 The Register shall include the following:

a the nutrition claims and the conditions applying to them as set out in the Annex;

b restrictions adopted in accordance with Article 4(5);

c the authorised health claims and the conditions applying to them provided for in **[**[F106]the list in the Annex to Commission Regulation (EU) 432/2012, as amended from time to time**]**, Articles 14(1), 19(2), 21 [F107]...;

d a list of rejected health claims and the reasons for their rejection.

Health claims authorised on the basis of proprietary data shall be recorded in a separate Annex to the Register together with the following information:

1) the date **[**[F108]the health claim was authorised**]** and the name of the original applicant that was granted authorisation.

2) **[**[F2]the fact that **[**[F108]the health claim was authorised**]** on the basis of proprietary data and restricted use;

3) in the cases referred to in Article 17(3), second subparagraph, and Article 18(5), second subparagraph, the fact that the health claim is authorised for a limited duration.**]**

3 The Register shall be made available to the public.

Textual Amendments

F2 Substituted by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission.

F103 Word in Art. 20 heading omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F104 Words in Art. 20(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F105 Word in Art. 20(1) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F106 Words in Art. 20(2)(c) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(c)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F107 Words in Art. 20(2)(c) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(c)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F108 Words in Art. 20.2(1)(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(21)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 21

Data protection

1 The scientific data and other information in the application required under Article 15(3) may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

a the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and

b the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and

c the health claim could not have been authorised without the submission of the proprietary data by the prior applicant.

2 Until the end of the five-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the **[**[F109]appropriate authority**]** takes a decision on whether a claim could be or could have been **[**[F110]authorised under**]** Article 14 or, where appropriate, Article 13 without the submission of data designated as proprietary by the prior applicant.

Textual Amendments

F109 Words in Art. 21(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(22)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F110 Words in Art. 21(2) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(22)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

I[F111] *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.

Textual Amendments

F111 Arts. 21A-21D inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(23)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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 or Wales 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.

Textual Amendments

F111 Arts. 21A-21D inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(23)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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).

Textual Amendments

F111 Arts. 21A-21D inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(23)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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.**]**

Textual Amendments

F111 Arts. 21A-21D inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(23)** (as amended by S.I. 2020/1476, regs. 1(2), **5(2)(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F112 Article 22

National provisions

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Article 23

Notification procedure

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Article 24

Safeguard measures

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Article 25

Committee procedure

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Article 26

Monitoring

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Article 27

Evaluation

. . . . . .

Textual Amendments

F112 Arts. 22-27 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(24)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 28

Transitional measures

1 F113...With regard to the provisions in Article 4(1), foods may be marketed until twenty-four months following adoption of the relevant nutrient profiles and their conditions of use.

2 Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.

F114 3 . . . . . .

F114 4 . . . . . .

F114 5 . . . . . .

F114 6 . . . . . .

Textual Amendments

F113 Words in Art. 28(1) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(25)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F114 Art. 28(3)-(6) omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(25)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 29

Entry into force

F115 . . . . . .

Textual Amendments

F115 Art. 29 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651), regs. 1(1), **17(26)**; 2020 c. 1, Sch. 5 para. 1(1)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX

Nutrition claims and conditions applying to them

LOW ENERGY

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

ENERGY-REDUCED

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

ENERGY-FREE

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

LOW FAT

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).

FAT-FREE

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as ‘X % fat-free’ shall be prohibited.

LOW SATURATED FAT

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

SATURATED FAT-FREE

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.

LOW SUGARS

A claim that a food is low in sugars, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids.

SUGARS-FREE

A claim that a food is sugars-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugars per 100 g or 100 ml.

WITH NO ADDED SUGARS

A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any

added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.

LOW SODIUM/SALT

A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.

VERY LOW SODIUM/SALT

A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.

SODIUM-FREE or SALT-FREE

A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g.

[[F116]NO ADDED SODIUM/SALT

A claim stating that sodium/salt has not been added to a food and any claim likely to have the same meaning for the consumer may only be made where the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.**]**

SOURCE OF FIBRE

A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.

HIGH FIBRE

A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 (kcal.

SOURCE OF PROTEIN

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.

HIGH PROTEIN

A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 % of the energy value of the food is provided by protein.

SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]

A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[17].

HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]

A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]'.

CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]

A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.

INCREASED [NAME OF THE NUTRIENT]

A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30 % compared to a similar product.

REDUCED [NAME OF THE NUTRIENT]

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a similar product, except for micronutrients, where a 10 % difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.

[[F116]The claim 'reduced saturated fat', and any claim likely to have the same meaning for the consumer, may only be made:

(a) if the sum of saturated fatty acids and of trans-fatty acids in the product bearing the claim is at least 30 % less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and

(b) if the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product.

The claim 'reduced sugars', and any claim likely to have the same meaning for the consumer, may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product.**]**

LIGHT/LITE

A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.

NATURALLY/NATURAL

Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.

[[F117]SOURCE OF OMEGA-3 FATTY ACIDS

A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

HIGH OMEGA-3 FATTY ACIDS

A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

HIGH MONOUNSATURATED FAT

A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20 % of energy of the product.

HIGH POLYUNSATURATED FAT

A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.

HIGH UNSATURATED FAT

A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 70 % of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20 % of energy of the product.**]]**

(1) **[**[X1]OJ C 110, 30.4.2004, p. 18.**]**

(2) **[**[X1]Opinion of the European Parliament of 26 May 2005 (OJ C 117 E, 18.5.2006, p. 187), Council common position of 8 December 2005 (OJ C 80 E, 4.4.2006, p. 43) and Position of the European Parliament of 16 May 2006 (not yet published in the Official Journal). Council Decision of 12 October 2006.**]**

(3) **[**[X1]OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).**]**

(4) **[**[X1]OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.**]**

(5) **[**[X1]OJ L 316, 9.12.1994, p. 2.**]**

(6) **[**[X1]OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).**]**

(7) **[**[X1]OJ L 250, 19.9.1984, p. 17. Directive as last amended by Directive 2005/29/EC of the European Parliament and of the Council (OJ L 149, 11.6.2005, p. 22).**]**

(8) **[**[X1]OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51).**]**

(9) **[**[X1]OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).**]**

(10) **[**[X1]OJ L 55, 6.3.1996, p. 22.**]**

(11) **[**[X1]OJ L 184, 17.7.1999, p. 23.**]**

(12) **[**[X1]OJ L 229, 30.8.1980, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.**]**

(13) **[**[X1]OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003.**]**

(14) **[**[X1]OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).**]**

(15) **[**[X1]The name of the nutrient exceeding the nutrient profile.**]**

(16) **[**[X1]**[**[F34]OJ L 304, 22.11.2011, p. 18.**]]**

(17) **[**[X1]OJ L 404, 30.12.2006, p. 26.**]**

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 404 of 30 December 2006).

Textual Amendments

F34 Substituted by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (Text with EEA relevance).

Status:
Point in time view as at 01/10/2023.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1924/2006 of the european parliament and of the council.