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Department of Health & Social Care (https://www.gov.uk/government/organisations/department-of-health-and-social-care)

Guidance

Nutrition legislation information sheet

Updated 10 November 2022

Applies to England, Scotland and Wales

Contents

This publication is available at https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet--2

Nutrition law

Following the UK's departure from the EU on 31 January 2020, the UK entered a time limited transition period until 31 December 2020. Since the transition period has ended, regulation is an autonomous matter for both the UK and the EU as 2 separate legal and regulatory systems.

From 1 January 2021, EU regulations and tertiary legislation relating to nutrition were retained in accordance with the European Union (Withdrawal) Act 2018 as UK law. Retained EU regulations and tertiary legislation were subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities and functions to legislate, in respect of nutrition legislation from the EU Commission to the competent authorities in Great Britain (GB). The Department of Health and Social Care (DHSC), Food Standards Scotland (FSS) and the Welsh Government are the competent authorities for each nation.

The Protocol on Ireland/Northern Ireland (NIP) provides that EU legislation relating to nutrition, as detailed in Annex 2 of the NIP, continues to be directly applicable in Northern Ireland (NI).

Northern Ireland continues to play a vital role in policy development for nutrition legislation in GB, as Northern Ireland's full participation in risk assessment and risk management processes ensure that any decisions taken in GB account for the potential impacts across the UK, as set out under the arrangements agreed in the UK-wide provisional common framework for nutrition labelling, composition and standards (NLCS). This is to ensure among other things, that any impacts on the UK internal market are minimised. The UK government remains committed to promoting robust food standards nationally and internationally, to protect consumer interests, and to ensure that consumers can have confidence in the food they buy.

Important information

If you are a food business operator, the information provided in this document will help you understand the specific nutrition-related rules you must comply with if you are providing nutrition information on foods and drinks, or selling, manufacturing or importing food supplements, fortified foods, foods making health claims or nutrition claims and food for specific groups (FSG), for example, food for infants and young children (infant formula, follow-on formula, processed cereal-based baby foods and baby foods), food for specific medical purposes (FSMP), and total diet replacement for weight control.

If after reading this information your query is not resolved, seek further advice from your local authority Trading Standards or Environmental Health office (https://www.gov.uk/find-local-trading-standards-office). You may also obtain your own independent legal advice from a legal professional.

If you are a consumer with a complaint about a product, contact the Citizens Advice Consumer Helpline (CACH) Advice Guideline For Consumers (http://www.adviceguide.org.uk/england/consumer_e/consumer_protection_for_the_consumer_e/consumer_citizens_advice_consumer_service_e/if_you_need_more_help.htm).

Citizens Advice has an agreement with Trading Standards to help you report a problem to them.

If you are a local authority enforcement officer, refer your enquiry to your local and neighbouring Authorities. If your enquiry is not resolved, the matter should be referred to your Regional Liaison Group. The Knowledge Hub's (https://khub.net/web/foodstandardsandlabelling) Food Standards and Labelling Group is also a useful forum to seek advice. If the Regional Liaison Group or Knowledge Hub is not able to answer the query, it should be forwarded to the National Food Standards and Labelling Focus Group. Information relating to the process of referring queries involving food standards and labelling issues can be found on the Knowledge Hub and on the Food Standards Agency (FSA) website (http://www.food.gov.uk/).

a) Registering a food business (for food businesses)

If you are selling foods and drinks, including any of the food categories referred to in this guidance, you must register your business with the Environmental Health or Trading Standards service at your local authority. For further advice you are advised to speak to the food law enforcement office in your local authority (https://www.gov.uk/find-local-trading-standards-office). You can download an application form (https://www.food.gov.uk/business-guidance/register-a-food-business) on the FSA website.

There is useful information about setting up your business at:

- GOV.UK information on setting up a food business (https://www.gov.uk/browse/business/food)
- GOV.UK Business support helplines (https://www.gov.uk/business-support-helpline)
- Food Standards Agency information on setting up a food business (http://www.food.gov.uk/business-industry/caterers/startingup)

You may also wish to consider establishing a primary authority partnership (PDF, 969KB) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data

/file/301512/13-1310-pa-handbook.pdf) with a single local authority.

b) Guidance documents

Many questions about nutrition and general food labelling on foods and drinks, food supplements, fortified foods, nutrition and health claims, and food for specific groups (for example, infant formula, follow-on formula, processed cereal-based baby foods and baby foods, food for special medical purposes, and total diet replacement for weight control) will be answered by the following guidance documents:

- technical guidance on the nutrition labelling provisions of retained Regulation (EU) No 1169/2011 (https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling)
- food labelling: giving food information to consumers (https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers)
- Regulation (EU) No 1169/2011 (https://www.legislation.gov.uk/eur/2011/1169/contents)
- UK front-of-pack guidance (https://www.gov.uk/government/publications/front-of-pack-nutrition-labelling-guidance)
- food supplements guidance and FAQs (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs)
- guidance on fortified foods (https://www.gov.uk/government/publications/fortified-foods-guidance-to-compliance-with-european-regulation-ec-no-1925-2006-on-the-addition-of-vitamins-and-minerals-and-certain-other-substances-to-food)
- guidance on nutrition and health claims (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods)
- guidance and notification forms for introducing medical foods and infant formula on the GB market (https://www.gov.uk/government/publications/infant-formula-and-foods-for-particular-nutritional-uses-parnuts-notification-requirements)
- Department of Health and Social Care (DHSC) bulletins on nutrition and health claims (https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2014)
- DHSC bulletins on food for specific groups (https://www.gov.uk/government/publications/updates-about-legislation-on-food-for-specific-groups-2013)
- information on food labelling (https://www.gov.uk/food-labelling-and-packaging)

c) Department of Health and Social Care

DHSC is unable to authorise the composition or labelling of individual products. For advice on a specific product, including the checking of labels and interpretation of nutrition legislation, you must contact the food law enforcement office in your local authority. This tool will help you find your nearest Trading Standards office (https://www.gov.uk/find-local-trading-standards-office). You may also obtain your own independent legal advice from a legal professional.

d) Food Standards Agency

The Food Standards Agency (FSA) is responsible for policy on food safety, food hygiene, (including allergens labelling), imported foods, novel foods and genetically modified food. Advice on these issues for businesses can be obtained from your local enforcement authority. Other enquiries on FSA lead policy issues should be forwarded to helpline@food.gov.uk.

e) Novel foods

If you think an ingredient or a food may be novel – for example, it does not have a significant history of consumption in the UK or European Union prior to 15 May 1997 – we recommend that you check its status with the Food Standards Agency.

f) Department for Environment, Food and Rural Affairs

The Department for Environment, Food and Rural Affairs (Defra) is responsible for policy on general food labelling (for example, other than nutrition and allergens labelling rules). This includes the provisions of retained Regulation (EU) No 1169/2011 (https://www.legislation.gov.uk/eur/2011/1169/contents) relating to areas such as ingredients listing and country of origin labelling. Advice on these issues for businesses can be obtained from your local enforcement authority. Other enquires on Defra lead policy issues should be forwarded to helpline@defra.gov.uk.

g) Medicines and Healthcare products Regulatory Agency

Where the regulatory status of a product is uncertain, responsibility falls to the Medicines and Healthcare products Regulatory Agency (MHRA) to determine whether it might be a medicine rather than a food. Contact the Medicines Borderline Section borderline_medicine@mhra.gov.uk using the Medicines Borderline advice form (http://info.mhra.gov.uk/forms/borderline_advice.aspx).

MHRA has produced a guide to what is a medicinal product (PDF, 161KB) (http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544.pdf), which may also be useful.

h) E-learning

Developed by the FSA with Defra and DHSC, this food labelling e-learning course (https://labellingtraining.food.gov.uk/) will provide you with a general understanding of current food labelling legislation.

i) Other useful sources of advice and information

These should not necessarily be considered as DHSC recommendations:

- advice from government on setting up and running a business (https://www.gov.uk/browse/business/setting-up)
- advice from government to businesses related to food (https://www.gov.uk/food-labelling-and-packaging)
- Business Companion (http://www.businesscompanion.info/) – information for businesses that sell goods and provide services to consumers
- trade associations and organisations providing analytical services – following are some trade associations and organisations that provide a wide range of services to support food businesses including guidance on complying with legislation:
  - British Retail Consortium (http://www.brc.org.uk/brc_home.asp) (BRC)
  - British Soft Drinks Association (http://www.britishsoftdrinks.com) (BSDA)
  - British Specialist Nutrition Association Ltd (http://www.bsna.co.uk/) (BSNA)
  - Campden BRI (http://www.campdenbri.co.uk/)
  - Council for Responsible Nutrition (http://www.crnuk.org/) (CRN)
  - Dairy UK (http://www.dairyuk.org/)
  - European Specialist Sports Nutrition Alliance (http://www.essna.com/) (ESSNA)
  - Eurofins (http://www.eurofins.co.uk/food-testing/nutritional-analysis.aspx)
  - Food and Drink Federation (https://www.fdf.org.uk/) (FDF)
  - Health Food Manufacturers' Association (http://www.hfma.co.uk/) (HFMA)
  - Leatherhead Food (http://www.leatherheadfood.com/health-claims-substantiation)
  - Proprietary Association of Great Britain (http://www.pagb.co.uk/regulatory-resources/food-supplements/) (PAGB)
  - Provision Trade Federation (http://www.provtrade.co.uk/)
  - Health Supplements Information Service (http://www.hsis.org/)

- Institute of Food Science and Technology publishes a list of food consultants and technical advisers (https://www.ifst.org/organisations/consultants)
- Advertising Standards Authority (https://www.asa.org.uk/) is the independent UK body responsible for administering and enforcing advertising rules in broadcast (TV and radio) and non-broadcast media. There are 2 advertising content codes: the Committee on Advertising Practice writes and maintains the non-broadcast advertising code (the CAP code), and the Broadcast Committee of Advertising Practice writes and maintains the TV and radio advertising standards code (the BCAP code). ASA is able to require advertisers and broadcasts to remove non-compliant claims. In the online sphere, ASA's remit covers companies' marketing communications on their own websites and in other, third-party space under their control, for example, advertiser-controlled pages on social network sites

1. Nutrition labelling

1.1 Regulation of nutrition labelling

From 31 December 2020, nutrition labelling is regulated in GB by retained Regulation (EU) No 1169/2011 (https://www.legislation.gov.uk/eur/2011/1169/contents) on the provision of food information to consumers. The Protocol on Ireland/Northern Ireland (NIP) provides that EU legislation relating to nutrition as detailed in Annex 2 to the NIP, including Regulation (EU) No 1169/2011 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R1169), continues to be directly applicable in Northern Ireland.

Retained Regulation (EU) No 1169/2011 is enforced in England by The Food Information Regulations 2014 (https://www.legislation.gov.uk/uksi/2014/1855/made). Similar legislation applies in Scotland, Wales and Northern Ireland.

The provision of mandatory food information applies to most prepacked food. Both the retained and EU regulations also contain rules governing the provision of voluntary food information, the provision of food information on the 'front of pack' of prepacked foods, nutrition labelling for non-prepacked foods, and nutrition labelling for alcoholic drinks.

Annex V of Regulation (EU) No 1169/2011 includes a list of products which are exempt from the mandatory requirement to provide ('back of pack') nutrition labelling which include minimally processed foods and foods with little nutritional value.

The nutrition labelling rules of retained Regulation (EU) No 1169/2011 do not apply to:

- food supplements (which are legislated under the Food Supplements (England) Regulations 2003 (https://www.legislation.gov.uk/uksi/2003/1387/made), and the equivalent regulations in Scotland and Wales)
- natural mineral waters (which are legislated under the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (https://www.legislation.gov.uk/uksi/2007/2785/contents) and the equivalent regulations in Scotland and Wales)

In addition, the nutrition labelling rules in retained Regulation (EU) No 1169/2011 apply without prejudice to the food categories of retained Regulation (EU) No 609/2013 on food for specific groups (FSG). In other words, where there are separate nutritional labelling information requirements for the food categories legislated for under retained Regulation (EU) No 609/2013, these will take precedence over the requirements of retained Regulation (EU) No 1169/2011.

See Technical guidance on nutrition labelling (https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling) on compliance with the nutrition-related provisions of retained Regulation (EU) No 1169/2011.

1.2 Mandatory (back of pack) nutrition labelling

The mandatory nutrition declaration comprises energy value (in both kilojoules (kJ) and kilocalories (kcal)) plus amounts (in grams (g)) of fat, saturates, carbohydrate, sugars, protein and salt.

The mandatory nutrition declaration can be supplemented, on a voluntary basis, with information on the amounts (in grams (g)) of one or more of the following: mono-unsaturates; poly-unsaturates; polyols; starch; fibre; any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII.

For further details on ‘back of pack’ nutrition labelling, see Technical guidance on nutrition labelling (https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling).

1.3 Front of pack nutrition labelling

Certain key nutrition information may be repeated on a voluntary basis on the ‘front of pack’ (principal field of vision).

Front of pack nutrition information must be in one of the following formats:

- energy value (kJ and kcal) alone

- energy value (kJ and kcal) plus amounts (in grams) of fat, saturates, sugars and salt

For further details on 'front of pack' labelling, see guidance on front of pack nutrition labelling (https://www.gov.uk/government/publications/front-of-pack-nutrition-labelling-guidance).

1.4 Non-prepacked food

There is no requirement for nutrition information to be provided for food sold non-prepacked. But if provided voluntarily, it must be in one of the following formats:

- the full 'mandatory' nutrition declaration (energy value plus amounts of fat, saturates, carbohydrate, sugars, protein and salt)
- energy value only
- energy value plus amounts of fat, saturates, sugars and salt

1.5 Alcoholic drinks

Retained Regulation (EU) No 1169/2011 exempts all alcoholic drinks sold in GB from mandatory nutrition labelling. See further guidance on the FSA website (https://labellingtraining.food.gov.uk/module10/overview_2.html). There have been discussions regarding the development of voluntary initiatives to provide ingredient and nutrition information.

In the meantime, it is possible to provide a voluntary energy declaration (in kJ and kcal) on alcoholic drinks without the need to provide the full list of ('back of pack') nutrients, which would otherwise be mandatory on prepacked food. Alternatively, you may provide a full ('back of pack') nutrition declaration on a voluntary basis on alcoholic drinks.

1.6 Reference intakes

'Reference intakes' (RIs) have replaced 'guideline daily amounts' (GDAs) for energy and the mandatory nutrients. RIs have also replaced 'recommended daily allowances' (RDAs) for vitamins and minerals.

2. Food supplements

For further information on food supplements see DHSC guidance on food supplement use and labels (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs).

2.1 Registering and licensing food supplements in the UK

There is no requirement to register food supplements in the UK. As long as they comply with the law (the law specific to food supplements and all other applicable food law) then they are permitted for sale. It is the responsibility of the manufacturer, importer or retailer to ensure that they comply with the law. Food supplements are regulated in the UK under the Food Supplements (England) Regulations 2003, and the equivalent regulations in Scotland, Wales and Northern Ireland as well as all other applicable food law. Check the Legislation website (https://www.legislation.gov.uk/) for any version changes.

When the UK was an EU member state, details of vitamins and minerals, and vitamin and mineral substances that may be used in the manufacture of food supplements were contained in lists in annexes to Directive 2002/46/EC, which is implemented in England by the Food Supplements (England) Regulations 2003. These lists have now been inserted as Schedules to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 to ensure that they continue to have effect in GB following the UK's withdrawal from the EU.

The regulations do not control the use of substances other than vitamins and minerals and vitamin and mineral substances which may be used in the manufacture of food supplements, but any other ingredients used must be safe for human consumption and not be injurious to health.

2.2 Maximum levels of vitamins and minerals in food supplements

The UK does not have any national legislation setting maximum levels for vitamins and minerals and vitamin and mineral substances which may be used in the manufacture of food supplements. However, we do have voluntary guideline safe upper levels which are based upon a report issued in 2003 by the Expert Group on Vitamins and Minerals (EVM), Safe upper levels for vitamins and minerals (PDF, 1,406KB) (https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf).

Guidance on the use of label advisory statements and suggested reformulations related to the levels of vitamin and mineral substances which may be used in the manufacture of food supplements (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs) is available.

2.3 Prohibited ingredients in food supplements in the UK

Many products which are freely sold in other countries are not permitted or are considered to be medicinal or novel in the UK. Before you place your product on the market, you are advised to contact the Medicines and Healthcare products Regulatory Agency (MHRA) to check if the product, any of its ingredients, or

claims, are considered medicinal. Food supplements are not permitted to contain medicinal ingredients, therefore the MHRA will determine if your product is medicinal.

Imported food supplements may need to be relabelled and possibly reformulated to meet UK composition and labelling requirements. Therefore, it would be prohibited to sell any products directly imported that are not in compliance with UK food legislation. For further advice you are advised to speak to the food law enforcement office in your local authority. You may also obtain your own independent legal advice from a legal professional.

Find your local Trading Standards office (https://www.gov.uk/find-local-trading-standards-office)

2.4 Medicinal claims and products

See paragraph g) Medicines and Healthcare products Regulatory Agency, under Important information above.

2.5 Novel foods

See paragraph e) Novel foods, under Important information above.

2.6 National rules in the UK for certain substances

You should also be aware that there is additional national legislation in the UK which:

- prohibits the sale of any food consisting of or containing Kava-kava (including food supplements)
- places restrictions on the addition of tryptophan to food and the sale of food containing tryptophan and which permits the addition of only laevorotatory tryptophan (L-tryptophan) to food supplements subject to purity and dose criteria

Links to the legislation relating to England are listed below. Equivalent legislation exists in Scotland, Wales and Northern Ireland.

Kava-kava

The Kava-kava in Food (England) Regulations 2002 (http://www.legislation.gov.uk/uksi/2002/3169/contents/made)

The Kava-kava in Food (England) (Amendment) Regulations 2004 (http://www.legislation.gov.uk/uksi/2004/455/contents/made)

Tryptophan

The Tryptophan in Food (England) Regulations 2005 (http://www.legislation.gov.uk/uksi/2005/2630/contents/made)

The Food supplements: guidance and FAQs (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs) includes guidance to the legislation on the composition and labelling of food supplements as well as nutrition labelling requirements.

2.7 General food labelling

Food supplements also have to comply with many of the general food labelling requirements. See section 1.

3. Fortified foods or vitamin and minerals added to food

Fortified foods are foods that contain added vitamins, minerals or other substances with a nutritional or physiological effect. This may have been achieved through voluntary fortification by food businesses, in products such as breakfast cereals and soft drinks, or through mandatory fortification, such as is required by The Bread and Flour Regulations 1998 (http://www.legislation.gov.uk/uksi/1998/141/contents/made).

3.1 Registering or licensing fortified foods in the UK

There is no requirement to register or licence fortified foods in the UK. It is the responsibility of the manufacturer, importer or retailer to ensure that they comply with the law. Businesses are advised to contact their local Trading Standards or Environmental Health office (https://www.gov.uk/find-local-trading-standards-office) if they wish to discuss this further. You may also obtain your own independent legal advice from a legal professional.

3.2 Regulating fortified foods

Fortified foods are regulated in GB by retained Regulation (EC) No 1925/2006 (https://www.legislation.gov.uk/eur/2006/1925/contents) on the addition of vitamins and minerals and of certain other substances to foods. The Protocol on Ireland/Northern Ireland (NIP) provides that EU legislation relating to nutrition as detailed in Annex 2 to the NIP, including Regulation (EC) No 1925/2006 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1925), continues to be directly applicable in Northern Ireland.

Annex I of the retained regulation is a list of vitamins and minerals which may be added in fortified foods. Annex II is a list of the vitamin formulations and mineral substances which may be added to foods. Annex I and Annex II have been amended by Regulation (EC) 1170/2009 (https://www.legislation.gov.uk/eur/2009/1170/introduction/adopted), Regulation (EU) No 1161/2011 (https://www.legislation.gov.uk/eur/2011/1161/contents/adopted) and Regulation (EU) No 119/2014 (https://www.legislation.gov.uk/eur/2014/119/contents) to include additional substances. Annex III is a list of substances whose use in foods is prohibited, restricted or under Community scrutiny. The regulation is enforced in England by The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 (http://www.legislation.gov.uk/uksi/2007/1631/made) and equivalent legislation in Scotland, Wales and Northern Ireland.

For further information see DHSC guidance to compliance with Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to food (https://www.gov.uk/government/publications/fortified-foods-guidance-to-compliance-with-european-regulation-ec-no-1925-2006-on-the-addition-of-vitamins-and-minerals-and-certain-other-substances-to-food).

3.3 New substances which need adding to the list

On 1 January 2021, the UK government and devolved administrations in Scotland and Wales adopted the Community Register of Vitamins, Minerals, and Certain Other Substances as it existed on 31 December 2020 (see the Great Britain Register on the addition of vitamins and minerals and of certain other substances to foods (GB VMS Register) (https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods/great-britain-register-on-the-addition-of-vitamins-and-minerals-and-of-certain-other-substances-to-foods).

Further information is available in the DHSC guidance to compliance with Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to food (https://www.gov.uk/government/publications/fortified-foods-guidance-to-compliance-with-european-regulation-ec-no-1925-2006-on-the-addition-of-vitamins-and-minerals-and-certain-other-substances-to-food). This document includes information on adding new substances to the register.

3.4 Substances prohibited, restricted or under community scrutiny

Article 8 of retained Regulation (EC) No 1925/2006 (https://www.legislation.gov.uk/eur/2006/1925/contents) gives the possibility to put under scrutiny, to restrict and, if necessary, to prohibit the use of substances added to foods or used in the manufacture of foods under conditions that would result in the

ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

Prior to the UK leaving the EU, the Commission received a request from a member state to initiate the procedure under Article 8 of Regulation (EC) No 1925/2006 (https://www.legislation.gov.uk/eur/2006/1925/contents) for Ephedra species (Ephedra spp.) and for yohimbe (Pausinystalia yohimbe). The following available information was submitted to the European Food Safety Authority (EFSA) for a safety assessment:

- scientific assessment of yohimbe (https://www.efsa.europa.eu/en/efsajournal/pub/3302)
- scientific assessment of Ephedra species (https://www.efsa.europa.eu/en/efsajournal/pub/3467)

These EFSA scientific opinion decisions still stand.

Annex III of Regulation (EC) No 1925/2006 was amended by Regulation (EU) 2015/403 (https://www.legislation.gov.uk/eur/2015/403/contents), placing Ephedra herb and its preparations originating from Ephedra species in Part A of Annex III (prohibited substances), and by Regulation (EU) 2019/650 (https://www.legislation.gov.uk/eur/2019/650/contents), placing Yohimbe bark and its preparations originating from Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) in Part A of Annex III (prohibited substances).

Following EFSA's scientific assessment of trans fats in 2018 (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1433), Regulation (EU) 2019/649 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32019R0649) places trans fats in Part B of Annex III (restricted substances). From 3 April 2020, the foods containing trans fats (other than trans fat naturally occurring in fat of animal origin) exceeding 2 grams per 100 grams of fats are prohibited.

Details of other Article 8 substances under scrutiny and decisions will be published on the GB VMS Register (https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods).

3.5 GB VMS Register

UK government and devolved administrations in Scotland and Wales will maintain the GB VMS Register (https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods/great-britain-register-on-the-addition-of-vitamins-and-minerals-and-of-certain-other-substances-to-foods) on the additions of vitamins and minerals and of certain other substances to foods.

Any amendments to the GB VMS Register are communicated via regular bulletins published on the register on adding vitamins and minerals to foods (https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods).

4. Nutrition and health claims made on food

4.1 Nutrition and health claims legislation

From 31 December 2020, voluntary nutrition or health claims must comply with the requirements of retained Regulation (EC) No 1924/2006 (https://www.legislation.gov.uk/eur/2006/1924/contents) on nutrition and health claims made on foods. The Protocol on Ireland/Northern Ireland (NIP) provides that EU legislation relating to nutrition as detailed in Annex 2 to the NIP, including Regulation (EC) No 1924/2006, continues to be directly applicable in Northern Ireland.

Guidance to compliance with Regulation (EC) No 1924/2006 (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) is designed to help you comply with the retained regulation if you choose to make a nutrition or health claim for a food product. There is also a short ‘quick start guide’ designed as an entry point to the guidance.

A nutrition claim is a claim that states, suggests or implies that a food has beneficial nutritional properties, such as ‘low fat’ or ‘high in fibre’. A health claim is any claim that states, suggests or implies that health benefits can result from consuming a given food, such as ‘maintenance of bones’. Retained Regulation (EC) No 1924/2006 applies to nutrition claims and health claims made in commercial communications, including labels, leaflets, websites and advertisements. Claims must also comply with general food labelling legislation that prohibits any claim that a food has the property of preventing, treating or curing a human disease or any reference to such a property.

Regulation (EC) No 1924/2006 requires nutrition and health claims to be authorised and listed in a Community Register. The EU Register (http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home) of nutrition (https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/nutrition-claims_en#permitted-nutrition-claims) and health (https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search) claims made on foods, lists all EU authorised and rejected claims set out in legislation.

As of 1 January 2021, all nutrition and health claims that were listed in the EU Register on 31 December 2020 were adopted and included in the Great Britain nutrition and health claims register (https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register) (GB NHC).

For clarity, the register lists those health claims for which applications for authorisation have been unsuccessful – these claims are listed as non-authorised and may no longer be used.

Further information on nutrition and health claims and the GB NHC register is available in the guidance to compliance with Regulation (EC) No 1924/2006 (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods).

4.2 Nutrition claims

Nutrition claims that are not in the register but would be understood to have the same meaning to consumers as a listed claim may be used. For example, ‘rich in protein’ is likely to have the same meaning to consumers as ‘high in protein’ and can therefore be used on foods that meet the criteria to use that claim. Claims not on the list, such as ‘low carbohydrate’ or ‘cholesterol-free’, cannot be used.

4.3 Health claims

Only authorised health claims listed in the Great Britain nutrition and health claims register (https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register) may be used in the GB market. The only exception to this is:

- general, non-specific claims (subject to the conditions of Article 10.3 of retained Regulation (EC) No 1924/2006)

Previously, trademarks or brand names that were also considered nutrition or health claims which existed before 1 January 2005 (subject to the conditions of Article 1.3 and Article 28.2 of retained Regulation (EC) No 1924/2006) were also exempt from the provisions of retained Regulation (EC) No 1924/2006. However, since 19 January 2022, this transition period has now ended. After this date, the provisions of retained Regulation (EC) No 1924/2006 apply, irrespective of when the trademark or brand name was introduced. Any nutrition or health claims implied by a trademark, brand name or fancy name appearing in the labelling, presentation or advertising of a food must be accompanied by a related authorised nutrition or health claim. Existing trademarks or brand names suggesting health or nutrition benefits that do not meet the requirement of retained Regulation (EC) No 1924/2006 are not authorised.

Authorised claims may be used subject to their conditions of use and in compliance with the relevant requirements of retained Regulation (EC) No 1924/2006.

Further information on health claims and 'on hold' claims can be found in the Guidance to compliance with Regulation (EC) No 1924/2006 (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods).

Our Article 13(1) bulletin (PDF, 147KB) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/307453/DH_BULLETIN_-_Searching_Article_13.1_on_hold_health_claims_acc.pdf) provides further information relating to 'on hold' claims. The full list of 'on hold' claims referenced by the 2014 bulletin is available (https://www.gov.uk/government/publications/on-hold-health-claims-on-foods).

Local enforcement officers are able to easily identify on hold health claims by accessing our spreadsheet on the Knowledge Hub website (https://khub.net/group/foodstandardsandlabelling/forum/-/message_boards/search?_19_formDate=1494420480015&_19_redirect=https%3A%2F%2Fkhub.net%2Fgroup%2Ffoodstandardsandlabelling%2Fforum%3Fp_p_id%3D19%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_count%3D1&_19_breadcrumbsCategoryId=0&_19_searchCategoryId=0&_19_keywords=on+hold+health+claims).

See other bulletins on updates relating to information on nutrition and health claims made on food (https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2014).

4.4 Principles that should be respected when authorised health claims are made

Some flexibility of wording for authorised health claims is possible provided that its aim is to help consumer understanding, considering factors such as linguistic and cultural variations and the target population. For a document setting out the principles that should be respected when authorised health claims are made, but the wording used is not exactly as authorised. See principles on flexibility of wording for health claims (https://www.gov.uk/government/publications/update-on-flexibility-of-wording-for-health-claims-published).

The same principles should be respected whenever authorised claims are used in commercial communications whether in labelling, presentation or advertising and in whatever medium including on websites, radio and television. Retained Regulation (EC) No 1924/2006 also controls general references to overall health and well-being, such as 'healthy' or 'super food' and the DHSC guidance to compliance provides advice on the use of such terms in section 5.1.

Article 10 of retained Regulation (EC) No 1924/2006 requires some specific conditions to be met when a health claim is made.

4.5 New health claim applications

If you wish to submit a new health claim application you should read the guidance to compliance with Regulation (EC) No 1924/2006 (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods).

4.6 Nutrient profiles

Retained Regulation (EC) No 1924/2006 provides the competent authority the power to establish a nutrient profile criteria which foods must meet to make nutrition and health claims. The establishment of nutrient profiles aims to prevent claims masking the true nature of foods and so misleading consumers who are trying to make healthy dietary choices. In the EU, nutrient profiles were originally required to be established by January 2009, but this deadline was not met by the EU and a new deadline has not yet been set.

4.7 Enforcement

Food law enforcement in the UK is the responsibility of local authorities and where false or misleading information is provided, enforcement action may be taken by the local authority.

You may wish to contact your relevant local authority to seek a view on whether your particular product labelling and claims comply with Regulation (EC) No 1924/2006. This tool will help you find your nearest Trading Standards office (https://www.gov.uk/find-local-trading-standards-office).

5. Food for specific groups (FSG) formerly known as foods intended for particular nutritional uses (PARNUTS)

5.1 Food for specific groups

From 31 December 2020, Regulation (EU) No 609/2013 (https://www.legislation.gov.uk/eur/2013/609/contents) was retained in GB. The Protocol on Ireland/Northern Ireland (NIP) provides that EU legislation relating to nutrition as

detailed in Annex 2 to the NIP, including Regulation (EU) No 609/2013, continues to be directly applicable in Northern Ireland.

Regulation (EU) No 609/2013 on food for specific groups (FSG) came into effect in July 2016 (with the exception of some articles which applied from July 2013 and other articles and the annex to the regulation that apply from the date referred to in article 22 of the regulation).

Food for specific groups comprises of infant formula and follow-on formula, processed cereal-based foods and baby foods, food for special medical purposes and total diet replacement for weight control.

Previously FSGs were regulated under Directive 2009/39/EC (https://www.legislation.gov.uk/eudr/2009/39/contents) on PARNUTS. Under this directive there were further directives setting out specific composition and labelling rules for each of these food categories. Directive 2009/39/EC was repealed by Regulation (EU) No 609/2013. The specific directives are being replaced by Commission delegated regulations made under Regulation (EU) No 609/2013. Not all of the directives have been repealed, and these continue to apply, as implemented in the UK, until delegated regulations have been adopted and apply for each category of FSG.

Food categories where an FSG delegated regulation has not yet been adopted under Regulation (EU) No 609/2013 are:

- processed cereal-based foods and other baby foods. In England, this is covered by The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (as amended) (https://www.legislation.gov.uk/uksi/2003/3207) and there is equivalent legislation in Scotland, Wales and Northern Ireland

Food categories where EU delegated regulations made under Regulation (EU) No 609/2013 currently apply are:

- infant formula and follow-on formula. In GB, this is covered by retained Commission Delegated Regulation (EU) 2016/127 (https://www.legislation.gov.uk/eur/2016/127/contents). This came into force on 22 February 2020 and 22 February 2022 for infant formula and follow-on formula manufactured from protein hydrolysates
- food for special medical purposes. In GB, this is covered by retained Commission Delegated Regulation (EU) 2016/128 (https://www.legislation.gov.uk/eur/2016/128/contents). This came into force on 22 February 2019 and 22 February 2020 in respect of FSMP for infants

- total diet replacement for weight control. This is covered by Commission Delegated Regulation (EU) 2017/1798 (https://www.legislation.gov.uk/eur/2017/1798/contents). Any regulation that did not apply at the end of the UK's transition period ending on 31 December 2020 was not retained and has not become part of GB legislation. Therefore in GB total diet replacement for weight control products are regulated by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (as amended) (http://www.legislation.gov.uk/uksi/1997/2182/contents/made)

Both the EU and GB retained Regulation (EU) No 609/2013 lays down general requirements for each of the food categories. In terms of labelling, there are only general requirements established for not misleading the consumer or attributing to the food the property of preventing, treating or curing a human disease. There are additional requirements for infant formula and follow-on formula which require the labelling, presentation and advertising to be designed so as not to discourage breastfeeding and must not include pictures or text idealising the use.

In summary, Regulation (EU) No 609/2013:

- aims to protect specific vulnerable groups of consumers by regulating the content and marketing of food products specifically created for them. It also aims to increase legal clarity for business and to facilitate correct application of the rules
- sets general compositional and labelling rules
- establishes that foods for other population groups previously regulated under the PARNUTS framework, such as young child formula ('growing-up milks'), food intended for sports people, 'meal replacement products for weight control' and gluten free and very low gluten foods, will be treated as general foods and regulated under Regulation (EU) No 1169/2011 on food information to consumers and Regulation (EC) No 1924/2006 (https://www.legislation.gov.uk/eur/2006/1924/contents) on nutrition and health claims made on foods

EU Commission reports on young-child formula ('growing-up milks') and food intended for sports people concluded that there is no necessity for specific provisions for these products. Since 20 July 2016, young-child formula and food intended for sportspeople are exclusively covered by horizontal rules of food law.

5.2 Infant formula and follow-on formula

Infant formula and follow-on formula are products designed to satisfy the specific nutritional requirements of healthy infants and young children.

Infant formula is suitable from birth and is the only food which can be marketed as satisfying by itself the nutritional requirements of infants during the first months of life. Follow-on formula are foods intended for older infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants.

Commission Delegated Regulation (EU) 2016/127, which provides the detailed labelling and compositional rules for infant formula and follow-on formula, was adopted on 25 September 2015 and came into force on 22 February 2020 except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, which applied from 22 February 2022. Retained Commission Delegated Regulation (EU) 2016/127 (https://www.legislation.gov.uk/eur/2016/127/contents) is enforced in England by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (https://www.legislation.gov.uk/uksi/2016/688). Similar legislation applies in Scotland, Wales and Northern Ireland.

In summary, Commission Delegated Regulation (EU) 2016/127:

- prohibits nutrition and health claims being made on infant formula
- strengthens the requirement for infant and follow-on formula labels to be clearly distinct from each other
- updates the compositional requirements to reflect the latest scientific evidence, including the mandatory addition of docosahexaenoic acid (DHA)

DHSC guidance on Commission Delegated Regulation (EU) 2016/127 (https://www.gov.uk/government/publications/infant-and-follow-on-formula-and-food-for-special-medical-purposes/commission-delegated-regulation-eu-2016127-supplementing-regulation-eu-no-6092013-guidance) is available.

5.3 Processed cereal-based foods and baby foods

These are foods which fulfil the requirements of infants and young children while they are being weaned. They are also used as a supplement to the diet of young children for their progressive adaptation to ordinary food.

These foods are regulated in England by The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (http://www.legislation.gov.uk/uksi/2003/3207/made). Similar legislation applies in Scotland, Wales and Northern Ireland.

Regulation (EU) No 609/2013 requires the EU Commission to adopt, through delegated regulations specific compositional and labelling rules for processed cereal-based foods and baby foods in the EU. Any finalised delegated regulations regarding this category of food made by the EU would apply in Northern Ireland through the requirements of the NIP.

5.4 Food for special medical purposes (FSMP)

Food for special medical purposes (FSMP) are for the dietary management of a specific disease, disorder or medical condition. These are specialist foods intended for the exclusive or partial feeding of people whose dietary management cannot be achieved by modification of the normal diet alone.

Commission Delegated Regulation (EU) 2016/128 replaced Directive 1999/21/EC (https://www.legislation.gov.uk/eudr/1999/21/contents), providing the detailed labelling and compositional rules for FSMP.

In summary, Commission Delegated Regulation (EU) 2016/128:

- updates existing rules on FSMP, taking account of scientific developments and new legislation on food information to consumers
- prohibits nutrition and health claims on FSMP. This is to avoid inappropriate promotion of these specialist products which are for use under medical supervision
- extends to FSMP intended for infants and young children the same rules on pesticides that apply to infant and follow-on formula and processed cereal-based foods and baby foods
- requires the addition of Docosahexaenoic acid (DHA) for infant formula marketed as FSMP
- requires the presentation of FSMP for infants to be clearly distinct from infant and follow-on formula
- places restrictions on advertising of infant formula marketed as FSMP

Retained Commission Delegated Regulation (EU) 2016/128 (https://www.legislation.gov.uk/eur/2016/128) is enforced in England by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (https://www.legislation.gov.uk/uksi/2016/688). There is similar legislation in Scotland, Wales and Northern Ireland.

5.5 Foods for total diet replacement for weight control

Low and very low-calorie diet foods are specially formulated foods which replace the whole of the diet. Foods for total diet replacement for weight control are regulated in Great Britain by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (http://www.legislation.gov.uk/uksi/1997/2182/contents/made) (1997 Regulation). This legislation only applies when the whole diet is replaced. These regulations implemented Directive 96/8/EC.

Since July 2016, the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 only applies when the whole diet is replaced and no longer applies to foods presented as a replacement for one or more meals of a daily diet.

From 27 October 2022, Commission Delegated Regulation (EU) 2017/1798 applied in the EU and in Northern Ireland under the terms of the NIP. This replaces EU Directive 96/8/EC. Under the process set out in the Nutrition Related Labelling, Composition and Standards Provisional Common Framework (https://www.gov.uk/government/publications/nutrition-labelling-composition-and-standards-provisional-common-framework-command-paper) the 1997 Regulation is currently being considered by the 4 UK countries.

5.6 Notification procedures

When an FSMP, infant formula or follow-on formula based on protein hydrolysates or follow-on formula containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 are placed on the market, food business operators are required to notify the competent UK authority where the product is being marketed. DHSC is centrally coordinating notification forms for all 3 GB nations for the purposes of notifying each of the applicable competent GB authorities.

The competent UK authorities are the Department of Health and Social Care, Food Standards Agency in Northern Ireland, Food Standards Scotland and the Welsh Government.

Food business operators must complete a notification form and forward a model of the product label for:

- new or updated formulations of infant formula
- follow-on formula based on protein hydrolysates or follow-on formula containing substances other than those listed in Annex II of retained Commission Delegated Regulation (EU) 2016/127
- food for special medical purposes (FSMP)

FSMP notification is required under retained Commission Delegated Regulation (EU) 2016/128 (https://www.legislation.gov.uk/eur/2016/128/contents) and is enforced in England by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016.

Infant formula, follow-on formula based on protein hydrolysates or follow-on formula containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127) notification is required under retained Commission Delegated Regulation (EU) 2016/127 (https://www.legislation.gov.uk/eur/2016/127/contents) and is enforced in England by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (https://www.legislation.gov.uk/uksi/2016/688).

See the notification forms (https://www.gov.uk/government/publications/infant-formula-and-foods-for-particular-nutritional-uses-parnuts-notification-requirements).

Notification procedures for placing on the market within Great Britain

For FSMP, the notification forms along with a model of the product label, and any other information that may be reasonably requested to establish compliance with retained Commission Delegated Regulation (EU) 2016/128, may be sent to DHSC. Notification forms and accompanying information may be sent to nutritionlegislation@dhsc.gov.uk (which centrally coordinates notification forms for all 3 GB nations) for the purposes of notifying each of the applicable competent GB authorities.

For infant formula, follow-on formula based on protein hydrolysates or follow-on formula containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127, the notification forms along with a model of the product label, and any other information that may be reasonably requested to establish compliance with Commission Delegated Regulation (EU) 2016/127, may be sent to DHSC. Notification forms and accompanying information may be sent to nutritionlegislation@dhsc.gov.uk (which centrally coordinates notification forms for all 3 GB nations) for the purposes of notifying each of the applicable competent UK GB authorities.

Notification procedures for placing on the market within the European Union

The FSA is the designated competent authority in Northern Ireland. This means that notification forms for FSMP, along with a model of the product label, and any other information that may be reasonably requested to establish compliance with Commission Delegated Regulation (EU) 2016/128 must be sent to the FSA in Northern Ireland using nutritionlegislation-ni@food.gov.uk.

Notifications forms for infant formula, follow-on formula based on protein hydrolysates or follow-on formula containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127, along with a model

of the product label, and any other information that may be reasonably requested to establish compliance with Regulation (EU) 2016/127 must be sent to the FSA in Northern Ireland using nutritionlegislation-ni@food.gov.uk.

5.7 Foods for sports people

There is no specific legislation on foods intended to meet the expenditure of intense muscular effort, especially for sports people, general food law therefore applies. Products presented as 'food supplements' need to comply with the Food Supplements (England) Regulations 2003 and equivalent legislation in Scotland, Wales and Northern Ireland. All products presented for sports people need to ensure that any nutrition or health claims made are compliant with retained Regulation (EC) No 1924/2006 (https://www.legislation.gov.uk/eur/2006/1924/contents).

5.8 Foods suitable for people intolerant to gluten

There are no specific rules for food that is 'gluten-free' and 'very low gluten'. The general labelling requirements of foods in retained Regulation (EU) No 1169/2011 (https://www.legislation.gov.uk/eur/2011/1169/contents) on the provision of food information to consumers apply.

The FSA is responsible for policy on allergens generally. See guidance on allergen labelling for food manufacturers (https://www.food.gov.uk/business-guidance/allergen-labelling-for-food-manufacturers) and food allergy and intolerance (https://www.food.gov.uk/safety-hygiene/food-allergy-and-intolerance).

5.9 Diabetic foods

There are no specific rules regulating 'diabetic foods'.

The EU Commission published a report in 2008 on foods for persons suffering from carbohydrate metabolism disorders (COM (2008) 392 (PDF, 155KB) (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0392:FIN:EN:PDF), which stated that specialised foods for diabetics are not necessary. This report resulted in the Commission, European Parliament and Member States agreeing to remove diabetic foods from the scope of the Framework Directive 2009/39/EC (https://www.legislation.gov.uk/eudr/2009/39/contents). Regulation (EU) No 609/2013 (https://www.legislation.gov.uk/eur/2013/609/contents) reiterated that specific compositional requirements would not be developed for foods for diabetics due to lack of scientific evidence. This confirms that there is no specific category of dietetic products that may make claims of their suitability for diabetics. These products are regulated under general food law, including that on general labelling and nutrition and health claims. These decisions still stand.

Government advice is that people with diabetes should consume a healthy balanced diet and do not require specialist foods. Food labelling terms indicating suitability for diabetics are not specifically permitted under food law and DHSC considers them to be not helpful and possibly misleading. Many of the products bearing such phrases are inherently high in fat and calories and run counter to current dietary recommendations for a healthy balanced diet.

Alternative informative claims have been approved under the nutrition and health claims legislation. See the GB NHC register (https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register) – for example, 'no added sugar' and 'Consumption of foods or drinks containing <name of sugar replacer> instead of sugar* induces a lower blood glucose rise after their consumption compared to sugar-containing foods or drinks'.

*In the case of D-tagatose and isomaltose this should read 'other sugars'.

5.10 Substances that may be added to FSG products

Nutritional substances belonging to the following categories: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol, that may be used in the manufacture of food for specific groups.

The list of substances which can be added to processed cereal-based foods and baby foods in England is provided in the annex of The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (http://www.legislation.gov.uk/uksi/2003/3207/made), and the equivalent legislation in Scotland, Wales and Northern Ireland.

The list of substances which can be added to foods for total diet replacement for weight control in GB is provided in the annex of The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (http://www.legislation.gov.uk/uksi/1997/2182/contents/made).

Regulation (EU) No 609/2013 includes an annex which consolidates lists of substances that may be added to products included within the categorisation of FSG.

In GB, the annex is referred to as the GB list, and article 16 of the retained regulation makes provisions for the list to be updated by regulations made by any of the appropriate GB authorities. The GB list only applies to food for special medical purposes and infant formula and follow-on formula.

In the EU, the annex of the regulation is known as the Union list. In the EU this applies to foods for special medical purposes, infant formula and follow-on formula and foods for total diet replacement for weight control.

Food business operators, or other interested parties, that wish to sell products within the categorisation of FSG in Northern Ireland still need to refer to the Union list (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013R0609&from=EN#d1e32-48-1).

GB list

Substances belonging to the categories of substances listed below may be added to the categories of FSG provided they are contained within the GB list and comply with any stipulated conditions:

- vitamins
- minerals
- amino acids
- carnitine and taurine
- nucleotides
- choline and inositol

The GB list contains the following elements:

- the category of food, outlined above, to which substances belonging to the categories of substances listed above may be added
- the name of the substance, and where appropriate the specification of its form
- where appropriate, the conditions of use of the substance
- where appropriate, the purity criteria applicable to the substance

Modifying the GB list

In order to take into account technical progress, scientific developments, or the protection of consumer health, the appropriate GB authorities may make regulations to modify the GB list.

Food business operators, or other interested parties, that wish for vitamin and mineral substances or certain other substances to be considered for inclusion in the GB list may submit a scientific dossier concerning the safety and bioavailability of the individual substance for consideration for use in the GB market by the appropriate UK authorities to DHSC using nutritionlegislation@dhsc.gov.uk (which centrally coordinates dossiers on behalf of GB).

Modifying the Union list in the EU and Northern Ireland

Food business operators wishing to add vitamin and mineral substances or certain other substances to FSGs in the EU or Northern Ireland must continue to comply with the requirements of Regulation (EU) No. 609/2013 and other applicable delegated regulations and national legislation in the EU and Northern Ireland regarding the regulation and Union list.

We recommend that food business operators who wish for additional substances to be considered for inclusion in the Union list, which applies to the EU and Northern Ireland refer to the extensive guidance on the addition of substances for specific nutritional purposes (https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/dietetic_en), specifically administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

5.11 FSG GB legislation summary

In summary, the specific rules for the following groups of foods in GB are as follows.

Infant formula and follow-on formula

Retained Commission Delegated Regulation (EU) 2016/127 (https://www.legislation.gov.uk/eur/2016/127/contents) on infant formula and follow-on formula which replaced Directive 2006/141/EC (https://www.legislation.gov.uk/eudr/2006/141/contents) from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, which applied from 22 February 2022.

Processed cereal-based foods and baby foods

The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (http://www.legislation.gov.uk/uksi/2003/3207/made) on processed cereal-based foods and baby foods for infants and young children (and equivalent legislation in Scotland, Wales and Northern Ireland).

Food for special medical purposes

Retained Commission Delegated Regulation (EU) 2016/128 (https://www.legislation.gov.uk/eur/2016/128/contents) on the specific compositional and information requirements for food for special medical purposes. This replaced Directive 1999/21/EC from 22 February 2019 and 22 February 2020 in respect of FSMP for infants.

Foods for total diet replacement for weight control

The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (as amended) (http://www.legislation.gov.uk/uksi/1997/2182/contents/made) on foods intended for use in energy-restricted diets for weight reduction. This legislation only applies when the whole diet is replaced.

Contact details

If you have any questions or comments on this guidance, please contact the Nutrition Legislation Team at nutritionlegislation@dhsc.gov.uk.

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