Department of Health & Social Care

Nutrition Legislation Information Sheet

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Target audience: This document is intended to help food businesses comply with nutrition legislation. It may also be of use to others with an interest in the legislation, such as food law enforcement officers and trade associations.
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1. IMPORTANT INFORMATION

If you are a food business operator, the information in this document will help you understand the specific nutrition-related rules you must comply with if you are providing nutrition information on food and drinks, or selling food supplements, fortified foods, foods making health claims or nutrition claims and Food for Specific Groups (FSG), i.e. food for infants and young children (infant formula, follow-on formula and weaning foods), food for specific medical purposes, and total diet replacement for weight control.

You will need to read all the information in pages 3-5 prior to reading the contents page and then the following sections that are relevant to you.

If after reading this information your query is not resolved, please seek further advice from your local authority Trading Standards or Environmental Health office. This tool will help you find your nearest office.

If you are a consumer with a complaint about a product, please contact the Citizens Advice Consumer Helpline (CACH): Advice Guideline For Consumers

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

If you are a local authority enforcement officer, please 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 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 & Labelling Focus Group. Information relating to the process of referring queries relating to food standards and labelling issues can be found on the Knowledge Hub and on the Food Standards Agency (FSA) website

a) Registering a food business (For food businesses)

If you are selling food products, which includes all the food categories listed above, 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. This tool will help you find your nearest office: Search for a local authority. You are able to download an application form on the FSA website.

There is useful information about setting up your business at:

- GOV.UK information on setting up a food business
- GOV.UK Business support helplines
- Food Standards Agency information on setting up a food business
- You may also wish to consider establishing a Primary Authority Partnership with a single local authority: See: Primary Authority Handbook

b) Many questions about nutrition and general food labelling on food and drinks, food supplements, fortified foods, nutrition and health claims, and Food for Specific Groups (i.e. infant formula, follow-on formula, weaning foods, food for specific 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 the EU Food Information for Consumers Regulation (EU FIC)
- European Commission Q&A guidance on the EU Food Information for Consumers Regulation
- EU Food Information For Consumers Regulation (EU FIC)
- UK Front of Pack Guidance
- Food Supplements Guidance and FAQs
- Guidance on Fortified Foods
- Guidance on Nutrition and Health Claims
- Guidance and Notification Forms For Introducing medical foods and infant formula to the UK
- DH Bulletins on Nutrition & Health Claims
- DH Bulletins on Food For Specific Groups
- GOV.UK Information on Food Labelling

c) The Department of Health 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 office: Search for a local authority

d) 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 i.e. it does not have a significant history of consumption in the European Union prior to 15 May 1997 you should check its status by contacting: novelfoods@food.gov.uk

f) The Department for Environment, Food & Rural Affairs (Defra) is responsible for policy on general food labelling (i.e. other than nutrition and allergens labelling rules). This includes the provisions of the EU Food Information for Consumers Regulation (EU FIC) 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 such as questions about upcoming regulations, and requests to change existing laws should be forwarded to: helpline@defra.gsi.gov.uk

g) Where the regulatory status of a product is uncertain, responsibility falls to the Medicines and Healthcare products Regulatory Agency' (MHRA) to determine whether it is a medicine. Please contact the Medicines Borderline Section borderline_medicine@mhra.gov.uk using the borderline advice form. MHRA has produced guidance which may also be useful: A guide to what is a medicinal product

h) E- Learning – Food labelling course for you. This e-learning course has been developed by the Food Standards Agency with the Department for Environment, Food & Rural Affairs

(Defra) and the Department of Health (DH). It will provide you with a general understanding of current food labelling legislation: E Learning

i) Other useful sources of advice & information (these should not necessarily be considered as DH 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
- ERWIN (Everything Regulation, Whenever It's Needed) This is a one-stop website for all your Trading Standards and Environmental Health related information across England and Wales
- Business Companion Information for businesses that sell goods and provide services to consumers
- Trade Associations & some organisations providing analytical services: These are some trade associations and organisations providing a wide range of services to support food businesses including guidance on complying with legislation:
  - British Retail Consortium (BRC)
  - British Soft Drinks Association (BSDA)
  - British Specialist Nutrition Association Ltd (BSNA)
  - Campden BRI
  - Council for Responsible Nutrition (CRN)
  - Dairy UK
  - European Specialist Sports Nutrition Alliance (ESSNA)
  - Eurofins
  - Food and Drink Federation (FDF)
  - Health Food Manufacturers' Association (HFMA)
  - Leatherhead Food
  - Proprietary Association of Great Britain (PAGB)
  - Provision Trade Federation
- The Health Supplements Information Service
- The Institute of Food Science & Technology publishes a list of food consultants / technical advisors: Consultancy Service
- The Advertising Standards Authority: The ASA is the independent UK body responsible for administering and enforcing advertising rules in broadcast (TV and radio) and non-broadcast media. There are two 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). The ASA is able to require advertisers and broadcasts to remove non-compliant claims. In the online sphere, the ASA's remit covers companies' marketing communications on their own websites and in other, third-party space under their control e.g. advertiser-controlled pages on social network sites.

2. NUTRITION LABELLING

2.1 Regulation of nutrition labelling

Nutrition labelling is regulated at a European level by the Regulation (EU) No. 1169/2011 on the provision of food information to consumers (EU FIC). EU FIC is enforced in England by the Food Information Regulations 2014. Similar legislation applies in Scotland, Wales and Northern Ireland.

Mandatory nutrition labelling applies to the majority of prepacked food. EU FIC also contains rules governing the provision of voluntary nutrition information in the following circumstances:

- "repeat" nutrition information on the "front of pack" of prepacked foods
- nutrition labelling for non-prepacked foods
- nutrition (energy) labelling for alcoholic drinks

The nutrition labelling rules do not apply to:

- Food supplements (these fall within the scope of Directive 2002/46/EC); or
- Natural mineral waters (these fall within the scope of Directive 2009/54/EC).

In addition, the nutrition labelling rules in EU FIC apply without prejudice to the Directives on foods for particular nutritional uses (PARNUTS) and Regulation (EU) 609/2013 on Food for Specific Groups (FSG). In other words, where there are separate nutrition labelling provisions in the PARNUTS or FSG legislation, these will take precedence over the EU FIC requirements.

Technical guidance on compliance with the nutrition-related provisions of EU FIC is available here.

2.2 Key dates for application of nutrition labelling provisions

From 13 December 2016, it became mandatory to provide ("back of pack") nutrition labelling for prepacked food, subject to certain exemptions contained in Annex V of EU FIC. These exemptions relate mainly to minimally processed foods and those with little nutritional value.

2.3 Mandatory (Back of pack) 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.

The main changes in nutrition labelling from the previous legislation are:

- The term "salt" must be used since it is more readily comprehensible to consumers than "sodium".
- Fibre is no longer a mandatory nutrient, although it can be declared on a voluntary basis.
- The order of the mandatory nutrients has changed, e.g. protein moves from second to second last (see Annex XV for full order of the mandatory and supplementary nutrients).

2.4 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; or
- Energy value (kJ and kcal) plus amounts (in grams) of fat, saturates, sugars and salt (energy + 4)

For further details on “front of pack” labelling, please see our Guidance.

2.5 Non pre-packed 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 (energy + 4).

2.6 Alcoholic drinks

EU FIC exempts all alcoholic drinks from mandatory nutrition labelling. A European Commission report of March 2017 on labelling for alcohol concluded that voluntary initiatives should be further developed to provide ingredient and nutrition information. The Commission has asked industry to provide a self-regulatory proposal for labelling of alcohol within a year, which they will then assess. If the proposal is deemed unsatisfactory the Commission will review alternative options, particularly regarding energy labelling.

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 pre-packed food. Alternatively, you may provide a full (“back of pack”) nutrition declaration on a voluntary basis on alcoholic drinks.

2.7 New Terminology

“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.

3. FOOD SUPPLEMENTS

3.1 Registering/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 EC Food Supplements Directive 2002/46/EC (link to consolidated version of legislative text) as well as all other applicable food law. Please check the EUR-LEX web site for any version changes.

This is implemented in national law by the Food Supplements (England) Regulations 2003, which has been amended several times to reflect updates to the Annexes of permitted vitamin and mineral substances. There is equivalent legislation in Scotland, Wales and Northern Ireland. The Regulations do not control the use of substances other than vitamins and minerals added to food supplements, but any other ingredients used must be safe for human consumption and not be injurious to health.

3.2 Maximum levels of vitamins and minerals in food supplements

The UK does not have any national legislation on setting maximum levels for vitamins and minerals used in 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".

3.3 Prohibited ingredients in food supplement in the UK

Many products which are freely sold in the United States and 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 products, 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.

Food supplements from the USA and non EU countries usually need to be relabelled and possibly reformulated to meet UK/EU composition and labelling standards, therefore it would be prohibited to sell any products directly imported that are not in compliance with EU food legislation. For further advice you are advised to speak to the food law enforcement office in your local authority. This tool will help you find your nearest office: Search for a local authority

3.4 Medicinal claims and products

Please see paragraph (g) on page 6 of this document

3.5 Novel Foods

Please see paragraph (e) on page 6 of this document

3.6 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 which permits the addition of only laevoratory tryptophan (L-Tryptophan) to food supplements subject to purity and dose criteria.

Please find links to the legislation relating to England below. Equivalent legislation exists in the other countries of the UK.

Kava-kava:

The Kava-kava in Food (England) Regulations 2002

The Kava-kava in Food (England) (Amendment) Regulations 2004

Tryptophan:

The Tryptophan in Food (England) Regulations 2005

The Food Supplements: Guidance & FAQs includes guidance to the legislation on the composition and labelling of food supplements as well as nutrition labelling requirements.

3.7 General Food Labelling

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

4. FORTIFIED FOODS / 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

4.1 Registering/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. This tool will help you find your nearest office: Food Standards Agency: Search for a local authority

4.2 Regulating fortified foods

Fortified foods are regulated by Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. Annex I of the Regulation is a list of vitamins and minerals which may be added in fortified foods. Annex II is a list of the sources of vitamins and minerals which may be used. Annex I and Annex II have been amended by Commission Regulation (EC) 1170/2009, Commission Regulation (EU) No 1161/2011 and Commission Regulation (EU) No 119/2014 to include additional substances. Annex III is a list of substances whose use in foods is prohibited, restricted or under Community scrutiny. The Regulations are implemented in the UK by The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 and equivalent legislation in Scotland, Wales and Northern Ireland.

For further information see:

DHSC guidance to compliance with Regulation EC 1925/2006 on the addition of vitamins and minerals and certain other substances to food

4.3 New substances which need adding to the list

Requests for the inclusion of a new nutritional substance should be submitted to the European Commission. Guidance on the procedure that should be followed for the submission of requests for substances to be considered for inclusion in the permitted list is available on the European Commission's website

4.4 Substances prohibited, restricted or under Community scrutiny

Article 8 of Regulation 1925/2006 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.

The Commission received a request from a Member State to initiate the procedure under Article 8 of the Regulation 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

Scientific assessment of Ephedra species

The EFSA assessment on the evaluation of the safety in use of Ephedra species and yohimbe can be found on the EFSA website.

Annex III of Regulation EC No 1925/2006 has been amended by Commission Regulation (EU) 2015/403, placing Ephedra herb and its preparations in Part A of Annex III (prohibited substances) and Yohimbe bark and its preparations originating from Yohimbe in Part C of Annex III (substances under Community scrutiny).

Details of other Article 8 substances under scrutiny and decisions made by Member States and the Commission will be published on the Commission website.

4.5 Community Register

The European Commission maintains a community register on the additions of vitamins and minerals and of certain other substances to foods.

The European Commission is conferred with the task of establishing, publishing and maintaining this Register. The Register is updated regularly.

5. NUTRITION & HEALTH CLAIMS MADE ON FOOD

5.1 Nutrition & Health Claims Legislation

Voluntary nutrition or health claims must comply with the requirements of European Regulation EC 1924/2006 on nutrition and health claims made on food.

Guidance to compliance with European Regulation (EC) No 1924/2006 is available at the link below together with a very short 'quick start guide' designed to serve as an entry point to the guidance. The guidance is designed to help you comply with the Regulation if you choose to make a nutrition or health claim for a food product: Guidance to compliance with Regulation EC 1924/2006

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 'helps build strong bones'. Regulation 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 1924/2006 requires nutrition and health claims to be authorised and listed in the EU Register of authorised claims before they are used.

For clarity, the Register also 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.

5.2 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.

5.3 Health claims

Health claims may only be used now if they are authorised; are benefiting from a transition period specified in legislation; or are 'on hold'. Authorised claims may be used subject to their conditions of use and in compliance with the relevant requirements of Regulation 1924/2006. Claims 'on hold' are listed on the European Commission's website (On hold claims) under the heading 'Some 'function claims', for which the assessment by EFSA or the consideration by the Commission is not finalised'; this group includes a large number of claims on 'botanical' ingredients.

You can identify the subject of individual claims on hold by searching EFSA's Register of Questions: EFSA Register of Questions

Our bulletin provides further information relating to on hold claims.

Local enforcement officers are able to easily identify on hold health claims by accessing our spreadsheet on the Knowledge Hub website

See other bulletins for updates relating to information on nutrition & health claims made on food.

5.4 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, taking into account factors such as linguistic and cultural variations and the target population. 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

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. Regulation 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 Regulation 1924/2006 requires some specific conditions to be met when a health claim is made. See European Guidance on the how to comply with these requirements.

5.5 New Health Claim Dossiers

If you wish to submit a new health claim application you should read Section 5 of the DH guidance and, when putting together an application, you must follow the European Food Safety Authority's guidance on compiling and presenting dossiers as closely as possible: EFSA Guidance

5.6 Nutrient profiles

Regulation 1924/2006 requires a nutrient profile to be established as one of the criteria that foods must meet to make 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. The Regulation required nutrient profiles to be established by January 2009 but this deadline was not met. A new deadline has not been set, however discussions are expected to be held with Member States in EU Working Group meetings in due course.

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 1924/2006; you can find your local authority by using this search engine.

6. FOOD FOR SPECIFIC GROUPS (FSG) (formerly Foods Intended for Particular Nutritional Uses (PARNUTS)

6.1 Food for Specific Groups

New legislation was introduced in July 2016 replacing the rules on PARNUTS foods with a new Regulation 609/2013 on Food for Specific Groups (FSG). The Regulation repeals framework Directive 2009/39/EC on PARNUTS foods and covers:

- infant and follow-on formula,
- processed cereal-based food and baby food,
- food for specific medical purposes, and
- total diet replacement for use in energy restricted diets for weight control.

The new regulation:

- 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 and requires the Commission to adopt, through delegated acts, specific compositional and labelling rules for the above foods.
- Transfers rules on gluten-free foods and very low gluten under Regulation (EU) No 1169/2011 on food information to consumers (EU FIC) in order to ensure clarity and consistency.
- Establishes that foods previously regulated under the PARNUTS framework, such as meal replacement products for weight control, will be treated as general foods and regulated under Regulation (EC) No 1924/2006 on nutrition and health claims.

The delegated regulations made under the FSG Regulation will establish specific compositional and information requirements for these foods. Currently the Regulation lays down general requirements. 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. The additional rules to be adopted on labelling, presentation and advertising will include the authorisation of nutrition and health claims, the requirements concerning promotional and commercial practices relating to infant formula and information on appropriate infant feeding practices.

The Delegated Regulations providing the detailed labelling and compositional rules for these four categories of food will start to apply from 2019 onwards. So far only Delegated Regulation (EU) 2016/127 covering infant and follow-on formula and Delegated Regulation (EU) 2016/128 covering food for special medical purposes have been made.

Under the new approach, food for other population groups will be regulated as regular foodstuffs under general food law. Commission reports on young-child formulae ("growing-up milks") and food intended for sportspeople have concluded that there is no necessity for specific provisions for these products. Since 20 July 2016, young-child formulae and food intended for sportspeople are exclusively covered by horizontal rules of EU food law.

Summary reports of discussions from the expert group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control can be found on the European Commission website.

6.2 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 formulae 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.

Infant formulas and follow on formulas are regulated in England by the Infant Formula and Follow-on Formula (England) Regulations 2007 (as amended). Similar legislation applies in Scotland, Wales and Northern Ireland. These Regulations implement Commission Directive 2006/141/EC on infant formulae and follow-on formulae amending Directive 1999/21/EC.

For further information see DH guidance notes on the infant Formula and Follow-on Formula Regulations 2007 (as amended)

Delegated Regulation (EU) 2016/127 providing the detailed labelling and compositional rules for infant and follow-on formula will apply across the EU from 22nd February 2020. Until that date, the rules of Directive 2006/141/EC remain applicable.

6.3 Processed cereal based foods and baby foods

These are foods which fulfil the particular 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. Similar legislation applies in Scotland, Wales and Northern Ireland. These Regulations implement Commission Directive 2006/125/EC on processed cereal based foods and baby foods for infants and young children (as amended)

The new FSG Regulation requires the Commission to adopt, through delegated acts, specific compositional and labelling rules for processed cereal-based foods and baby foods, which will replace Directive 2006/125/EC. Until the finalisation of the delegated act, the rules of Directive 2006/125/EC remain applicable.

6.4 Food for special medical purposes (FSMP)

Medical foods are classified as dietary foods for special medical purposes (FSMP) for which the compositional and labelling requirements are laid down and regulated by the following Regulations: The Medical Food (England) Regulations 2000 (as amended). There is similar

legislation in Scotland, Wales and Northern Ireland. These Regulations implement Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Delegated Regulation (EU) 2016/128, providing the detailed labelling and compositional rules for FSMP, will apply from 22nd February 2019 or from 22nd February 2020 in the case of FSMP for infants. Until that date, the rules of Directive 1999/21/EC remain applicable.

6.5 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 (as amended). There is similar legislation in Northern Ireland (NI). These Regulations implement Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. Since 20 July 2016, Directive 96/8/EC no longer applies to foods presented as a replacement for one or more meals of the daily diet. Rules that regulate meal replacement for weight control are transferred to European Regulation EC 1924/2006 on nutrition and health claims made on food.

The new FSG Regulation requires the Commission to adopt, through delegated acts, specific compositional and labelling rules for foods for total diet replacement for weight control, which will replace Directive 96/8/EC. Until the finalisation of the delegated act, the rules of Directive 96/8/EC remain applicable to foods for total diet replacement.

6.6 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 Directive 2002/46/EC. All products presented for sports people need to ensure that any nutrition or health claims made are compliant with the Nutrition & Health Claims Regulation 1924/2006 and the EU Register of authorised claims.

6.7 Foodstuffs suitable for people intolerant to gluten

The rules on use of the statements 'gluten-free' and 'very low gluten' will be incorporated into EU Regulation 1169/2011 on the provision of food information to consumers. Further consideration will be given to how people that are intolerant to gluten are adequately informed of the difference between a food that is specially produced, prepared and/or processed in order to reduce the gluten content and other food that is made exclusively from ingredients naturally free of gluten.

The FSA is responsible for policy on allergens generally. See: Food Allergen Labelling & Gluten Advice For Consumers

6.8 Addition of substances to FSG for specific nutritional purposes

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 are laid down in the Annex to the FSG Regulation 609/2013. The category of food which each substance may be added to is specified in the Annex.

6.9 Notification procedures

When the following foods are placed on the market, the manufacturer or importer must notify the Department of Health in England, the Food Standards Agency in Northern Ireland, Food Standards Scotland or the Welsh Government by completing a notification form and forwarding a model of the product label as required by the Medical Food (England) Regulations 2000 (as amended) and The Infant Formula and Follow-on Formula (England) Regulations 2007. There is similar legislation in Scotland, Wales and Northern Ireland.

- New or updated formulations of Infant formula
- Dietary foods for special medical purposes (FSMP)

The notification form is available here.

Foods which are not required to be notified include:

- follow-on formulas (certain products will require notification from 2020 under (EU) 2016/127)
- processed cereal based foods and baby foods for infants and young children
- foods intended for the use in energy restricted diets (excluding Very Low Calorie Diets (VLCD))
- foods intended to meet the expenditure of intense muscular effort
- foods for persons suffering from carbohydrate-metabolism disorders (diabetes)
- Gluten free foods

6.10 Diabetic foods

There are no specific rules regulating “diabetic foods”. The European Commission published a report in 2008 on foods for persons suffering from carbohydrate metabolism disorders (COM (2008) 392), 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. The FSG Regulation 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.

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 the Department of Health 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 & health claims legislation. See the EU Register of Nutrition & Health Claims e.g. “no added sugar”, “Consumption of foods/drinks containing <name of sugar replacer> instead of sugar* induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks. *In the case of D-tagatose and isomaltulose this should read "other sugars".

6.11 European Parnuts/FSG legislation

In summary, specific rules have been set out by Commission Directives for the following groups of dietary foods. These will be repealed when the delegated acts of the FSG regulations apply from 2019 onwards:

Infant formulae and follow on formulae

Commission Directive 2006/141/EC on infant formulae and follow-on formulae amending Directive 1999/21/EC

Processed cereal based foods and baby foods (weaning foods)

Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children amending Commission Directive 96/5/EC

Foods for special medical purposes

Commission Directive 1999/21/EC on dietary foods for special medical purposes as amended by Commission Directive 2006/141/EC

Foods for total diet replacement for weight control

Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. Since July 2016, this no longer applies to foods presented as a replacement for one or more meals of the daily diet.