

IMPORTANT INFORMATION

If you are a food business operator the information in this document will help you understand the specific legislative rules you must comply with if you are selling food supplements, fortified foods, food for particular nutritional uses “parnuts” foods (i.e. infant formula, follow-on formula, medical foods, baby foods, slimming foods and gluten-free foods), and foods making health claims or nutrition claims.

You will need to read all the information in page 1-2 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 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 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
- Citizens Advice Bureau: Information on setting up a business
- You may also wish to consider establishing a **Primary Authority Partnership** with a single local authority: Primary Authority Handbook

b. Many questions about food supplements, fortified foods, nutrition and health claims, and foods known as ‘parnuts’ foods (i.e. infant formula, follow-on formula, medical foods, baby foods, slimming foods and gluten-free foods) nutrition labelling and general food labelling will be answered by these guidance documents:

- Food Supplements Guidance and FAQs
- Guidance on Fortified Foods
- Guidance on Nutrition and Health Claims
- Guidance and Notification Forms For Introducing Parnuts, medical foods and infant formula to the UK

- [UK nutrition labelling technical guidance on the Food Information for Consumers Regulation](#)
 - [UK Front of Pack Guidance](#)
 - [DH Bulletins on Nutrition & Health Claims](#)
 - [DH Bulletins on Food For Specific Groups](#)
 - [DH Food Supplements and Fortified Foods Interested Parties Updates](#)
 - [Food Information For Consumers Regulation applies December 2014](#)
 - [GOV.UK Information on Food Labelling](#)
 - [European Commission Q&A \(on the EU Food Information for Consumers Regulation\)](#)
- c. We are unable to authorise the composition or labelling of individual products. For advice on specific products, including the checking of labels, 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, 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@foodstandards.gsi.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@foodstandards.gsi.gov.uk
- f. The Department for Environment, Food & Rural Affairs (Defra) is responsible for policy on general food labelling other than nutrition labelling rules. This includes the general labelling provisions of the EU Food Information to Consumers Regulation (EU FIC), such as ingredients listing, country of origin labelling and other elements that are not nutrition 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 request to change existing law should be forwarded to: helpline@defra.gsi.gov.uk
- g. The **MHRA** will determine if a product needs to follow medicines or food law if there is uncertainty. Please contact Medicines.Borderline.advice@mhra.gsi.gov.uk This guidance may also be useful: [How the MHRA determine whether a product is medicinal](#)
- h. **E- Learning 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 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 web site for all your Trading Standards and Environmental Health related information across England and Wales

- **Trade Associations** provide 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)**
 - **Council for Responsible Nutrition (CRN)**
 - **Dairy UK**
 - **European Specialist Sports Nutrition Alliance (ESSNA)**
 - **Food and Drink Federation (FDF)**
 - **Health Food Manufacturers' Association (HFMA)**
 - **Proprietary Association of Great Britain (PAGB)**
- **The Health Supplements Information Service**
- The **Institute of Food Science & Technology (IFST)** publishes a list of food consultants / technical advisors: IFST list of food consultants

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SECTION 1: FOOD SUPPLEMENTS

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.

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 relevant 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.

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. 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](#)

4. Medicinal claims and products

[Please see paragraph \(f\) on page 2 of this document](#)

5. Novel Foods

[Please see paragraph \(e\) on page 2 of this document](#)

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 laevorotatory 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.

7. General Food Labelling

Food supplements also have to comply with many of the general food labelling requirements. Please see [paragraph \(b\) on page 2](#) for useful documents.

SECTION 2: 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](#)

8. 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](#)

9. 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:

- [DH guidance to compliance with Regulation EC 1925/2006 on the addition of vitamins and minerals and certain other substances to food](#)

10. 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](#)

SECTION 3: NUTRITION & HEALTH CLAIMS MADE ON FOOD

11. 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.

12. 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.

13. 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](#)

14. 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 DH 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.

15. 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](#)

16. 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 the [search engine](#) on the FSA website.

SECTION 4: FOODS INTENDED FOR PARTICULAR NUTRITIONAL USES (PARNUTS) / (After July 2016 PARNUTS foods will be known as Foods For Specific Groups (FSGs))

17. Types of Parnuts foods

Parnuts foods are foods which owing to their special composition or process of manufacture are clearly distinguishable from foods intended for normal consumption and in addition are sold in such a way as to indicate suitability for their claimed particular nutritional purpose. A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons a) whose digestive processes or metabolism are disturbed or b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or c) of infants or children in good health.

Foods intended for particular nutritional uses are regulated by framework [Directive 2009/39/EC](#) and by specific Directives adopted under that framework.

Parnuts foods can be grouped into the following categories:

- Infant formula and follow-on formula
- Processed cereal based foods and baby foods for infants and young children
- Certain weight reduction products
- Foods for special medical purposes

The framework Directive also includes within its scope sports foods, Very Low Calorie Diets (VLCDs) and diabetic foods, but there are no specific rules on their composition/labelling in the EU or UK.

18. 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 themselves the nutritional requirements of infants during the first months of life. Follow-on formulas 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.

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

19. Processed cereal based foods and baby foods

These are parnuts 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 \(as amended\)](#)

20. Foods intended for use in energy restricted diets for weight reduction

Low calorie diet foods are specially formulated foods which replace the whole of the diet or one or more meals of the daily diet. Very low calorie diets are outside the scope of the specific Regulations for Foods intended for use in energy restricted diets for weight reduction and therefore have to be notified as Article 11 products. (See paragraph 26 below).

Foods intended for use in energy restricted diets for weight reduction 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](#)

21. Foods for special medical purposes

Medical foods are classified as dietary foods for special medical purposes 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.

22. 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](#)

23. Foodstuffs suitable for people intolerant to gluten

[Commission Regulation \(EC\) No 41/2009](#) on the content and labelling of foodstuffs suitable for people intolerant to gluten. This legislation harmonises rules on the labelling related to the absence of gluten in food. It sets out the conditions under which foods may be labelled as "gluten-free" or "very-low gluten".

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

24. Addition of substances for specific nutritional purposes

[The Food for Particular Nutritional Uses \(Addition of Substances for Specific Nutritional Purposes\) \(England\) Regulations 2002 \(SI 2002 No. 1817\) \(as amended\)](#) implement Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (as amended). There is similar legislation in Scotland, Wales and Northern Ireland (NI).

25. Article 11 parnuts foods

Article 11 products, which also have to meet the requirements laid down in [Council Directive 2009/39 \(as amended\)](#) are parnuts products which are neither covered nor are to be covered by other specific Directives. This Article prohibits the sale of products by manufacturers and importers unless they have been notified to competent authorities; this is the Department of Health in England and the Food Standards Agency in Scotland, Wales and Northern Ireland.

26. Notification procedures

The notification of Article 11 products is regulated in England by The Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007 (SI 2007 No. 181). There is similar legislation in Scotland, Wales and Northern Ireland.

[Council Directive 2009/39/EC](#) requires that when a Parnuts product is placed on the market for the first time, the manufacturer or importer shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.

Similar requirements to notify also exist for certain categories of Parnuts foods, where rules are laid down in specific Directives/Regulations.

When the following foods are placed on the market, manufacturers must notify the Department of Health in England or the Food Standards Agency in Scotland or Northern Ireland or the Welsh Government.

- Article 11 Particular Nutritional Use foods (e.g. very low calorie diet foods)
- New or updated formulations of Infant formula
- Dietary foods for special medical purposes (FSMP)
- Gluten-free foods

Parnuts foods which are not required to be notified include:

- follow-on formulas
- 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)

Please complete the [notification form](#)

27. 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 State agreeing to remove diabetic foods from the scope of the [Framework Directive 2009/39/EC](#) on ‘parnuts’ foods and 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 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"

28. European Parnuts legislation

The [European framework Directive 2009/39/EC](#) lists the following groups of dietary foods for which specific rules have been set out by Commission Directives:

Infant formulae and follow on formulae

[Commission Directive 2006/141/EC](#) of 22 December 2006 on infant formulae and follow-on formulae and 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 intended for use in energy restricted diets for weight reduction
[Commission Directive 96/8/EC](#) on foods intended for use in energy-restricted diets for weight reduction

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](#)

Foodstuffs suitable for people intolerant to gluten
[Commission Regulations \(EC\) No 41/2009](#) on the content and labelling of foodstuffs suitable for people intolerant to gluten. Regulation 41/2009 will be transferred to [Commission Regulation 1169/2011](#) (applies from December 2014). Regulation (EC) No 41/2009 will therefore be repealed from December 2014.

Substances that may be added to parnuts foods
[Commission Directive 2001/15/EC](#) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (as amended)

Information on these foods can be found on the [European Commission website](#)

Date: 2 April 2014