

Food supplements

*Summary information on legislation relating to
the sale of food supplements*

This guidance applies to the whole of the UK and was prepared by the Department of Health in association with the Welsh Government, and Food Standards Agency in Scotland and Northern Ireland

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Intended audience

This document has been created with the aim of providing a summary guide for companies that manufacturer, process, distribute, use, sell or import food supplements.

Executive summary

The EU Food Supplements Directive 2002/46 came into force on 1 August 2005 and is implemented by the Food Supplements (England) Regulations 2003 and equivalent regulations in Scotland, Wales and Northern Ireland. The Regulations specify compositional and labelling requirements of food supplements, including the vitamin and mineral substances permitted for use in food supplements.

The information set out in this document contains details of the legislation that applies to the manufacture, import and sale of food supplements in the UK. It includes a number of links to relevant legislation and further guidance in this area.

Prepared by Food Supplements, Fortification and Claims Team

Last updated

September 2011 to update references to legislation in this area and reflect the transfer of responsibility for nutrition policy in England from the Food Standards Agency to the Department of Health on 1 October 2010. No other significant changes have been made.

The Department of Health has responsibility for national and EU legislation on food supplements within England. The responsibility for the policy area of food supplements legislation in Wales has moved to the Welsh Assembly. The Food Standards Agency Devolved Administrations of Scotland, and Northern Ireland are responsible for national legislation in their own administrations where separate but similar regulations apply.

January 2012 to insert references to Commission Regulation (EU) No 1161/2011, amending the list of mineral substances in Annex II of Directive 2002/46/EC.

Introduction

The Department of Health has responsibility for national and EU legislation on food supplements within England. The responsibility for the policy area of food supplements legislation in Wales has moved to the Welsh Assembly. The Food Standards Agency Devolved Administrations of Scotland and Northern Ireland are responsible for national legislation in their own administrations, where separate but similar regulations apply.

If you wish to address the wider EU market, you should contact the relevant food safety authorities (“National Competent Authorities”) within those countries in which you wish to market products. The following link will take you to the European Commission’s Food Supplements Gateway; approximately half way down the web page you will find a link to a document listing all of the National Competent Authorities of each Member State:

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

The food supplements EU Directive and national legislation

The EU Food Supplements Directive 2002/46 came into force on 1 August 2005 and is implemented in the UK by the Food Supplements (England) Regulations 2003 and equivalent regulations in Scotland, Wales and Northern Ireland¹. The Regulations specify the vitamin and mineral substances permitted for use in food supplements and identify the units of measurement, labelling, presentation and advertising allowed. Food Supplements are defined as:

- A concentrated source of a vitamin, mineral or other substance with a nutritional or physiological effect, alone, or in combination, sold in dose form.

List of permitted vitamins and minerals

Historically, several lists existed of vitamins, minerals and their sources permitted for use in food supplements. In 2009, Commission Regulation (EC) No.1170/2009 amended the Directive and consolidated these lists.

Commission Regulation EC/1170/2009 came into force on 1 January 2010 and is implemented in the UK by The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 (<http://www.legislation.gov.uk/ukxi/2009/3251/contents/made>), and equivalent regulations in Scotland, Wales and Northern Ireland². The UK Regulations refer to the amending EU

¹ The Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278; the Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186); and the Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273

² The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 SSI 2009 No. 438; The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 WSI 2009 No. 3252 (W282); The Food Supplements and the Addition of

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Regulation, simplifying the process of determining which vitamins and minerals may be used in food supplements.

Annex II of the Directive is further amended by Commission Regulation (EU) No 1161/2011: A consolidated version of the Directive is available on the Commission's website at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20111205:EN:PDF>

Adding new sources of vitamins and minerals to the permitted list

Dossiers of safety information for vitamins, minerals, and their sources not currently included in the Annexes of Directive 2002/46/EC can be submitted to the European Food Safety Authority (EFSA) at any time. Information on how to do this can be found at

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm under the heading Guidance for submission. If EFSA provide a favourable opinion on submitted dossiers, their opinion will be passed to the Standing Committee on the Food Chain and Animal Health for consideration before being passed into law and added to the lists in the Annexes.

The legislation currently contains positive lists only for vitamins and minerals. There are no requirements at this stage for other substances such as essential fatty acids, amino acids or other nutrients or botanicals to be listed and these continue to be available, however all substances are required to adhere to the generic areas of the legislation concerning packaging, labelling and safety.

Article 5 of the Directive contains a legal requirement for the setting of maximum and minimum levels for vitamins and minerals in food supplements, on the basis of science and safety. The European Commission's timetable for this work remains unclear.

Useful Links

Copies of the UK legislation are available from the Stationery Office Tel: 0870 600 5522; or free to view at: www.legislation.gov.uk

The link below will take you to the EU Commission Food Supplement Gateway.
http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

This site contains links to a variety of EU documentation including:

- The Food Supplements Directive 2002/46/EC
- Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements

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- Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods
- Guidance on the submission of dossiers of the safety evaluation of substances with a view to the addition of further vitamins, minerals and their sources to the Annexes to Directive 2002/46/EC.

The Food Supplements Gateway also has links to papers relating to the setting of maximum and minimum levels.

Other Relevant Legislation

Kava-Kava

You should 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)

This is implemented in the UK by the Kava-kava in Food (England) Regulations 2002 (as amended) and equivalent legislation in Scotland, Wales and Northern Ireland³. Copies of the regulations can be viewed at the below link:

<http://www.legislation.gov.uk/uksi/2002/3169/contents/made>

Tryptophan

The UK has national legislation that 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.

This is implemented in the UK by the Tryptophan in Food (England) Regulations 2005 (as amended) and equivalent legislation in Scotland, Wales and Northern Ireland⁴. Copies of the regulations can be viewed at the below link:

[The Tryptophan in Food \(England\) Regulations 2005](#)

Medical Claims

The Medicines and Healthcare Products Regulatory Agency (MHRA), which is an Executive Agency of the Department of Health, are responsible for ensuring that medicines and medical

³ The Kava-kava in Food (Scotland) Regulations 2002 No. 523 (as amended); The Kava-kava in Food (Wales) Regulations 2002 No. 3157 (W. 293) (as amended); and the Kava-kava in Food Regulations (Northern Ireland) 2003 No. 10 (as amended).

⁴ The Tryptophan in Food (Scotland) Regulations 2005 No. 479; The Tryptophan in Food (Wales) Regulations 2005 No. 3111 (W. 231); and the Tryptophan in Food Regulations (Northern Ireland) 2005 No. 440.

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devices work, and are acceptably safe. The majority of food supplements are covered by food law, but where they have a medicinal effect or make a medicinal claim (i.e. to prevent, treat or cure any disease or medical condition), they must be licensed under medicines legislation, which is the responsibility of MHRA. Medicines law is not harmonised across the EU and what may be freely sold in one EU Member State as a food may be classified as medicinal in another EU Member State.

In addition, many herbal ingredients are classified as medicines and, as such, are also under the jurisdiction of the MHRA. If you have any queries about medicinal claims, please contact:

Borderline Section, Inspection and Enforcement Division
Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road,
Victoria,
London, SW1W 9SZ
Tel: 020 3080 6759. www.mhra.gov.uk/

Herbal Products

Herbal products are regulated by the Traditional Herbal Medicines Directive, which is administered in the UK by the MHRA. The link below will take you to a webpage providing information on borderline products, including a paragraph on herbal ingredients in which you can find a guidance sheet on herbal ingredients and a list of herbal ingredients and their reported uses:

www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=91

Labelling and packaging of food supplements

In addition to the labelling requirements in Food Supplements legislation, the requirements of the Food Labelling Regulations 1996⁵, as amended, also apply (these implement in Great Britain the EU Food labelling Directive 2000/13/EC). General labelling enquiries should be directed to the helpline at the Department for Environment, Food and Rural Affairs (DEFRA), either by telephone on 08459 33 55 77 or by email at: defra.helpline@defra.gsi.gov.uk.

Responsibility for labelling of products falls to the manufacturer of the supplement rather than the raw material supplier, however, if the raw materials are organic in origin there must be certification evidence provided to support this. Manufacturers should also be aware of legislation relating to health claims and of advisory statements, which apply to some products containing high levels of vitamins and minerals (see below).

⁵ The Food Labelling Regulations (Northern Ireland) 1996 Statutory Rule 1996 No. 383 (for Northern Ireland)

Advisory statements

In 2004 a voluntary agreement was reached between Government officials and food supplements industry representatives covering food supplement products containing high levels of vitamins and minerals. The agreement covers advisory statements to be included on labels and, in a limited number of cases, suggests reformulation. The advisory statements, and an explanation of the background to it can be found on our website (click [here](#)).

Nutrition and Health Claims

Voluntary nutrition or health claims must comply with the requirements of European Regulation (EC) No 1924/2006 on nutrition and health claims made on food.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF>

Regulation 1924/2006 requires nutrition and health claims to be authorised at the EU level to be used. 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 which states suggests or implies that health benefits can result from consuming a given food, such as “helps build strong bones”, “maintains healthy cholesterol levels”. The Regulation also controls general references to overall health and well-being, such as “healthy” or “superfood”. Regulation 1924/2006 applies to claims made in any commercial communication, including on labels, leaflets and websites and in adverts.

Further guidance on nutrition and health claims is available on the Departments website at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130972

General Food Law

Under the Food Safety Act (as amended), it is an offence to sell food that is not of the nature, substance or quality demanded by the consumer or that is falsely or misleadingly described or labelled. <http://www.legislation.gov.uk/ukpga/1990/16/contents>

Article 16 of EC Regulation 178/2002 regulates the labelling, advertising and presentation of food. This includes its shape, appearance or packaging, the materials used, the manner in which they are arranged, the setting in which they are displayed, and the information which is made available about them through whatever medium. The Regulation stipulates that none of the above shall mislead customers.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

The General Food Regulations 2004 (as amended)⁶ make it an offence to contravene or fail to comply with this provision <http://www.legislation.gov.uk/uksi/2004/3279/contents/made>

⁶ The General Food Regulations (Northern Ireland) 2004 Statutory Rule 2004 No. 505 (for Northern Ireland)

Novel Foods

If any product you may wish to market contains any ingredients that are new to the EU then the terms of the Novel Food Regulation (EC) 258/97 may apply. Novel foods are defined as foods that do not have a significant history of consumption within the EU prior to 15 May 1997 and these are subject to a rigorous pre-market safety assessment. This could apply to vitamins and minerals that currently appear in Regulation 1170/2009 if they are obtained from a source that is subject to Regulation (EC) 258/97. Any nutrient derived from a genetically modified source would also be subject to safety assessment before it could be added to the positive lists in Regulation (EC) 1170/2009.

In the UK, the assessment of novel foods is carried out by the Advisory Committee on Novel Foods and Processes (ACNFP), an independent committee of scientists appointed by the Food Standards Agency. Novel sources of vitamins and minerals would also be subject to assessment by EFSA.

The link below will take you to the Food Standards Agency's website, which contains further information on the Novel Food Regulation:

<http://www.food.gov.uk/gmfoods/novel/>

Genetically Modified (GM) Food and Feed Regulation

Ingredients obtained from genetically modified (GM) organisms are only permitted for use in supplements if they have the necessary clearance, authorizing them for use in foods, under Regulation (EC) 1829/2003 on genetically modified food and feed. Under this regulation, labelling is required for all food and feed products derived from GM sources. Labelling is not dependent on the presence of detectable genetic material in the final product or on the quantity of GM ingredients used. The link below will take you to the Food Standards Agency's website, which contains further information on the GM Food Regulation:

<http://www.food.gov.uk/gmfoods/gm/>

Registration and Certification

There is no requirement for food supplements to be registered or authorised for sale in the UK but products must comply with the legal requirements as outlined in this document.

If you are exporting food supplements from the UK, Certificates of free sale, which state that a product is legally available for sale on the UK market, can be obtained from the Rural Payments Agency, an executive agency of the Department for Environment, Farming and Rural Affairs (DEFRA). More information about certificates of free sale can be found at:

www.rpa.gov.uk/rpa/index.nsf/0/38B7B6E1E45FE8E0802570D2005DB68A

Imports

It is the responsibility of the manufacturer, importer or distributor to ensure that their product complies with the legislation as detailed in this document. In addition, advice on complying with the appropriate legislation for the labelling and sale of individual products can be obtained from

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the Trading Standards Department or the Environmental Health Department of the local authority where your importer or your distributor is based (see <http://www.food.gov.uk/enforcement/enforceessential/yourarea/>). Alternatively, you can contact the local Port Health Authority based at your products point of entry in the UK. You can find out who this is by contacting the following:

Association of Port Health Authorities

3rd Floor

Walbrook Wharf

78-83 Upper Thames Street

London

EC4R 3TD

Tel: 08707 444505

<http://www.porthhealthassociation.co.uk/>

For information on the food hygiene requirements that apply to the import of food products, such as food supplements from countries outside the European Union, please contact the Imported Food Branch in the Food Standards Agency's Local Authority Enforcement Division: Telephone 020 7276 8018 Email imported.food@foodstandards.gsi.gov.uk

Import of gelatine capsules

Advice on importing gelatine capsules for food supplements can be found at:

HTTP://WWW.food.gov.uk/business-industry/imports/want_to_import/animalimports/gelatine

Contacts

The Department of Health is unable to authorise the composition or labelling of individual products. **For advice on specific products, including the checking of labels**, please contact your local Trading Standards office, the details of which can be obtained on the Food Standards Agency's website by using the on-line search engine at:

<http://www.food.gov.uk/enforcement/enforceessential/yourarea/>

For information **on food supplement legislation**, please contact the Department of Health helpline at:

Customer Service Centre

Department of Health

Richmond House

79 Whitehall

London SW1A 2NS

Tel: 020 7210 4850

or on-line enquiries: <http://www.info.doh.gov.uk/contactus.nsf/memo?openform>.