

Food Supplements (vitamins and minerals): How to ensure your Food Supplements are Compliant under the Law

In order to **supply food supplements** in the United Kingdom (“UK”), a manufacturer or distributor of food supplements must be compliant under the law, writes Dr Rosanna Cooper. In this article we explore the regulation of food supplements in the UK.

The industry sector for food supplements is wide and varied spanning across the whole of the European Community (“EU”), which means that the manufacture and sale of food supplements can be subject to national as well as EU laws.

The regulation of the sale of food supplements

Food supplements are sold 'in dose' form as pills, tablets, capsules or liquids and may be used to balance certain **nutritional deficiencies** or maintain an adequate intake of certain nutrients. The **EU Food Supplements Directive 2002/46 (“The Directive”)** as amended and other regulation aim to ensure safe use of food supplements.

The **Directive** as amended regulates **the composition and labelling of food supplements**, including their vitamins and minerals content, as well as the manufacture, import and sale of food supplements.

The Directive specifies:

- Which **vitamins and minerals** can be used in the preparation of food supplements;
- The **units of measurement** to be used;
- The **labelling requirements**;
- The **presentations** that are allowed for food supplements; and
- The **advertising** that is allowed for food supplements.

Commission Regulation EC/1170/2009¹, sets out the process to determine which **vitamins and minerals** may be used in food supplements².

¹ Annex II of Directive 2002/46 amended by Commission Regulation (EU) No 1161/2011. See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20111205:EN:PDF>

Article 5 of the Directive sets out the legal requirement for the maximum and minimum levels of vitamins and minerals that food supplements should contain.

Food supplements sold to the ultimate consumer must be pre-packed. The 'ultimate consumer' is defined as:

"any person who purchases otherwise than:

- a) for the purpose of resale;*
- b) for the purposes of a catering establishment; or*
- c) for the purposes of a manufacturing business".*

A "food supplement shall be regarded as "pre-packed", if:

- a) it is ready for sale to the ultimate consumer or to a catering establishment, and*
- b) it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging".*

Definition of food supplements

Food supplements are **defined** as:

Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological function, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

"..dose form means a form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities".

The term 'to supplement' may be interpreted as 'taken in addition to' the diet.

Food supplements may only contain the allowable **vitamins and mineral salts** laid down in Annex I of the Directive, and the **vitamin and mineral formulations (singly or in combination)**, as listed in Annex II. To date there are 13 vitamins with 45 allowable sources and 17 minerals with a total of 136 allowable sources.

The **purity criteria** of food supplements will be established by the European Commission ("Commission"), none have been set as yet. As no criteria have been laid down by the Commission, generally acceptable **purity criteria** recommended by international bodies may be used such as the Joint FAO/WHO Committee on Food Additives (JECFA) and the European Pharmacopoeia.

² http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.

The European Food Safety Authority (“EFSA”) through the Commission can **evaluate different vitamins and mineral substances** for inclusion in the lists in Annex I and Annex II. A **scientific dossier** will have to be submitted to the Commission by companies wishing to market new substances to be evaluated in relation to the **safety and bioavailability** of the individual substances.

The working of EFSA

EFSA produces opinions used by the Commission to adopt legislation. EFSA:

- Evaluates proposals for the addition of vitamins and minerals to the Food Supplements Directive;
- Evaluates nutrition and health claims;
- Assesses how to establish maximum limits for vitamins and minerals in food supplements and fortified foods;
- Provides opinions on substances other than vitamins and minerals;
- Works in close collaboration with national authorities.

Labelling and packaging of food supplements

The **manufacturer of food supplements** is responsible for labelling of such products, not the raw material supplier.

The words “food supplement” must appear on the label and can appear alone or with other words such as “**Food Supplement - containing vitamins and minerals**”. Manufacturers should use the more descriptive option wherever possible.

The **labelling** of all food supplements must comprise the following:

- The **names** of the categories of the nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
- The portion of the product recommended for **daily consumption** and a **warning of the risks** to health if this is exceeded;
- A declaration to the **effect that the supplement** is not a substitute for a varied diet;
- The reference “**This is not a medicinal product**”, where the presentation of the product is similar to that of a medicinal product;
- A **warning** to the effect that the product should be **stored out of the reach of young children**.

The labelling of food supplements must **not** contain any statement:

- Attributing to the product properties of **preventing, treating or curing a human disease**;
- Stating or implying that a **balanced and varied diet** cannot provide appropriate quantities of nutrients in general.

The Directive stipulates that there has to be **minimum dosage amounts** in order for a product to be considered a food supplement and upper safe limits to protect consumers (these limits are laid down by each Member State).

Examples of the *names of the categories of any vitamins or minerals or other substances with nutritional or physiological effect* include, but are not limited to:

- "vitamins"
- "minerals"
- "amino acids"
- "fatty acids"
- "Vitamins or minerals" or with "herbs".

Furthermore, the *names of the categories of any vitamins or minerals or other substances with nutritional or physiological effect* which characterises the products or an indication or the nature of those vitamins or minerals or other substances be included in the labelling **do not have to be in the in same field of vision as the term "food supplement"**. Practically, it may be useful for consumers to have them placed together.

The labelling requirements apply to all food supplements including those containing vitamins or minerals. There are no exemptions under the Directive for the labelling of small packages.

Food Supplements UK legislation

The legislation stipulates that³:

No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement". Without prejudice to the Food Labelling Regulations 1996, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars

- (a) *the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;*
- (b) *the portion of the product recommended for daily consumption;*
- (c) *a warning not to exceed the stated recommended daily dose;*
- (d) *a statement to the effect that food supplements should not be used as a substitute for a varied diet;*
- (e) *a statement to the effect that the product should be stored out of the reach of young children; and*
- (f) *the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.*

It is recommended:

³ <http://www.legislation.gov.uk/ukxi/2003/1387/contents/made>

- To have a warning against exceeding the recommended daily "intake";
- To state on the labels that food supplements should not be used as a substitute for a varied diet;
- To state on the labels that the products should be stored out of the reach of young children;
- That where the food supplement contains more than one source of a mineral that all sources should be considered when declaring the quantities of the mineral on the label;
- To use the units of measurement for vitamin A, E and niacin given in Annex I of the Directive such as "RE", "TE" and "NE" respectively.

VITAMIN	TO BE CALCULATED AS
Vitamin A	retinol <i>or</i> retinol equivalent on the basis that 6µg α -carotene or 12µg of other biologically active carotenoids
Vitamin D	ergocalciferol (vitamin D2) <i>or</i> cholecalciferol (vitamin D3)
Vitamin E	D- α tocopherol equivalent on the basis that 3.3 mg α tocotrienol or 10mg α tocopherol are equivalent to 1 mg D- α
Vitamin C	Ascorbic acid or dehydroascorbic acid
Thiamin	thiamin
Riboflavin	riboflavin
Niacin	nicotinic acid <i>or</i> nicotinamide <i>or</i> niacin equivalent on the basis that 60mg of tryptophan equal 1mg of niacin equivalent
Vitamin B6	pyridoxine
Folic Acid	total folates
Vitamin B12	cobalamines
Biotin	biotin
Pantothenic acid	D-pantothenic acid

Nutrition Labelling

In the UK, food supplements fall outside the requirements of the Nutrition Labelling Directive (90/496/EEC as amended). However, in the case of vitamins and minerals, the *name of the category of any vitamins or minerals or other substances with a nutritional or physiological effect which characterises the products or an indication of the nature of those vitamins or minerals or other substances* **must** be accompanied by the **percentage of the relevant Recommended Daily Allowance (RDA)**⁴.

Nutrition and Health Claims⁵

All health claims must comply with the requirements of European Regulation (EC) 1924/2006 on nutrition and health claims made on food ("Regulation")⁶. This

⁴ See Annex to Commission Directive 2008/100/EC <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0100:EN:NOT>

⁵ Regulation 1924/2006

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF>

Regulation applies to claims made in any commercial communication, including on labels, leaflets, packaging, websites and advertising.

This Regulation stipulates that all nutrition and health claims have to be authorised at the EU level to be used in labelling and packaging. A nutrition claim states, suggests or implies that a food has beneficial nutritional properties, such as “low fat” or “high in fibre”. A health claim states, suggests or implies that health benefits can result from consuming a given food, such as “helps build strong bones” or “maintains healthy cholesterol levels”. The Regulation also controls general references to overall health and well-being, such as “healthy” or “superfood”.

Only nutrition and health claims that are included in one of the EU positive lists will be allowed. Food supplements carrying claims must comply with the provisions of **nutritional labelling Directive 90/496/EC** as amended.

EFSA has accepted claims for vitamins, some minerals, omega-3s and sterols/stanols.

EU Regulation 178/2002 deals specifically with foods containing botanicals. See EFSA for specific claims you may be able to make regarding botanicals.

Prohibition in the UK on the sale of Food Supplements containing Kava-kava and Tryptophan

In the UK, any food supplement contain kava-kava is prohibited⁷. There is also a restriction in the UK on the addition of tryptophan to food supplements subject to purity and dose criteria.

Medical Claims

Any food supplement that has a **medicinal effect or makes a medicinal claim** (to **prevent, treat or cure any disease or medical condition**) must have a marketing authorisation. In the UK, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) will grant this marketing authorisation.

If you are selling or intend to sell food supplements in the EU, you must ensure that your supplements are compliant across each Member State as currently there is no harmonisation regarding the classification of food supplements and medicines.

It is worth noting that certain **herbal substances** may be classified as medicines requiring marketing authorisations⁸.

Advertising and sale

⁷ <http://www.legislation.gov.uk/ukxi/2002/3169/contents/made>

⁸ http://www.rtcoop.com/userfiles/Traditional_Herbal_Registration_June13.pdf

The **labelling, presentation or advertising** of a food supplement must not include any mention, express or implied, that “a balanced and varied diet cannot provide appropriate quantities of nutrients in general”.

When the marking or labelling of any food supplement is sold to the **ultimate consumer** or sold **ready for delivery to a catering establishment** in **pre-packed form**, the labelling particulars must be:

- On the **packaging**; or
- On a **label attached to the packaging**; or
- On a **label which is clearly visible through the packaging**.

In the case where the sale is not to the ultimate consumer, these particulars may be included on the commercial documents relating to the food supplements.

In addition, these particulars should be:

- **Easy to understand**;
- Clearly **legible and indelible**;
- When a food supplement is sold to the ultimate consumer these particulars should be **marked in a conspicuous place** in such a way as to be clearly visible;
- Not be **hidden, obscured or interrupted** by any other written or pictorial matter.

Although food supplements may only be sold to consumers in pre-packed form, food supplements may be delivered in bulk supply to retailers or catering establishments ready for packing on the premises for sale to the ultimate consumer.

The labelling of food supplements sold ready for delivery to catering establishments but not pre-packed stipulates that the labelling particulars must be:

- *On a label attached to the food supplement; or*
- *On a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food supplement; or*
- *In commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.*

The particulars for food supplements sold ready for delivery to catering establishments but not pre-packed:

- Must be easy to understand, clearly legible and indelible; and
- Not hidden, obscured or interrupted by any other written or pictorial matter.

In the UK, there is no requirement for food supplements to be authorised for sale. However, all food supplements must comply with the law.

If exporting food supplements from the UK, you must obtain certificates of free sale.

Novel Foods

If you intend to market or are marketing food supplements containing novel ingredients, you should check compliance with the Novel Food Regulation (EC) 258/97. Novel foods do not have a significant history of consumption within the EU prior to 15 May 1997 and are subject to a rigorous pre-market safety assessment.

Novel foods would have to be subjected to safety assessments before they could be included in the positive lists in Regulation (EC) 1170/2009. They may include:

- Vitamins and minerals that are obtained from a source that is subject to Regulation (EC) 258/97 (novel sources);
- Any nutrient derived from a genetically modified source.

Genetically Modified (GM) Food and Feed Regulation

Ingredients obtained from genetically modified (GM) organisms have to be cleared before they can be included in food supplements under Regulation (EC) 1829/2003 on genetically modified food and feed.

Imports

It is the responsibility of the manufacturer, importer or distributor to ensure that their products comply 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 us.

Conclusion

There are a number of legislation that must be complied with in the manufacture, sale, promotion, marketing, distribution and advertising of food supplements.

© RT COOPERS, 2013. This Briefing Note does not provide a comprehensive or complete statement of the law relating to the issues discussed nor does it constitute legal advice. It is intended only to highlight general issues. Specialist legal advice should always be sought in relation to particular circumstances.

The author is Dr Rosanna Cooper of RT Coopers Solicitors. She is an expert in [regulatory law](#), in particular, [herbal medicines](#) and [food supplements](#). Dr Cooper is a chartered chemist and a fellow of the Royal Society of Chemistry. She may be contacted on +44 (0) 207 488 9947 or by email:

enquiries@rtcooperssolicitors.com. For more information on the services provided by RT Coopers on food supplements law, visit http://www.rtcoopers.com/practice_foodsupplements.php.

Tags

Food Supplements Lawyers, Food Supplements Regulation, Regulating, Regulatory, Solicitors, Food Supplements Law, Lawyer, Product Authorisation, UK, Food Supplement, Labelling and Packaging, Dietary Supplements, Solicitor, Law Firm, Legal Services, Health and Medical Claims, Regulatory Law, Product Liability and Dietary Supplements, Food Supplement Advertising Requirements, Herbal Supplement Law, Dietary Supplement Regulation