Guideline: Food Information for Consumers Regulation and other Labelling Requirements for Food Supplements

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Background

This guideline is intended to assist PAGB members in understanding and complying with the complex area of food labelling. It has been developed in conjunction with advice from PAGB's Primary Authority, Westminster City Council, and reflects the current understanding of the interpretation of the Food Information for Consumers Regulation.

Regulators recognise that consumer choice is influenced by multiple factors including label information. However, food labelling within the EU over the last few decades has been subject to multiple amendments and additions, resulting in complex interrelated legislation.

Therefore regulators have consolidated many of the existing pieces of food labelling legislation into the EU Food Information for Consumers Regulation 1169/2011 **(**the **EU FIC**) with the intention of streamlining and simplifying labelling law.

The core objectives in the regulation of food labelling are:

- To facilitate the free movement of goods within the EU internal market;
- To provide appropriate information to consumers.

The EU FIC simplifies and modernises food labelling requirements and puts in place a number of new requirements relating to the provision of information to consumers at any point of purchase where food labels are not available, as in distance selling (e.g. selling via websites or catalogues). Annex I gives details of all mandatory labelling and information requirements; there is also a simplified check list in Annex III of this guidance.

The national competent authority in the UK for the EU FIC is the Department for Environment, Food and Rural Affairs (DEFRA), however the Department of Health (DH) and the Food Standards Agency (FSA) have also had input into the regulatory process as there is cross-over on labelling issues between departments.

As a Regulation, the EU FIC is directly applicable across the EU; each Member State implements the EU FIC via legislation that allows for its enforcement. Many provisions in the Regulation apply from 13 December 2014, however some will not come into full force until December 2016. DEFRA has elected to include a degree of flexibility in the UK Regulations enacting the EU FIC; the draft Statutory Instrument (SI) allows UK business to begin amending their labelling to comply early with the nutrition labelling provisions of the EU FIC. However, the SI is unlikely to come into force until mid 2014 as its implementation has been delayed.

One of the major changes to nutrition labelling is the change from the current use of Recommended Daily Allowances (RDAs) to the use of Nutrient Reference Values (NRVs). For labelling purposes NRVs may alternatively be referred to as Reference Intakes (RIs).

Enforcement have informed the wider food industry that they are aware of the practical issues associated with implementing changes to labelling to bring products into compliance with the EU FIC. They have advised that they will be taking a pragmatic view on products which begin to make changes before the EU Regulation is fully in force, and before the UK SI has been implemented. Therefore members

wishing to make labelling changes may begin to do so. PAGB have been advised that the Enforcement Group intend issuing a letter confirming this.

All food produced from 13 December 2014 must comply with the requirements of the Regulation, however, in common with other labelling law, **the Regulation allows for sell-through.** Foods legally placed on the market before the ending of transition may continue to be sold until stocks are exhausted. Although no official guidance has been received as to the definition of "legally placed on the market" from either DEFRA or the Commission, PAGB's view is that this is where batches have been produced and are ready for, or have been, shipped.

The following legislation has been consolidated into the EU FIC and will be repealed from 13 December 2014.

- Council Directive 90/496/EEC on the Nutrition Labelling of Foodstuffs
- Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs
- Commission Directive 2008/5/EC concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC
- Commission Directives 2002/67/EC on the labelling of foodstuffs containing quinine and foodstuffs containing caffeine
- Commission Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters
- Commission Directive 1999/10/EC providing for derogations from the provisions of Article 7 of Council Directive 79/112/EEC as regards the labelling of foodstuffs
- Commission Directive 87/250/EEC on the indication of alcoholic strength by volume in the labelling of alcoholic beverages

Reference to any of the above in related legislation should be taken to refer to the EU FIC **from 13 December 2014.**

Provisions of the EU FIC

The EU FIC puts in place some labelling requirements which are new and amends other existing requirements. Unlike previous labelling law, the EU FIC requires that all mandatory information be made available to consumers at any point of purchase, including distance selling (i.e. websites and catalogues) Freephone numbers may be used to provide the information so long as there is no cost to the consumer. A table including details of the mandatory information required under the EU FIC and the Food Supplements Regulations (England) 2003 can be found in Annex I.

Fair information practices

As with existing food law, the EU FIC requires that food information on labelling, packaging, in advertising and distance selling should not be misleading. This can include how foods are presented and the setting/s in which they are displayed.

Food information must be accurate, clear and easy to understand and cannot attribute any effect or property to food which it does not possess. Nor should it suggest that any food possesses special characteristics when all similar foods also possess similar characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients.

Food supplements are formulated to fulfil specific requirements, such as including 100% of the Nutrient Reference Value (NRV) of a nutrient, or being a "complete" multivitamin. Therefore, although there may be other similar products on the market, food supplements will still be able to make these kinds of claims.

"Free from" claims must be accurate and not misleading. It is worth noting that gluten free claims are regulated under Regulation 41/2009 on the composition and labelling for foods for people intolerant to gluten.

The prohibition of any food attributing the property of preventing, treating or curing a human disease, or referring to such properties is retained. Authorised Disease Risk Reduction claims are permitted under the Nutrition and Health Claims Regulation so long as they comply with the conditions of use for the claim.

Responsibilities

The Food Business Operator (FBO) is responsible for the presence and accuracy of all information on labels, packaging, advertising and distance selling.

The responsible FBO is the operator under whose name the food is marketed, or, if they are not established within the European Union, the importer into the EU market. Businesses throughout the food supply chain must also take responsibility to ensure that information is accurate, and must not supply food or raw materials that they know, or presume to be non-compliant with the law.

Field of vision

There are new requirements for the placement of information within specific fields of vision. "Field of vision" is defined as all the surfaces of a package that can be read from a single viewing point.

There is an additional requirement for certain information to be held within the same "field of vision":

- The name of the food
- The net quantity of the food
- If relevant the alcoholic strength by volume (ABV)
- If relevant, the caffeine warning statement and the amount of caffeine in the product, per portion for daily consumption.

- If relevant, "*with added plant stanols" / "with added plant sterols"*

Although there is no requirement for these to appear in the "principal field of vision" (defined as the field of vision most likely to be seen by the consumer, at first glance at the time of purchase) the Food Supplements Directive and national Regulations require that certain information should be marked in a conspicuous place in such a way as to be easily visible.

Best practice would therefore suggest that, at the least, the name of the food should be held in the principal field of vision to allow the consumer to identify the character, nature and brand name of the product.

The EU Commission has recently provided advice on this issue and has stated that because the net quantity of the food and any warnings need to be included in the same field of view as the name of the food, these particular aspects could be combined on back of pack if industry wishes to do so. Therefore the name of the food may be repeated on back of pack to accompany the other mandatory information. .

The Commission has also provided advice on the issue of inner and outer packaging and the kind of information which should be included on any inner packaging. Where food supplements are contained within a tube or bottle inside and outer carton, it is likely that the majority of consumers will discard the carton and with it the information held on this. Therefore it is advisable to include any mandatory or voluntary warnings on the label of the inner packaging; for example, allergen information or the warning in relation to iron and young children, which could present risk to the consumer if it were not available throughout the use life of the product/s.

The presentation of mandatory information

A full listing with explanatory details can be found in Annex I. This includes specified wording and field of vision information.

All mandatory food information must be in a language which is easily understood in the country the food is to be marketed in; although this does not preclude more than one language appearing on the label any secondary language must not be used to the detriment of space afforded to mandatory information.

Mandatory information cannot be presented in the format required by third countries such as the USA or Canada; it must appear in the format required in the European Union.

Mandatory information must be clearly visible and indelible. It must not be hidden, obscured, detracted from or interrupted in any way. For peel-back labels the Commission has advised that these should be assessed on a case-by-case basis to ensure that the requirements of the availability, visibility and placement of the mandatory information are fulfilled, including whether the information can easily be found. PAGB advises members who wish to use peel-back labels to discuss this with their local authority enforcement, such as Trading Standards; if members wish to obtain assured advice from a Primary Authority, contact PAGB who will seek advice on their behalf from Westminster City Council.

In the case of a “multipack”, for example if single doses are being sold in sachets, all mandatory information must appear on each individual sachet.

Food supplements are exempted from the Nutrition Declaration requirements in the Regulation (Articles 29-35). They will not be required to provide the following information (unless required to do so by the conditions of use against any nutrition or health claim that may be made on a food supplement product):

- Energy value;
- Amount of salt, saturates, carbohydrates, sugars, proteins and salt in a product;
- A breakdown of fat mono-unsaturates or polyunsaturates in a product;
- The amount of polyols in a product; **however**, if polyols are present at more than 10% of the product a warning statement must be included on pack, details of which can be found in Annex I
- The amount of starch or fibre in a product.

The EU FIC provides a derogation exempting packaging with a largest surface area of less than 10cm^2 from including an ingredients list. **However food supplements cannot take advantage of this, regardless of the size of their packaging, as they have a requirement to provide an ingredients list under the Food Supplements Directive 2002/46/EC and the Food Supplements (England) Regulations 2003.**

Font size and largest surface area

The EU FIC includes a requirement for a minimum font size to be used for **all mandatory information.**

Minimum font size is defined as where the “x” is equal to, or greater than, 1.2mm.

Approximately point 8 in standard Arial “x”

Approximately point 9 in standard Times New Roman “x”

In cases where the largest available surface area is less than 80cm^2 the minimum font size is defined as where the “x” is equal to, or greater than, 0.9mm.

The largest surface area of a box or carton is defined as a single side of the packaging.

For bottles and cylinders the largest surface area is defined as the circumference of the bottle/cylinder but excluding the flanges, shoulders, top, bottom and neck.

Where food supplements are supplied in a tube or bottle which is itself contained within an outer carton the minimum font size **only** applies to the information on the carton and not on the tube or bottle inside as the information provided in the minimum font size is intended to be available at point of sale.

Allergen labelling

The list of 14 foods which cause allergies and intolerance which must be noted remains the same and can be found in Annex II of this document. However the

requirements for the presentation of information on allergenic foods within an ingredients list have changed.

Any ingredient or processing aid from a food listed in Annex II, or derived from a substance or product from this list which is used in the manufacture of the food or an ingredient contained within a product, even if it is in altered form, **must** be emphasised within the ingredients list in such a way as to make clear that it is present in the product. This can be achieved by the use of a different font, font style (bold or italic), font colour or background colour.

If it is not obvious from the name of the ingredient that it is derived from or contains one of the listed allergens, this must be made clear by reference to the allergen, for example "*lactose (milk)*.

Allergen information must be clear and noticeable and not in any way hidden or obscured.

The use of allergen advisory statements such as "contains…" will not be permitted under the EU FIC to ensure that allergen information is provided in a standard format across all food sectors, helping to avoid consumer confusion.

If an ingredient is derived from either crustaceans or molluscs this must be listed in the ingredients list as shown:

Omega 3 oil (**mollusc**) if, for example it is derived from green lipped mussel.

Glucosamine (**crustacean**) if, for example it is derived from crab shell.

To aid consumer understanding of the different types of shellfish you may also wish to consider including the type; for example:

Omega 3 oil (**mollusc (mussels)**)

Glucosamine (**crustacean (crab)**)

The EU FIC stipulates that allergen information should only appear in the ingredients list as outlined above and should not appear anywhere else on labels. However, as UK consumers are more familiar with viewing allergen information in a box format, the DEFRA guidance (point 83) states that allergen information may be signposted. For example, a box could be placed directly below the ingredients list with a statement such as:

"Allergy information is in **bold** in the list above"

Additive labelling

Detailed regulation of food additives is contained within Regulation 1333/2008 on food additives and Regulation 1129/2011 which establishes a list of permitted additives. Flavourings are covered by Regulation 1334/2008. The EU FIC does cover some requirements in the labelling of food additives.

Food additives and food enzymes which are present because they were contained in one or more ingredients and serve no technological function are subject to the "carry-over" principle and are exempt from labelling requirements, as are food

additives which are used solely as processing aids **unless these are derived from one or more of the allergens listed in Annex II**. If derived from any of the listed allergens, even if none of the original substance remains, they must be labelled as:

"Additive name" (category) (derived from X allergen).

"Carry over" allows the presence of a permitted additive in a compound food to the extent that the additive is permitted for use in one of the ingredients of the compound food. It is worth noting that the "carry over" principle **does not apply** to foods for infants and young children.

In addition, there are requirements for warning statements, which are detailed in Annex I for certain ingredients including phytosterols and phytostanols, some sweeteners, the "Southampton colours" and caffeine, where it has been added for physiological effect rather than as a flavouring.

Nutrition labelling requirements

Food supplements must continue to provide information on the nutrients or other substances contained in a product, as set out in the Food Supplements Directive 2002/46/EC, the Food Supplements (England) Regulations 2003 and separate parallel legislation in the devolved administrations of Scotland, Wales and Northern Ireland.

To Note:

The EU FIC has amended the name of the reference intake amounts of vitamins and minerals. What were Recommended Daily Allowances (RDAs) have become **Reference Intakes (RIs)** or **Nutrient Reference Values (NRVs).** The EU Commission recently advised that although they prefer the use of RI, they cannot prevent industry from using NRV in labelling and noted that it is a matter for each individual Member State to determine.

The Food Supplements Directive links to Directive 90/946 EEC on Nutrition Labelling which is repealed by the EU FIC and all references to that Directive will be construed as being to the EU FIC. Therefore, despite food supplements being specifically exempt from the nutrition labelling requirements of the EU FIC, vitamins and minerals will need to be expressed as percentages of **Nutrient Reference Values (NRVs) or Reference Intakes (RIs)** rather than percentages of RDAs (which will no longer exist).

PAGB are seeking clarification on whether it will be possible to make use of the new labelling terminology in conjunction with RDA; for example a statement under the nutrition panel could state:

Nutrient Reference Value (NRV) used to be known as Recommended Daily Allowance (RDA)

PAGB hopes this will provide sufficient explanation to prevent consumer confusion over the new terminology.

Although the UK legislation will enable changes to be made to labels before the full coming into force on 14 December 2014, the requirement to label using NRV/RIs is covered by legislation which will not be repealed until the EU FIC comes into force.

It is also worth noting that the requirement to use NRV/RIs is associated with the nutrition labelling requirements, which do not come into full force until 13 December 2016. RDAs can continue to legally be used until that date and sell-through will apply to all products legally on the market up to that date.

The EU FIC states that vitamins and minerals should be listed in the nutrition reference panel only if they are present in significant amounts (as a rule 15% of the NRV) as defined in Annex XIII of the EU FIC. However, food supplements are subject to their own nutrient labelling requirements under the Food Supplements Directive, and the Directive includes the intention to set minimum levels. Clearly, where claims are made, they can only be made against vitamins and / or minerals where a minimum of 15% of these substances is present. Where claims are not made it is PAGB's view that best practice would be to list **all vitamins and minerals present in the product in the nutrition reference panel, irrespective of the percentage of NRV.**

Caffeine labelling

Any **drink** where caffeine is added, **from any source**, must include the warning statement " *High caffeine content. Not recommended for children or pregnant or breast-feeding women* " in the same field of vision as the name of the food, followed by a reference, in brackets, to the caffeine content, expressed as per portion as recommended for daily consumption on the label.

The drafting of the legislation does not require food, including food supplements, to include a warning statement unless caffeine itself has been added to a product, for a physiological purpose. . However, the Commission has recently stated that **any** products containing caffeine, **from any source** should include the warning statement *"Contains caffeine. Not recommended for children or pregnant women" in the same field of vision as the name of the food. Food supplements must also express the caffeine content per portion as recommended for daily consumption on the labelling*.

Voluntary information

The EU FIC allows for voluntary information to be provided on labels and in advertising such as nutrition and health claims; however it stipulates that voluntary information must:

- Not be displayed to the detriment of space for mandatory information;
- Not be misleading to the consumer;
- Not be ambiguous or confusing for the consumer;
- Be based on relevant scientific data (where appropriate)

Voluntary information on the following may also be provided:

- Information on the **possible unintentional presence** of substances causing allergies or intolerances (i.e. "produced in a factory which processes nuts; may contain nuts")
- Information on the suitability for vegetarians or vegans

- Information on public health messages (i.e. “Government advice: adults aged 65 and over should take a supplement containing 10mcg of vitamin D”)
- Voluntary statements agreed between industry and the FSA in 2004 (see Annex IV)
- The use of a nutrition or health claim; for more information about the use of nutrition and health claims please see PAGB’s Food Supplements Advertising Guideline (http://www.pagb.co.uk/codes/pdfs/FoodsupplementsadvertisingguidelineMarch2013.pdf)

“Best Before” date / Date of minimum durability

The current requirement under Directive 2000/13 is that the “best before” date must appear in the same field of vision as the name under which the product is sold, the net quantity and (if relevant) the alcoholic strength by volume (ABV). The EU FIC removes this requirement and the “best before” date can be placed anywhere on the label. However, as the legislation consolidated into the EU FIC remains current up to and including 13 December 2014, this particular piece of information must remain in its current legal position on the label until the EU FIC comes into full force on 14 December 2014.

Detailed information about how the “Best before” date should be formatted and displayed can be found in Annex I.

Country of Origin

The country of origin or provenance of a food is mandatory **where** failure to provide the information could be misleading to consumers. This is unlikely to impact on food supplements, however if a company wishes to state the origin of an ingredient (for example a fish oil) it should have substantiating evidence to show that the ingredient was sourced as claimed.

A number of the country of origin regulations have not yet been finalised. The Regulation includes a requirement for the Commission to submit reports on a number of issues. These will be taken into consideration when drafting implementing rules to amend the existing Regulation.

There may be some amendments in future requiring country of origin notification on single ingredient products and on ingredients which represent more than 50% of a food which may have some impact on food supplements.

Lot Markings

Requirements for Lot Markings for food products are not included in the EU FIC but remain under the regulation of the national Food (Lot Marking) Regulations 1996.

A **Lot** is a batch of sales units of food produced, manufactured or packaged under similar conditions. Lot marking is intended to make identification easier.

A **Lot marking indication** allows identification of the lot to which a sales unit of food belongs. Any food which forms part of a lot (or "batch") must be accompanied by a lot marking indication. Lot markings must be preceded by the letter "L" unless clearly differentiated from other indications on the packaging or label.

The producer, manufacturer, packer or first seller within the EU must determine the size of lot which they would consider most appropriate. A number of factors should be considered, including the practicality and implications of a lot mark based on a large run. If a product recall should be necessary, a large lot mark batch would need to be recalled.

Certain products or units are exempt from the requirements:

a) Agricultural products when sold to a temporary storage, preparation or packaging station or to a producers' organisation or for collection for immediate integration into an operational preparation or processing system;

b) food which is sold to the ultimate consumer and is not prepacked, is packed at the request of the purchaser or is prepacked for immediate sale;

c) sales units in containers where the area of the largest side is less than 10cm^2;

d) a sales unit which is prepacked, sold as an individual portion for immediate consumption, and is intended as a minor accompaniment to another food or service;

e) a sales unit of an individual portion of an edible ice supplied to its seller in bulk packaging which bears the required lot marking indication;

f) a sales unit marked or labelled before 1.7.1992;

g) a sales unit which is marked or labelled with an indication of minimum durability or "use by" date consisting of at least the uncoded indication of the day and month (as required by the Food Labelling Regulations, and which will continue to be required under the EU FIC.)

It is worth noting that the exemption allowed by g) above means many foods do not need to have a specific lot mark. Therefore foods with "Best before end" dates which list month and year will be exempt from lot markings as the indication of the day and month (as required by the Regulations) is implicit (e.g. "best before end October 2015" means best before 31 October 2015).

Distance selling

"Distance selling" includes the sale of products through web sites, telephone and catalogue sales.

All mandatory information, with the exception of the date of minimum durability ("use by" date) and the lot number, relating to the food must be made available to the consumer before the food is purchased. "Mandatory information" includes the information required by the Food Supplements Directive and national Regulations.

The EU FIC stipulates that this information must be provided with no additional cost to the consumer, i.e. the use of paid for or premium telephone lines for sales is not

permitted. If information is provided via a telephone line it must be either a freephone number or a landline, where no cost will be incurred by the consumer.

All mandatory information, including the date of minimum durability or “use by” date must be available to the consumer at the moment of delivery.

USEFUL LINKS

The Food Information for Consumers Regulation

Commission Regulation (EU) 1169/2011 on the provision of food information for consumers

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

The Food Supplements Directive 2002/46/EC

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20091221:en:PDF

The Food Supplements (England) Regulations 2003

http://www.legislation.gov.uk/uksi/2003/1387/contents/made

The Nutrition and Health Claims Regulation 1924/2006

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

Food Additives

Regulation 1333/2008 on food additives

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF

Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:EN:PDF

Food Flavourings

Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:en:PDF

Gluten free claims etc

Regulation 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0041:EN:NOT

The Food (Lot Marking) Regulations 1996 (SI 1996 1502)

http://www.legislation.gov.uk/uksi/1996/1502/contents/made

DEFRA guidance

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/82663/consult-fic-guidance-20121116.pdf

EU Commission Q&A

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/docs/qanda_application_reg1169-2011_en.pdf

Annex I

Food Supplement labels must show the following particulars (in the language of the EU country in which the product will be sold)

Food supplements are exempt from the nutrition labelling aspect of the EU FIC (Articles 29-36)	**On the label**	**In legislation**
The name of the food The legal name must be used: Under Directive 2002/46/EC the legal name is **Food Supplement/s**. • A customary name or descriptive name may also be used (i.e. Brand Name and "multivitamin and mineral")	Principal field of vision May be voluntarily repeated in other fields of vision	Directive 2002/46/EC Regulation 1169/2011 Article 17 & Annex VI
The list of ingredients must be: Listed in descending order of weight. The Commission has advised that full chemical names for vitamins and minerals must be used in the ingredients list. Concentrated or dehydrated ingredients reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration. Ingredients making up less than 2% of the finished product may be listed in a different order at the end of the list (i.e. additives may be listed alphabetically if they constitute less than 2% of the finished product). Refined vegetable oils may be grouped in the list as "vegetable oils" but must be followed **immediately** by the specific vegetable origins of the oil/s. This may be followed by the phrase "in varying proportions". If grouped together vegetables oils must be listed as the total weight of the oils present. Carrier oils used in vitamin preparations do not need to list the origin of the oil **unless** derived from allergens Partially or fully hydrogenated vegetable oils must be indicated in the ingredients list. There are additional requirements under Annex VII Parts A & B of the EU FIC; those listed here are the primary ingredient requirements likely to be pertinent to food supplements.	Position not specified	Directive 2002/46/EC Regulation 1169/2011 Articles 18 & 19; Annex VII

Additive labelling Requirements for Additives Labelling have been consolidated under Regulations 1333/2008 and 1129/2011. **Additives must be listed by category (i.e. acidity regulator) followed by either name or E number.** The EU FIC allows for certain types of additives to be omitted from the list of ingredients: Constituents of an ingredient, separated in processing and reintroduced, not in excess of their original proportions; Food additives and enzymes contained within one or more ingredients of the food which serve no technical function in the finished product and have carried over; Food additives and enzymes used as processing aids; Carriers and substances which are not food additives but which are used in the same way as processing aids and which are still present in the finished product, even in altered form; Water used solely for reconstitution of a concentrated or dehydrated ingredient or in a liquid medium which is not normally consumed.	Within ingredients list	Regulation 1333/2008 and Regulation 1129/2011 on Additives Regulation 1169/2011 Article 20
Additional requirements for certain additives or substances relevant to food supplements Foods containing sweeteners must include the statement “with sweetener(s)”. Foods containing both added sugar(s) and sweetener(s) must state “with sugar(s) and sweetener(s) Foods containing aspartame or aspartame-acesulfame salt must include “contains aspartame (a source of phenylalanine)” on the label where aspartame-acesulfame salt is listed only by its E number (E951). Where aspartame-acesulfame salt appears on the label in full the statement “contains a source of phenylalanine” must also appear on the label. Foods with more than 10% added polyol sweeteners must include the statement “excessive consumption may product a laxative effect”	Accompanying the name of the food Position not specified	Regulation 1169/2011 Annex III

Caffeine and quinine used as flavourings Flavourings must comply with the requirements laid down in Regulation 1334/2008 on flavourings; where caffeine or quinine are used **<u>as flavourings</u>** these must be listed by name in the ingredients list immediately after the term 'flavouring(s)'	In the ingredients list	Regulation 1169/2011 Annex VII (C)
Foods with added phytosterols, phytosterol esters or phytostanol esters Must state: "With added plant sterols" or "with added plant stanols" The amount of added phytosterols, phytosterol esters or phytostanol ester content (as % or as g of free plant sterols/plant stanols per 100g or 100ml of the food) A statement that the food is intended exclusively for people who wish to lower their blood cholesterol level and that consumption of more than 3g/day of added plant sterols / plant stanols should be avoided A statement that patients on cholesterol lowering medication should only consume the product under medical supervision An easily visible statement that the food is not nutritionally appropriate for pregnant or breastfeeding women and children under the age of 5 years Advice that the food is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetable to help maintain carotenoid levels A definition of a portion of the food or food ingredient concerned (preferably in g or ml) with the amount of the plant sterol / plant stanol that each portion contains.	Accompanying the name of the food In the ingredients list Position not specified	Regulation 1169/2011 Annex III (5)
The "Southampton" colours A statement: "(*) name or E number of the colour(s) may have an adverse effect on activity and attention in children "where any of the following colours are used: Sunset yellow (E 110) Quinoline yellow (E 104) Carmoisine (E 122)	Position not specified	Regulation 1333/2008 Annex V

Allura red (E 129) Tartrazine (E 102) Ponceau 4R (E 124)		
Allergen labelling (see Annex II for full listing of allergenic substances) Allergens listed in Annex II of the Regulation must be declared in the ingredients list if they are present in the finished product, **even if they are in an altered form**. Allergen labelling will not be required if the name of the food clearly refers to the allergenic substance; i.e. if the name of the food is "Fish Oil" then fish will not need to be highlighted as an allergen in the ingredients list. Allergen information must not be repeated elsewhere on the labelling, however products may signpost allergen information as being within the ingredients list If more than one ingredient or processing aid originates from allergenic substance/s this must be included for each ingredient or processing aid; the presence of an allergen/s from multiple sources must be noted for each ingredient in which it appears.	Within the ingredients list, **clearly distinguished by font, style or background colour**.	Regulation 1169/2011 Article 21 & Annex II
The quantity of certain ingredients or categories of ingredients The amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product, in numerical form, in the amount as recommended for daily consumption	Position not specified	Directive 2002/46/EC
The net quantity of the food Net quantity declarations are not mandatory if products are normally sold by number, provided that the number of items can clearly be seen or counted from the outside, or, if not, **is indicated on the labelling.**	Accompanying the name of the food	Regulation 1169/2011 Article 23 & Annex IX
Date of minimum durability "Use by" refers only to foods which are highly perishable and are likely to constitute an immediate microbiological danger to human health. For foods with minimum durability of less than three (3) months, **the date shall be preceded by the words "Best before" in the following format**	In the same field of view as storage conditions and /or conditions of use	Regulation 1169/2011 Article 24 & Annex X

For shelf life less than 3 months: **day / month** For foods with minimum durability of between three (3) and 18 months, **the date shall be preceded by the words "Best before end" in the following format** For shelf life 3-18 months: **month / year** For shelf life over 18 months: **year** There is no prohibition on foods with shelf life greater than 18 months stating month/year, and therefore manufacturers can use this format on their label if they wish This information must be followed by a description of storage conditions which must be observed if the product is to keep for the specified period.		
Special storage conditions and / or conditions of use The EU FIC requires the indication of any special storage conditions and or conditions of use The Food Supplements Directive and the Food Supplements (England) Regulation 2003 require a statement that food supplements must be stored out of the reach of young children. Conditions of use for any claims made must be complied with, including any storage conditions of specific amounts that must be consumed to gain the beneficial effect.	In the same field of view as Best Before date	Regulation 1169/2011 Article 25 Food Supplements (England) Regulations 2003 6.2(e) Regulation 1925/2006
Responsibility & name of the business The name and business address of the responsible food business operator (FBO) must appear on the label; if the FBO is not established in the EU the name and address appearing on the label must be that of the FBO responsible for importing the food into the EU. The FBO whose name appears on the label is responsible for ensruing accuracy and compliance with the law for any information on the label.	Position not specified	Regulation 1169/2011 Articles 8 & 9.1(h)
Instructions for use The portion of the product recommended for daily consumption A warning not to exceed the stated recommended daily dose	Position not specified	Food Supplements (England) Regulations

A statement to the effect that food supplements should not be used as a substitute for a varied diet Where a health claim is made, the above statement must also include advice on the importance of a healthy lifestyle		2003 6.2(b); (c) & (d) Regulation 1924/2006
Country of origin The EU FIC allows for the establishment of mandatory information on country of origin or place of provenance if its absence might mislead the consumer. This is subject to a long transition period awaiting a Commission report and implementing rules have not yet been drafted.		Regulation 1169/2011 Article 26

Annex II

Allergenic substances or products that must be noted in the ingredients list

1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:

    (a) wheat based glucose syrups including dextrose (1);

    (b) wheat based maltodextrins (1);

    (c) glucose syrups based on barley;

    (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;

2. Crustaceans and products thereof;

3. Eggs and products thereof;

4. Fish and products thereof, except:

    (a) fish gelatine used as carrier for vitamin or carotenoid preparations;

    (b) fish gelatine or Isinglass used as fining agent in beer and wine;

5. Peanuts and products thereof;

6. Soybeans and products thereof, except:

(a) fully refined soybean oil and fat (and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.)

(b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;

    (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;

    (d) plant stanol ester produced from vegetable oil sterols from soybean sources;

7. Milk and products thereof (including lactose), except:

    (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;

    (b) lactitol;

8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;

9. Celery and products thereof;

10. Mustard and products thereof;

11. Sesame seeds and products thereof;

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

13. Lupin and products thereof;

14. Molluscs and products thereof.

Annex III

Checklist for labelling

To note: Principal Field of Vision will generally mean Front of Pack (FoP)

COMPANY NAME:		
PRODUCT NAME:		
DATE RECEIVED:	**DATE REVIEWED:**	
REQUIREMENT	**FIELD OF VISION (**	**YES / NO**
Brand & Product Name/s	Principal	
Legal name of food (“food supplements”)	Principal	
Net quantity of the food	Accompanying the name of the food	
Best before date	Accompanying net quantity until 13 December 2013; post implementation, anywhere on the label	
Lot number / batch code	Easily visible, clearly legible and indelible	
Responsible FBO details	Not specified	
Sweetener statements (if relevant)	Accompanying the name of the food	
Instruction for use	Not specified	
Any specific conditions of use (if relevant)	Not specified	
Ingredients list (in descending order of quantity) to include:	Not specified	
Correct name/s of vitamin/ mineral other substance including botanical / plant name/s	Ingredients list	
Excipients	Ingredients list	
Additives labelling in compliance with Regulations 1333/2008 and 1129/2011	Ingredients list	
Allergen information – highlighted	Ingredients list	
Phenylalanine statement (if relevant)	Not specified	
Polyol statement (if relevant)	Not specified	
A statement that each tablet / capsule / serving etc contains X amount of active ingredients	Above the nutrition panel	
Any additional information required by the conditions of use for any nutrition or health claim made (if relevant)	Next to or directly following on from claim	
A warning for products or ingredients that may represent a health risk if consumed in excess (i.e. iron warning for children) (if relevant)	Not specified	
Caffeine warning statement (if relevant)	Accompanying the name of the food	
Quantities of active ingredients with correct unit values (mg. µg etc) and including percentage of NRV (where	Nutrition panel	

appropriate)		
“Food supplements should not be used as a substitute for a varied diet and healthy lifestyle”	Not specified	
“Do not exceed stated/recommended dose/use”	Not specified	
“Keep out of reach of young children”	Not specified	
FSA Advisory Statements – if applicable (see Annex IV)	Not specified	
Storage conditions	Not specified	
Place of origin (if applicable)	Not specified	
Tamper warning (if applicable)		
Weights & Measures (mandatory in France/Spain/Italy)		
Reviewed by	**Date**	

Annex IV

Food Standards Agency voluntary advisory statements for use on food supplement labels

NUTRIENT	THRESHOLD TO TRIGGER STATEMENT	LABEL ADVISORY STATEMENT / REFORMULATION
Vitamin C	> 1000 mg	'[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals
Iron	> 20 mg	'[This amount of Iron]* may cause mild stomach upset in sensitive individuals'
Calcium	> 1500 mg	'[This amount of Calcium]* may cause mild stomach upset in sensitive individuals.'
Magnesium	> 400 mg	'[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals.'
Nickel	All nickel-containing products	'[Nickel]* may cause a skin rash in sensitive individuals.'
Beta-carotene	1) >7 mg 2) See footnote[1]	1) Encourage reformulation to ≤ 7 mg/day. 2) Label statement: '[Beta-carotene]* should not be taken by heavy smokers.'
Nicotinic acid	> 20 mg	1) Encourage reformulation to nicotinamide. 2) If nicotinic acid is used, label statement: '[This amount of Nicotinic acid]* may cause skin flushes in sensitive individuals'.
Zinc	> 25 mg	Label statement: 'Long term intake [of this amount of zinc]* may lead to anaemia.'
Manganese	See footnote[2]	Label statement: 'Long term intake [of this amount of manganese]* may lead to muscle pain and fatigue.'
Phosphorus	> 250 mg	Label statement: '[This amount of Phosphorus]* may cause mild stomach upsets in sensitive individuals.'[3]
Vitamin B6	> 10 mg > 100 mg	Label statement: 'Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness.' Encourage reformulation to lower daily amount.
Label advisory statement agreed with DH and MAFF in 1991		
Vitamin A	> 800µg of preformed vitamin A (as retinol, not beta-carotene)	This product contains vitamin A. Do not take if you are pregnant or likely to become pregnant except on the advice of a doctor or antenatal clinic.

* For single nutrient products, the words in square brackets may be deleted.

[1] The Food Standards Agency considers that the labels of all food supplements containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.' Industry considers that this should only be on products recommending a daily amount > 7mg. This footnote is for information here; it will not appear on labels.

[2] The Food Standards Agency considers that the labels of all food supplements recommending a daily amount greater than 0.5mg manganese should carry this advisory statement. Industry considers that this statement could only be justified on products recommending a daily amount greater than 4mg. This footnote is for information here; it will not appear on labels.

[3] The Food Standards Agency wants a second sentence 'Long term intake [of this amount of phosphorus] may weaken bones' to be included in the advisory statement for phosphorus. Industry does not agree that inclusion of the second sentence is warranted. The Agency has asked the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) to look in detail at the effects of phosphate intake on parathyroid hormone and bone metabolism including new data on phosphate regulation.* The wording of the advisory statement will be reconsidered following receipt of COT advice. This footnote is for information here; it will not appear on labels.

*The COT has subsequently reviewed this issue and taken into account the publication of new data. The outcome of this review can be found at the link further down this page entitled 'COT statement on phosphate and the calcium parathyroid hormone axis'. In the light of the COT advice, there is insufficient data to proceed with an advisory statement on bone. Since the long-term effects of phosphate are unknown, the FSA considers this issue to be unresolved and will keep this under review.