The Health Food Manufacturers' Association
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FOOD LABELLING GUIDELINES
FOOD SUPPLEMENTS

Food supplement labelling is principally governed by the EU Food Information to Consumers Regulation (EU No. 1169/2011, EU FIC) which entered into force on 13th December 2014 (implemented in the UK by the Food Information Regulations 2014) and the Food Supplements Regulations 2003 (FSR), as amended, which implement EC Directive 2002/46/EC (FSD), as amended.

A food supplement is defined by the Food Supplements Regulations as ***any food the purpose of which is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination, and which is sold is dose form***

Dose form is defined as 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 quantities*.

Mandatory labelling particulars [EU FIC Article 9]
Under the Regulation there is a mandatory requirement to provide (subject to exemptions) certain food information particulars (mandatory food information); these are –

- Name of the food [name required by law]
- List of ingredients
- Indication of allergenic ingredients or processing aids, or those derived from allergens
- The quantity of certain ingredients or categories of ingredients (QUID) [*not applicable to food supplements]*
- The net quantity of the food
- The date of minimum durability
- Any special storage conditions and/or conditions of use
- Name or business name and address of the food business operator
- The country of origin or place of provenance
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- With respect to beverages containing more than 1.2% by volume of alcohol the actual alcoholic strength by volume [*not applicable to food supplements]*
- A nutrition declaration [*format prescribed by EU FIC Articles 29-35 not applicable to food supplements; a declaration in the manner indicated by the FSD/FSR is required*]

Mandatory labelling particulars [FSD Articles 6 & 8/FSR Regulation 6]

- Prescribed name is 'Food Supplement'
- An indication of the names of the categories of nutrients or substances that characterise the product or an indication of the nature of the nutrients/substances
- The portion of the product recommended for daily consumption
- A warning not to exceed the recommended daily intake (or 'dose')
- A statement to the effect that food supplements should not be used as a substitute for a varied diet
- A statement to the effect that product is stored out of the reach of young children
- A declaration of the amount of the nutrients or substances with a nutritional or physiological effect which are provided by the recommended daily intake of the product; the units for the declaration of the vitamins and minerals must be those specified
- An indication of the percentage reference intake value for vitamins and minerals

Additional mandatory labelling particulars [EU FIC Article 10 & Annex III]
Additional labelling particulars are required for food supplements:

- Containing sweeteners
- Containing glycyrrhizinic acid or its ammonium salt
- With added caffeine (added for a physiological purpose)

Vitamin and mineral compositional requirements – only the vitamins and minerals indicated in FSR Schedule 1/FSD Annex I in the forms provided for by FSR Schedule 2/FSD Annex II are permitted for use in food supplements.

Notification – food supplements are currently not required to be notified to the competent authority before first marketing in the UK (this is a requirement in many other EU countries).

Name – the prescribed name is ***Food Supplement***

Product description - the name(s) of the main characterising ingredients or category of ingredients or an indication of the nature of the 'active' ingredients must be provided. This product description need not accompany the prescribed name, but where a supplement contains nutrients/substances for which there are no authorised health claims CLEAR CHECK™ recommends the description accompanies the prescribed name, e.g. *Food Supplement containing vitamins and co-enzyme Q10*.
This will assist in overcoming the provision of potentially unpermitted 'contains' nutrition claims.

Quantity marking – The EU FIC requires an indication of the net volume/weight, however foods normally sold by number are exempted from this requirement.
Food supplements in tablet and capsule form have for many years in the UK been permitted to be sold by number and this allowance will continue.

Minimum durability indication – consists of the 'Best Before Date' marking plus any applicable storage conditions which may be required to keep the product until the date indicated. Where storage instructions are provided these should follow the best before date indication.
If the shelf life of the product is over 3 months, the date marking can be indicated by month/year only, in which case the words 'Best Before End' should be used. If the date is given using a day/month/year format use the words 'Best Before'.
A reference as to where to find the actual date marking can be given, e.g. *Best Before End: see base of container*.

Field of vision requirements – the prescribed name (Food Supplement) and quantity marking must be able to be seen at the same time without the viewer moving the container or their head.

Ingredients list – must be headed 'Ingredients'.

- All ingredients, including additives, excipients, components of compound ingredients (e.g. vitamin preparations) unless exempted, must be listed, in descending order by weight in the product at the 'mixing bowl' stage.
- Compound ingredient components can be grouped, e.g. Capsule shell (hydroxypropyl methyl cellulose, colour: iron oxide)
- The name of an ingredient must be the name that would be required to be used if the ingredient was sold as a food, i.e. a prescribed name, or where none a customary name or where neither a fully descriptive name.
- Trade names for ingredients will not suffice as the ingredient name alone.
- For vitamin ingredients best practice is to provide both the vitamin source name and specific vitamin name e.g. Vitamin C (as ascorbic acid) or Ascorbic acid (Vitamin C).
- Use full mineral compound names; specific additive names (as given by legislation); fully descriptive name for other ingredients (e.g. indicate if a botanical ingredient is present as an extract).
- Insert additive function categories where applicable (EU FIC Regulation Annex VII Part C refers).
- Indicate allergens or ingredients derived from allergens (emphasis of allergen name via a typeset that clearly distinguishes it from the rest of the ingredients list, for example by means of font, style or background colour, is required; full details of relating allergens and requirements provided by EU FIC Article 21 & Annex II)

- Indicate ingredients derived from or containing GMOs
- Ingredients in the form of engineered nano-materials should be clearly indicated, following the ingredient name by the word 'nano' in brackets
- Flavourings should be listed by the term flavouring(s) or by a more specific name or description of the flavouring

Best practice guidance is to provide in linear (run-on) format although this is not mandatory.

In some circumstances certain constituents of a food supplement may be omitted from inclusion in the list of ingredients, e.g. carry-over food additives contained in an ingredient of the food provided that they do not serve a technological function in the finished product (Re: EU FIC Article 20).

Product Information

- Quantification per portion as recommended for daily consumption of any vitamin, mineral or other substance with a nutritional or physiological effect.
- Use the units as specified in FSR Schedule 1/FSD Annex I for vitamins and minerals.
- Insert the % NRV where applicable, inserting meaning of NRV (Nutrient Reference Value) at foot of table.
- CLEAR CHECK™ recommend listing vitamins and minerals first in the order as set down by the Reference Intake (NRV) table [EU FIC Annex XIII Part A]
- These can be followed by declarations for other nutrients, micro-nutrients and non-nutrients.
- Vitamin B1 and Vitamin B2 can be used in place of Thiamin and Riboflavin.

Best practice recommendation is to provide in tabular format although this is not mandatory, with the heading 'Product Information' ['Nutrition Information' could be used where all of the declarations relate to 'nutrients']

Nutrient levels - levels declared should be defendable as 'significant'; declaring very low levels may be regarded as misleading to the consumer.
There are no minimums set by legislation but for vitamins and minerals with NRVs* HFMA CLEAR CHECK™ recommends that nutrients present at below 7-8% NRV/daily intake may be regarded as insignificant.
[* The EC are tasked by the FSD to set minimum levels for vitamins and minerals; projections are these will follow the rules for foods, i.e. 15% NRV]

In regards to maximum levels for vitamins and minerals follow HFMA recommended best practice (except for certain nutrients the recommendations of the EVM (UK Expert Vitamin and Mineral Group) report should be followed).

For other nutrients and substances with a nutritional or physiological effect a company must be able to defend the level as safe/non-medicinal.

Directions for use – these should indicate the recommended daily intake and pattern of consumption, e.g. take 2 tablets twice daily. 'Intake' or similar is preferred by HFMA rather than 'dosage'.

Mandatory labelling statements

- a warning *not to exceed the stated recommended daily intake/dose*
- a statement to the effect that the product should be *stored out of the reach of young children/children*
- a statement to the effect that *food supplements should not be used as a substitute for a varied diet*. To take account of labelling requirements laid down by the EC Regulation on Nutrition and Health Claims, where a health claim is made this statement should be amended to *food supplements should not be used as a substitute for a varied and balanced diet and healthy lifestyle (a shorter, simpler statement such as 'food supplements must not replace a balanced diet and healthy lifestyle' could be used if label space is limited)*

Additional labelling information may be required due to the presence of certain ingredients, e.g. phytosterols; artificial ('Southampton six') colours.

Country of origin or place of provenance – must be indicated if failure to do so might mislead the purchaser.

Name and Address - this must be that of the food business operator [defined as 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control']
The food business operator responsible for the food information shall be the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market. I.e. the name and address must be of a business established in the EU.
A post office box is acceptable as an address but a telephone number, e-mail address or web address is not an acceptable replacement.

Batch/Lot number – must be on the product container itself. Usual practice is to also insert on any outer packaging.

Label Information/Claims - Food information must be accurate, clear and easy to understand and not must mislead the consumer in regards to the characteristics of the product; or by attributing to the supplement effects or properties it does not possess, or by suggesting the product possess special characteristics when all similar products possess the same characteristics, in particular by emphasising the presence or absence of certain ingredients and/or nutrients.

All claims must be capable of substantiation and it is the responsibility of the food business operator to defend the claims made if they are challenged.

Direct or indirect claims that a food supplement has the property to treat, prevent or cure any adverse condition are prohibited.

Medicinal claims, that a supplement can restore, correct or modify physiological function are not allowed.

Nutrition and health claims made on foods are governed by the EC Regulation on Nutrition and Health Claims (No. 1924/2006) which came into effect from 1st July 2007; only authorised claims are permitted, although at present 'on hold' claims may continue to be used.

Marketing terms such as fresh/pure/natural should be used with caution.

'New' (product/formulation) should only be used for one year from placement on the market.

Cautions/warnings - may be required; e.g. advisory statements triggered by high levels of certain nutrients (mandatory for HFMA members); HFMA mandatory cautions relating to iron, vitamin A & vitamin K; herb contra-indications.

Voluntary label statements for vitamin D supplements – following consultation with industry and clinicians the Department of Health has produced some voluntary label statements which may be applied to vitamin D supplements for at risk groups.

Presentation of mandatory particulars (minimum font size) - Mandatory food information (the labelling information required by the FSD, EU FIC and other applicable legislation) must be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible and must not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

The mandatory particulars shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height (see diagram) is equal to or greater than 1.2 mm.
In case of packaging or containers the largest surface of which has an area of less than 80 cm^2, the x-height shall be equal to or greater than 0.9 mm.

In regards to the determination of the largest surface area, for rectangular or box-shaped packages the largest surface is regarded as one entire side of the pack.

For non-rectangular containers the EC advice, which is echoed by the UK competent authority, is that the 'largest surface for cylindrical or bottle-shaped packaging, or packaging with uneven shapes, should be the whole area excluding tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles and jars'.
[*During the latter part of 2015 a relaxing of member states interpretation of this point was intimated potentially favouring the use of the area of the principal display panel of a cylindrical-shaped container (according to the International Organisation of Legal Metrology this is determined as 40% of the surface area, excluding top, bottoms, flanges, shoulders and necks) as the means by which to determine the largest surface area; HFMA has yet to receive further comment from the EC or UK competent authority*]

DEFINITION OF x-HEIGHT

Legend

1	Ascender line
2	Cap line
3	Mean line
4	Baseline
5	Descender line
6	x-height
7	Font size

Vitamins and Minerals permitted for use in food supplements

Schedule 1 (FSR)/Annex I (FSD)

Vitamins	**Unit**	**Minerals**	**Unit**
Vitamin A	µg RE	Calcium	mg
Vitamin D	µg	Magnesium	mg
Vitamin E	mg α-TE	Iron	mg
Vitamin K	µg	Copper	µg
Vitamin B1	mg	Iodine	µg
Vitamin B2	mg	Zinc	mg
Niacin	mg NE	Manganese	mg
Pantothenic acid	mg	Sodium	mg
Vitamin B6	mg	Potassium	mg
Folic acid	µg	Selenium	µg
Vitamin B12	µg	Chromium	µg
Biotin	µg	Molybdenum	µg
Vitamin C	mg	Fluoride	mg
		Chloride	mg
		Phosphorus	mg
		Boron	mg
		Silicon	mg

RE = Retinol equivalents; α-TE = alpha-tocopherol equivalents; NE = Niacin equivalents

Reference Intakes for Vitamins and Minerals (Adults)
Vitamins and Minerals that may be declared and their nutrient reference values (NRVs)
EU Food Information to Consumers Regulation (1169/2011) Annex XIII Part A

Vitamin	NRV	Mineral	NRV
Vitamin A	800 µg	Potassium	2000 mg
Vitamin D	5 µg	Chloride	800 mg
Vitamin E	12 mg	Calcium	800 mg
Vitamin K	75 µg	Phosphorus	700 mg
Vitamin C	80 mg	Magnesium	375 mg
Thiamin	1.1 mg	Iron	14 mg
Riboflavin	1.4 mg	Zinc	10 mg
Niacin	16 mg	Copper	1 mg
Vitamin B6	1.4 mg	Manganese	2 mg
Folic acid	200 µg	Fluoride	3.5 mg
Vitamin B12	2.5 µg	Selenium	55 µg
Biotin	50 µg	Chromium	40 µg
Pantothenic acid	6 mg	Molybdenum	50 µg
		Iodine	150 µg

Information & Guidance
Food Information to Consumers Regulation [EU No 1169/2011]
http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm
http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32011R1169
[The latest consolidated version can be used as a working document]

EC Food Supplements Directive [EC No 2002/46]
http://ec.europa.eu/food/safety/labelling_nutrition/supplements/index_en.htm
http://eur-lex.europa.eu/legal-content/EN/LKD/?uri=CELEX:32002L0046
[The latest consolidated version can be used as a working document]

UK statutory instruments [FSR England SI 1387; Scotland SSI 278; Wales WSI 186, Northern Ireland SR 273; all as amended]
http://www.legislation.gov.uk/

Department of Health food supplements guidance and FAQs
https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs

Department of Health guidance on product label statements for vitamin D supplements for at risk groups
https://www.gov.uk/government/publications/department-recommends-product-label-messages-on-vitamin-d-supplements-for-at-risk-groups

Food Allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance
http://www.food.gov.uk/sites/default/files/food-allergen-labelling-technical-guidance.pdf

Food Standards Agency – Criteria for use of terms Fresh, Pure, Natural etc. in Food Labelling
http://www.food.gov.uk/multimedia/criteriafoodlabelling.pdf

EVM report
https://cot.food.gov.uk/cotreports/cotjointreps/evmreport