nutribl
private label supplements

FOOD SUPPLEMENTS LABELLING GUIDELINES

This is not a comprehensive document, but guidelines aimed to give you a better understanding of the information we have included on 'Label Templates' and why. It also provides information on other requirements, such as 'Field of Vision' and 'Minimum Font Size' which are not obvious from the label templates, but which are legal requirements. We appreciate that all companies will want to convey their own brand feel and message, but it is really important that this is done within the confines of regulation. Please follow the 'Label Templates' provided ,and read this document and associated links, to help with this.

The guidance in this document reflects Troo Health Ltd.'s opinion only of applicable regulatory requirements. Enforcement and interpretation of legislation is a matter for the appropriate regulatory body and/or the courts. The legal responsibility for the labelling and presentation of foodstuffs remains with the food business operator.

The guidance is for UK labels only. Though it follows the principles of EU legislation each jurisdiction may also have its own local laws and/or interpretation.

We would always recommend that clients use a consultant or agency to proof their label artwork before print.

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In England, food supplement labelling is principally governed by the

- Food Information Regulations 2014 (FIR) (which implement the EU Food Information to Consumers Regulation (EU No. 1169/2011, FIC) and,
- Food Supplements Regulations 2003 (FSR), as amended (which implement EC Directive 2002/46/EC, FSD, as amended). There are equivalent regulations in Scotland, Wales and Northern Ireland.

From 1st January 2021 - when the UK left the EU, existing EU Regulation was retained as UK law under the powers of the European Union (Withdrawal) Act 2018, including the EU FIC and EC FSD. Additionally on 1st January 2021, The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB) and fixed inoperability of the retained FSD. In Northern Ireland, the Northern Ireland Protocol means that EU legislation continues to be directly applicable in Northern Ireland.

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 come from different Articles of regulation and lay out the Information which you MUST include on labels.

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);

- 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)

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. It is recommended that 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, Product Information, Directions for Use & other necessary Cautions

- Have to be displayed in a certain way, giving particular information by law.
- We have done this for you, to the best of our ability, and these details are provided for you in our 'Label Templates'.
- This information must be included on your labels.

Country of origin or place of provenance – must be indicated if failure to do so might mislead the purchaser. If you voluntarily indicate the origin of the product (i.e. by using a 'made in Britain/UK' tag line or logo) it is necessary to indicate the origin of the primary ingredient(s) if it is different to the product. Troo are unable to provide this information so would suggest you do not use such made in the UK/Britain claims.

You must not use the EU emblem or label as 'origin EU' for goods produced in GB.

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 market, the importer into the market. I.e. the name and address must be of a business established in the market.
For EU or Northern Ireland, this must be an address in the EU or Northern Ireland.
For GB, this must be an address in the UK.

The address must be sufficient for written correspondence to reach the Food Business Operator or Importer; a telephone number, e-mail address or web address alone is not an acceptable.

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; this EU Regulation was retained as UK law under the powers of the European Union (Withdrawal) Act 2018. 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.

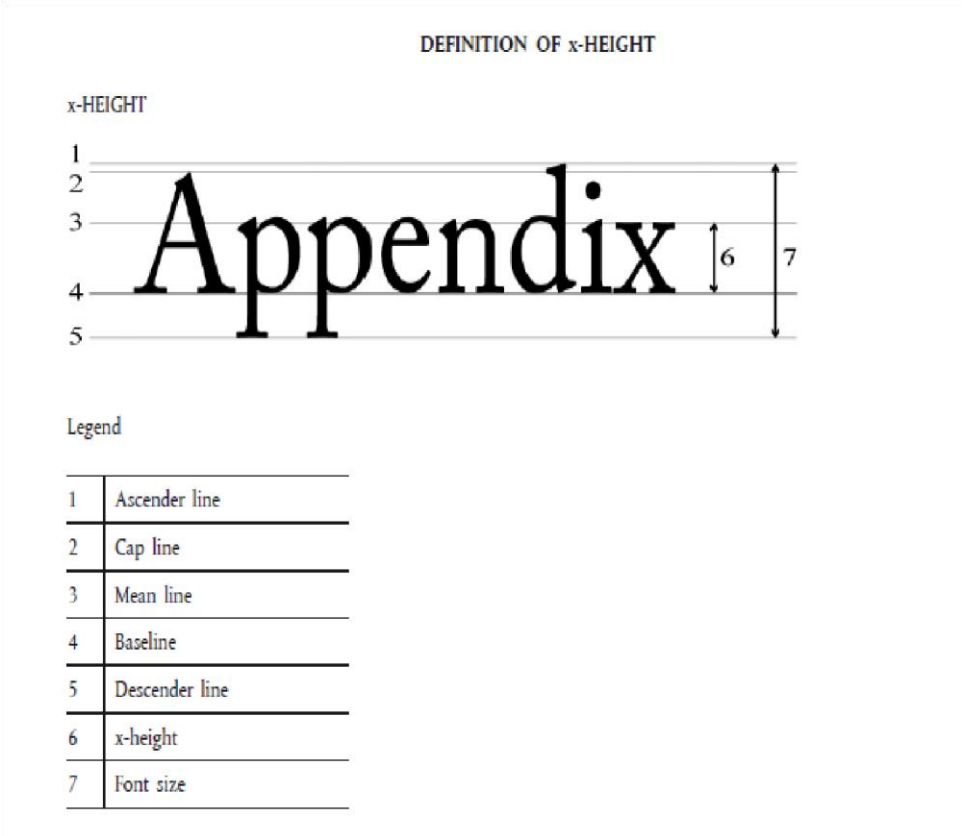
Presentation of mandatory particulars (minimum font size) - Mandatory food information (the labelling information required by the FSD, EU FIC and other applicable legislation) must be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible and must not in any 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 xheight 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; we are yet to receive further comment from the EC or UK competent authority*]



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/

The Food Supplements (England) Regulations 2003
https://www.legislation.gov.uk/uksi/2003/1387/contents/made

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and 2020
https://www.legislation.gov.uk/uksi/2019/651/contents/made
https://www.legislation.gov.uk/ukdsi/2020/9780348212549/contents

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

Nutrition legislation information sources, including the nutrition legislation information sheet
https://www.gov.uk/government/publications/nutrition-legislation-information-sources

Great Britain register on the addition of vitamins and minerals and of certain other substances to foods

https://www.gov.uk/government/publications/register-on-adding-vitamins-and-minerals-to-foods/great-britain-register-on-the-addition-of-vitamins-and-minerals-and-of-certain-other-substances-to-foods#section-f-substances-referred-to-in-annex-3-of-regulation-ec-no-19252006-as-amended

Department of Health Guidance on Nutrition and Health Claims
https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-19242006

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

Technical guidance on nutrition labelling
https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling

Food Standards Agency – Labelling and allergens
http://www.food.gov.uk/multimedia/criteriafoodlabelling.pdf

Food Standards Agency - Criteria for use of terms Fresh, Pure, Natural etc. in Food Labelling
http://www.5aldia.org/datos/60/PDF_4_5106.pdf

EVM report
https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf

Version 2. Updated post Brexit