



CTA Guidelines for Product Regulation Compliance Product Labelling and Measures

The aim of this document is to provide a summary guide for UK based companies that manufacture, process, import or sell food supplements containing cannabidiol (CBD).

If you are the manufacturer/producer or the first importer of CBD containing products in the UK, your company is responsible for ensuring that the labelling of these products complies with current UK/EU legislation.

Because CBD is a botanical compound (not a vitamin or mineral), it is not currently listed with the Department of Health and is therefore classed as 'other substance'. However, the MHRA have classified CBD as having a medicinal effect.

According to the Food Standards Agency (FSA) "some scientific studies suggest CBD can affect the liver if taken at higher doses, but there have been very few studies. As a precaution, we recommend that healthy adults do not take more than 70mg a day, unless a doctor agrees more. This is about 28 drops of 5% CBD"

<https://www.food.gov.uk/safety-hygiene/cannabidiol-cbd>

This doesn't mean that these levels are definitely safe, but that the evidence we have suggests adverse health effects could potentially be seen above this.

Until this issue is resolved, the CTA ask that all companies comply with a maximum 70mg CBD daily dosage on labelling for all products. All 'other substances' are required by the Department of Health to adhere to the generic areas of the legislation concerning packaging, labelling and safety.

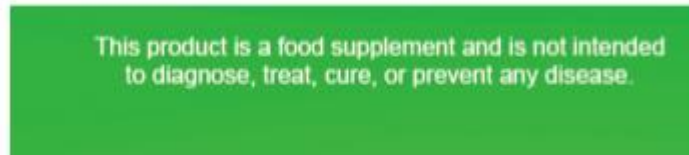
Food Supplements legislation

Food supplements have their own labelling requirements, laid out in the Food Supplements (England) Regulations 2003 and equivalent regulations in Scotland, Wales, and Northern Ireland

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

The term "food supplement" must appear on the label and can appear stand-alone as stated in the Food Labelling Regulations 1996 6(1), which requires the name prescribed by law to be used. However, Regulation 6(3) of this regulation allows a qualification of this with other words

to make it more precise e.g. “Food Supplement –containing vitamins and minerals”. Manufacturers would be encouraged to use the more descriptive option (Stating that the product is a food supplement and precisely that it is not intended to be used as medicine, whilst not a requirement by law, when MHRA are making a final determination, it may be beneficial for us to have this statement)



It is a requirement that Food Supplements are 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.
 - CBD can be considered (CBD or Cannabidiol)
 - Other phyto-cannabinoids can be listed for marketing purposes i.e.: CBDA, CBG etc
 - Cannabis can be considered (Cannabis, Cannabis Sativa L., or Hemp)
(CBD/Cannabidiol should be the prominent active ingredient, clearly stated with mg per product. Cannabis/Hemp should be named to show the botanical source)
- b) **Recommended daily dose:** the portion of the product recommended for daily consumption.
(For drops this could be: Recommended use: Take 1 or 2 drops, twice daily. Do not exceed *X* drops per day/in a 24hr period. For capsules: Take *X* capsules twice daily or as required. Do not take more than *X* capsules per day/in a 24hr period). Ensure that these amounts do not exceed 70mg of CBD as per FSA guidance.
- c) A warning not to exceed the stated recommended daily dose; (See above)
- d) A warning that the product should not be used by pregnant or lactating women.
- e) A warning that the product may interact with medicines and to consult a medical professional.
- f) A statement to the effect that food supplements should not be used as a substitute for a varied diet; (This Food Supplement should be taken as part of a varied diet and healthy lifestyle)
- g) A statement to the effect that the product should be stored out of the reach of young children; (Keep out of the reach of children)
- h) The amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product. (Amount of CBD in mg prominent on the front of the label. For capsules, this should be CBD mg per capsule)

Nutrition Labelling

Food supplements are exempt from the requirements of the Nutrition Labelling Directive (90/496/EEC as amended). However, the Food Supplements (England) Regulations 2003 requires, in the case of vitamins and minerals, the information in point (f) above, to be

accompanied by the percentage of the relevant Recommended Daily Allowance (RDA) as set out in the Annex to Commission Directive 2008/100/EC:

<https://eur-lex.europa.eu/eli/dir/2008/100/oj>

You must label pre-packed food products with nutritional information if:

- you make a nutritional or health claim on the packaging (for example 'high in fibre' or 'good source of calcium')
- vitamins or minerals have been added to the food (This should only be relevant if your product contains additional listed vitamins or minerals)

General labelling requirements

The provisions of the Food Labelling Regulations 1996 (as amended) govern food labelling in the UK (apart from Northern Ireland, which has similar parallel legislation). These regulations lay down detailed requirements for the labelling of most foods to carry:

- **A Product Name:** (Product name; ensure that this does not indicate a medical/health claim)
- **A list of ingredients:** (You must list the ingredients by weight from the most to the least that your product contains (based on the ingredient weights at the time of manufacture))
- **The amount of certain ingredients used:** (state the amount of CBD present in the product in mg and to avoid confusion, state the cannabis content in mg within the ingredients list only)
- **A date mark:** (Best before or Use by) We recommend a 12-month period.

BEST BEFORE 17 NOV 2020

- **Any special storage conditions or conditions of use:** (store upright in a cool, dark place)
- **The name and address of the manufacturer, packer, or EC seller:** (see notes below)
- **Instructions for use:** (Liquids: Place X drops under the tongue and hold for X amount of time or take drops sublingually; see below for pure extract)



Suggested Use:

Take 0.1ml (75mg) - Twice daily.

Place between your gum and cheek and hold there pressing firmly against the gum without moving for about 8-10 seconds. Then move your finger (circular or side to side) until you feel it grab to your gum.

- **The place of origin of the food** if failure to give it might mislead. (The place of origin means. Manufactured in EU or you can say the individual EU country, i.e. Spain, or Manufactured in USA.)

Business Name and Address

You must include a business name and address on the packaging or food label of pre-packed food products. This must be either:

- the name of the business whose name the food is marketed under, if based in the EU
- the address in the EU of the business that has imported the food from outside the EU (Here you would need to put: Distributed by: xxxx Ltd, address)

The address needs to be a physical address within the EU where your business can be contacted by mail. You can't use an e-mail address or phone number. (This can be as simple as: Company Name, 3 Station Rd, NE36 9TT)

Standardisation

For the benefit of our customers, it would make sense to have standardisation for certain elements of the labelling. Below are some suggestions:

- CBD with mg content should be prominent on the front of the labelling
- Individual servings in mg: (For liquids: each drop contains Xmg or 1 pipette = Xmg, For syringe: 1ml = Xmg etc...)
- We would prefer that you use metric measurements opposed to percentage.
- The amount of cannabis should only be shown in the ingredients list unless it is a pure extract or isolate.

External Packaging

External packaging should contain the same information as the label requirements.

- **Allergens**
Below the ingredients list it is best practice to state 'Allergens are listed in Bold' even if there are no allergens present.



- **Organic ingredients**
If the raw materials are organic in origin there must be certification evidence provided to support this. In order to make an organic claim on a label, a food manufacturer must be registered with a recognised organic control body.
Summary information on the labelling of food supplements approved UK organic control bodies; please contact the Department for Environment, Food and Rural Affairs (DEFRA)
- **Non-GM**
Similar to organic ingredients, certification of evidence needs to be provided.

Nutrition and Health Claims

(Under no circumstances should you make any medical claims)

COA's, THC and other Cannabinoids:

- All hemp-based materials should have an independent 3rd party Certificate of Analysis (COA) for every batch stating the full cannabinoid profiles.
- Mandatory purity tests per batch are required for any hemp products extracted using chemicals and/or solvents.
- Periodic purity testing is required for hemp extracts using other extraction methods (CO2, Pressure, alcohol etc). These should show analysis for heavy metals, microbiological contaminants, mycotoxin screening and herbicide/pesticide residues (if not organic certified).

Minimum text size

You must print all the mandatory information using a font with a minimum x-height of 1.2 millimetres.

If the largest surface area of packaging is less than 80cm squared, you can use a minimum x-height of 0.9mm



The x-height (6) must be 1.2 millimetres.

Labelling from outside the EU

If you are importing products from outside the EU for resale, check that the labelling meets all of the labelling requirements for the UK/EU.

- Many products from the USA are not compliant with UK/EU requirements. Dietary Supplement is non-compliant.
- Some products may only need simple modification such as a sticker stating Food Supplement and a disclaimer.

Measurements

Feedback from consumers has shown that many people are confused by the measurements of active compounds stated in CBD products. Labelling for food supplements cannot be misleading to the consumer. Some examples of misleading measurement information can include:

- Daily CBD drops – 200mg CBD (this may infer that each drop contains 200mg).
- 2000mg of Hemp extract, 20% CBD (this may infer that the whole product contains 2000mg and is 20% CBD where in fact, if in a 10ml bottle, there would be 400mg CBD and it would be 4% CBD)
- A pack of 30 capsules, each containing 1000mg Hemp Extract, 20% CBD. • CBD capsules, 2000mg CBD, 30 capsules in pack. And so on....

Finished products should clearly state the mg of CBD on the label. Examples:

- 10ml bottle of Hemp extract, 1000mg CBD, Approx. 200 drops, each drop contains approx. 5mg CBD
- Pack of 30 capsules each containing 30mg CBD.



Disclaimer

The information within this document is for advice/guidance only. The CTA cannot guarantee accuracy in any part of this document and we will not be held responsible for any action taken against a company who have depended on any part of this document. Companies are wholly responsible for their own marketing materials and should read all the relevant UK/EU legislation to ensure conformity. If in doubt, please contact the relevant authorities.

If you notice any discrepancies, inaccurate and/or outdated information within this document, please contact the CTA Compliance Officer so that corrections can be made.

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