

The Health Food Manufacturers' Association  
CLEAR CHECK™ (Copy • Labelling • Education • Advertising • Regulation)  
1 Wolsey Road  
East Molesey  
Surrey KT8 9EL  
t: 020 8481 7100  
e: [CLEARCHECK@hfma.co.uk](mailto:CLEARCHECK@hfma.co.uk)  
w: [www.hfma.co.uk/CLEARCHECK](http://www.hfma.co.uk/CLEARCHECK)



## **FOOD SUPPLEMENTS CONSIDERATIONS RELATING TO PRESENTATION ON UK MARKET**

The **Food Safety Act 1990** makes it an offence to sell food not of the nature, substance or quality demanded by the consumer or that is falsely or misleadingly described or labelled.

**EC Regulation 178/2002** (General Food Law) stipulates that food must not be injurious to health or unfit for human consumption; that the labelling, advertising and presentation of food, including its shape, appearance or packaging, the materials used, the manner in which they are arranged and the setting in which displayed, and the information which is made available about them through whatever medium, shall not mislead customers.

Suppliers/importers also need to consider and take account of other relevant areas of food law, such as:

- Traceability requirements
- Responsibilities of manufacturers/suppliers
- Food Hygiene rules
- Chemical safety rules (e.g. contaminants, pesticides, heavy metals, food contact materials)
- Import rules/health certificates relating to products of animal origin, e.g. gelatin, fish oils

It is the responsibility of the food business operator (manufacturer, importer, distributor) to ensure that product complies with relevant regulatory requirements.

### **Notification**

There is no requirement for food supplements to be registered or notified to the competent authority before being placed on the UK market.

### **Labelling**

EU Food Information to Consumers Regulation (No 1169/2011), implemented in the UK by The Food Information Regulations 2014 (SI 1855), and The Food Supplements Regulations 2003, as amended, which implement EC Directive 2002/46/EC, apply.

### **Ingredients**

**Vitamins and minerals** and their source substances must be permitted for use in food supplements - refer to positive lists in Food Supplements Directive, as amended

**Food Additives** - must be permitted for use in food supplements - refer to applicable EC Regulations

**Botanicals** - consideration must be given as to whether a botanical ingredient can be defended as appropriate for use in a food supplement, i.e. not medicinal or novel and safe. A number of herbal ingredients are restricted on safety grounds.

[Account can be taken of - MHRA list of restricted herbs; MHRA list of herbs & known uses; MHRA final determinations; herbs present in Traditional Herbal Medicines; EFSA compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements]

**Novel ingredient** - if no significant history of consumption in a food supplement prior to 1997 can be demonstrated an ingredient will be regarded as novel - pre-market authorisation by EC will be required

**Allergens**) check for and declare if present

**GM** )

Indication of presence applies to allergenic ingredients and ingredients derived from allergens, GM ingredients and ingredients derived from GMOs

## Levels

Minimum and maximum levels of vitamins and minerals not yet set [EC dialogue stalled]

Until levels are set consider:

Minimum - 6-8% NRV per daily intake (HFMA guidance only)

Maximum - follow HFMA and EVM (UK Expert Group on Vitamins and Minerals) recommendations

For other nutrients and substances, safety is the overriding factor, but consideration should be given to levels that might be considered medicinal.

Where a health claim is made the level provided by the recommended daily intake of the product must be sufficient to satisfy the benefit claimed/meet the conditions of use of an authorised claim [for vitamins and minerals at least 15% NRV (nutrient reference value) per daily intake must be provided before a health and/or nutrition claim could be considered].

## Claims

Claims should not be false or misleading and should not infer a product possesses special characteristics when all similar products possess the same characteristics.

Claims should not infer that a food supplement is needed or that it can replace a varied and balanced diet.

**Medicinal claims** (direct or implied) - not permitted

For information on medicinal claims and borderline between food supplements and medicinal products refer to MHRA guidance note 8 'A guide to what is a medicinal product'.

**Nutrition claims** - limited to those included in the Annex of EC Regulation on Nutrition and Health Claims.

**Health Claims** - must be authorised under the EC Regulation on Nutrition and Health Claims.

**Organic** - foods/ingredients can only be named and claimed 'organic' if they meet with EC Standards and are certified by an EC authorised body/association. Specific rules apply where less than 95% of the agricultural ingredients are organic. Specific arrangements exist for imports from third countries.

**Green claims** - refer to DEFRA guidance

**New** - should only be used for one year from launch of product onto market

**Natural** - use with caution, a finished product should not be described as 'natural' - refer to FSA guidance

**Free-from X** - [other than those restricted by legislation] e.g. artificial colours, sweeteners - can be made but food business operator should be confident the claim can be supported and would not be regarded as misleading (e.g. if the same property will apply to all similar supplements).

**Gluten-free** - specific rules apply [Ref: Implementing Regulation (EU) no. 828/2014]. 'Normal foods' for the general population can be claimed 'gluten-free' where the level of gluten can be demonstrated to be not more than 20 mg/kg.

**GM Free** - not considered appropriate for finished products or ingredients. It may be possible to claim individual ingredients are non-GM if all relevant traceability requirements can be satisfied

*The guidance in this document reflects HFMA CLEARCHECK™ 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.*

## **Sources of information**

### ***Food Supplements***

Department of Health

<https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs>

Department of Health Nutrition Legislation Information Sheet

<https://www.gov.uk/government/publications/nutrition-legislation-information-sources>

European Commission

[http://ec.europa.eu/food/safety/labelling\\_nutrition/supplements\\_en](http://ec.europa.eu/food/safety/labelling_nutrition/supplements_en)

Food Standards Agency Food Supplements Trade Information sheet

<http://www.food.gov.uk/sites/default/files/trade-info07.pdf>

### ***Food Additives, contaminants, pesticide residues etc.***

The Food Standards Agency UK

<http://www.food.gov.uk/policy-advice/additivesbranch/>

<https://www.food.gov.uk/business-industry/manufacturers/additives-supps-guidance/foodadlegguid>

European Commission

[http://ec.europa.eu/food/safety/food\\_improvement\\_agents\\_en](http://ec.europa.eu/food/safety/food_improvement_agents_en)

[http://ec.europa.eu/food/safety/chemical\\_safety\\_en](http://ec.europa.eu/food/safety/chemical_safety_en)

### ***Food labelling***

Department for Environment, Food and Rural Affairs UK;

<https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers>

European Commission;

[http://ec.europa.eu/food/safety/labelling\\_nutrition\\_en](http://ec.europa.eu/food/safety/labelling_nutrition_en)

Food Standards Agency guidance notes

<https://www.food.gov.uk/business-industry/guidancenotes>

FSA marketing terms (fresh, pure, natural etc) guidance:

<http://www.food.gov.uk/sites/default/files/multimedia/pdfs/markcritguidance.pdf>

### ***Health & Nutrition Claims***

The EC Regulation on Nutrition and Health Claims which controls 'claims' made for foods:

[http://ec.europa.eu/food/food/labellingnutrition/claims/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm)

Department of Health NHCR guidance

<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>

### ***Green claims***

<https://www.gov.uk/environmental-claims-and-labels-guidance-for-businesses>

### ***Medicines borderline***

MHRA guidance note 8 'A guide to what is a medicinal product'

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/506397/a\\_guide\\_to\\_what\\_is\\_a\\_medicinal\\_product.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/506397/a_guide_to_what_is_a_medicinal_product.pdf)

MHRA Borderlines page

<https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device>

### ***List of banned and restricted herbal ingredients***

<https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients>

### **Herbal medicines granted a traditional herbal registration**

<https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr/herbal-medicines-granted-a-traditional-herbal-registration>

### **Novel foods**

A novel food/food ingredient is one with no known history of consumption as a food within the EU prior to 1997 (when EC Novel Foods legislation was introduced)

European Commission

[http://ec.europa.eu/food/safety/novel\\_food\\_en](http://ec.europa.eu/food/safety/novel_food_en)

Food Standards Agency

<http://www.food.gov.uk/science/novel>

### **Organic standards/labelling/legislation**

[http://ec.europa.eu/agriculture/organic/index\\_en](http://ec.europa.eu/agriculture/organic/index_en)

<https://www.gov.uk/guidance/organic-food-labelling-rules>

<https://www.gov.uk/guidance/organic-products-import-them-into-the-uk>

### **General safety/responsibilities/import controls**

All foods placed on the UK market must be safe for use; the food business operator is responsible for ensuring a product is safe and compliant with relevant legislation.

Relevant information can be found at:

<https://www.gov.uk/food-safety-your-responsibilities/food-safety>

<http://www.food.gov.uk/enforcement/regulation/foodlaw>

<http://www.food.gov.uk/business-industry/guidancenotes/hygguid/fsactguide>

<http://www.food.gov.uk/business-industry/guidancenotes/hygguid/generalfoodlaw>

<http://www.food.gov.uk/business-industry/imports/>

[http://ec.europa.eu/food/safety/general\\_food\\_law/index\\_en.htm](http://ec.europa.eu/food/safety/general_food_law/index_en.htm)

### **Advertising**

<http://www.asa.org.uk/>

<http://www.cap.org.uk/> [UK advertising Codes]

### **FSA Food Law Guide**

<http://food.gov.uk/enforcement/regulation/foodlaw/foodlawguide/>

### **UK Legislation**

<http://www.legislation.gov.uk>

### **EU legislation**

<http://eur-lex.europa.eu/homepage.html>