The Health Food Manufacturers' Association
CLEAR CHECK
1 Wolsey Road, East Molesey
Surrey KT8 9EL

t: +44(0)20 8481 7100
e: CLEARCHECK@hfma.co.uk
www.hfma.co.uk/CLEARCHECK

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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 – Retained EU Legislation now assimilated into UK 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, including (not an exhaustive list):

- Traceability requirements
- Responsibilities of manufacturers/suppliers – including FBO registration
- Food Hygiene rules
- Packaging and Waste Regulations/Extended Producer Responsibility (EPR)
- 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
- Consumer protection laws

It is the responsibility of the food business operator (the legal persons responsible for ensuring that the requirements of food law are met within the food business under their control, e.g. 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– now assimilated into UK law), 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 (Retained EU Legislation), apply.

Ingredients

Vitamins and minerals and their source substances must be permitted for use in food supplements – refer to positive lists in the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 for the UK, as amended

Food Additives – must be permitted for use in food supplements – refer to applicable EC Regulations (assimilated EU legislation)

PRIMARY AUTHORITY PARTNERSHIP WITH
Buckinghamshire&Surrey trading standards

Surrey and Buckinghamshire Trading Standards have assessed CLEAR CHECK service for its food standards support and concluded that *"The quality level has been independently reviewed and in our opinion is likely to provide users of those services with a defence of 'having taken all reasonable precautions and exercised all due diligence'…"*. Please contact CLEAR CHECK for further details.

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 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 will be required by the Food Standards Agency.

Allergens, GM - check for and declare if present
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 for the UK
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 (assimilated EU legislation).

Health Claims – must be authorised under the EC Regulation on Nutrition and Health Claims (Assimilated EU legislation).

Organic – foods/ingredients can only be named and claimed 'organic' if they meet with Organic Standards and are certified by an 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 be not be described as 'natural', although it could be described as comprising of natural ingredients.

An ingredient should not be described as natural except where it is provided in its natural form (with minimal processing such as to make it safe for consumption, e.g. cleaned, filtered).

Botanical extracts should not be described as natural.

[The same principle would apply to other marketing claims, such as 'pure']

Free-from X – [other than those restricted by legislation] e.g. 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, Assimilated EU legislation]. 'Normal foods' for the general population can be claimed as '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.

Sources of information

Note - 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. It is now assimilated into UK law and applies to products on the GB market. In Northern Ireland, the Northern Ireland Protocol means that EU legislation continues to be directly applicable in Northern Ireland.

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
Food Standards Agency Food Supplements Trade Information
Importing food supplements and health foods - GOV.UK

Food Additives, contaminants, pesticide residues etc.
The Food Standards Agency UK
https://www.food.gov.uk/safety-hygiene/food-additives
Chemical contaminants - GOV.UK
https://www.food.gov.uk/business-guidance/pesticides-in-food
European Commission
https://ec.europa.eu/food/safety/food_improvement_agents_en
https://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
Food Standards Agency
https://www.food.gov.uk/business-guidance/packaging-and-labelling

Health & Nutrition Claims
The EC Regulation on Nutrition and Health Claims which controls 'claims' made for foods:
https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims_en
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/Packaging and Waste Regulations/EPR/Consumer Protection
https://www.gov.uk/environmental-claims-and-labels-guidance-for-businesses
Extended producer responsibility for packaging - GOV.UK
Unfair commercial practices CMA 207

Medicines borderline
MHRA guidance note 8 'A guide to what is a medicinal product'
GN8_FINAL_20260512.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
https://ec.europa.eu/food/safety/novel_food_en
Food Standards Agency
Novel foods authorisation guidance - GOV.UK

Organic standards/labelling/legislation
http://ec.europa.eu/agriculture/organic/index_en
https://www.gov.uk/guidance/organic-food-labelling-rules
https://www.gov.uk/guidance/importing-and-exporting-organic-food

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
https://www.food.gov.uk/business-guidance/general-food-law
Food business registration - GOV.UK
Export or move food, drink and agricultural products - GOV.UK
https://ec.europa.eu/food/safety/general_food_law_en

Advertising
http://www.asa.org.uk/
https://www.asa.org.uk/codes-and-rulings.html

FSA Food Law Guide
Food-and-feed-law-guide.pdf

UK Legislation
http://www.legislation.gov.uk

EU legislation
https://eur-lex.europa.eu/homepage.html

The guidance in this document reflects HFMA CLEAR CHECK 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.